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INSIDE

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Ruling from the Supreme Court Raises Stakes on False Claims

In a decision that increases the risk of violating the False Claims Act (FCA), the U.S. Supreme Court ruled recently that an organization can violate the law if it relied on "implied false certification" when billing the government for services. The hospital or health system may have provided the services, but those services were rendered invalid because the organization — by not stating that it was noncompliant — falsely implied that it was in compliance.

The court's ruling came in the case of *Universal Health Services Inc. v. United States et al. ex rel. Escobar et al*, which involved a mental health facility that provided services to a teenage girl with bipolar disorder who died from the effects of prescribed medication. The girl's parents claimed a violation of the FCA because the facility billed the government knowing the staff were not properly authorized to provide counseling or medications. *(The court's ruling is available to readers online at http://1.usa.gov/1YuNhnA. See a summary of the decision in this issue.)*

"IF YOU BILL FOR MEDICAL SERVICES, DO I REALLY HAVE TO VERIFY THAT YOU'RE ACTUALLY A DOCTOR AND AUTHORIZED TO PRESCRIBE MEDICINE?"
— BRIAN MARKOVITZ, JD, JOSEPH GREENWALD & LAAKE

The ruling is a dual victory for the government and individuals who might make an FCA claim, says **Colin E. Wrabley**, JD, partner with the law firm of Reed Smith in Pittsburgh, PA, who co-authored an amicus brief in the case on behalf of the National Association of Criminal Defense Lawyers. (*See the story in this issue for excerpts from the amicus brief.)*

The court upheld an increasingly common theory of FCA liability and eliminated a key defense previously endorsed in some circuits: the requirement that only failure to disclose noncompliance with "express

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conditions of payment" could support implied certification liability, Wrabley explains.

Don't Play Innocent

The ruling makes clear that lying by omission, in effect, won't be tolerated when billing the government, says **Brian Markovitz**, JD, principal with the law firm of Joseph Greenwald & Laake in Greenbelt, MD. He represents whistleblowers in FCA and similar cases.

"You should look at it this way: Would this issue be something you would want to know about if you were entering a contract with another entity?" Markovitz says. "If the answer is yes, then the government would probably want to know too, and if you don't tell the government, then you're looking at a likely implied certification problem."

Rather than introducing a new FCA risk, the Supreme Court ruling affirms a theory that lower courts have favored in recent years, Markovitz says. Courts have increasingly decided that healthcare organizations are expected to know that they can't bill for services when out of compliance in a significant way. The government shouldn't have to remind them or seek an affirmative confirmation of compliance each time, courts have said.

"It's as if I hired a contractor to paint the exterior of my house, and he used interior paint. When I complain that the paint is falling off, he says I never told him to use exterior paint, so he didn't commit fraud," Markovitz says. "The court is taking a common sense approach and saying healthcare providers should know better. Don't try to play innocent when you knew you shouldn't have billed the government."

Markovitz notes that the FCA originally was enacted to protect the Union army from fraud during the Civil War, after experiences in which profiteers shipped boxes of sawdust instead of guns and sold the same horses to the cavalry several times. The "Escobar" ruling underscores that FCA's original purpose of putting the onus on the contractor to be honest, rather than requiring the government to verify honesty in each transaction, he says.

"If I want to buy some mules for the army, do I really have to specify that they be able to walk and carry things?" Markovitz says. "Or would it be fraud if you sell me a mule with two legs? It's still a mule, right? If you bill for medical services, do I really have to verify that you're actually a doctor and authorized to prescribe medicine?"

EXECUTIVE SUMMARY

The U.S. Supreme Court has determined that the False Claims Act applies when an organization fails to disclose noncompliance with certain requirements. The issue at hand is called "implied certification."

- The theory applies when seemingly legitimate medical services are provided, but noncompliance with regulations makes the services invalid.
- The regulation in question does not have to be a condition of payment.
- The onus is on healthcare organizations to know if they legitimately can bill for services.

Some Positive Effects

Still, the ruling contains several features favorable to defendants, Wrabley says. First, the court clarified that a mere request by a company for payment by the government is not enough to support implied certification liability. The implied certification theory now requires "specific representations" about the goods or services provided along with information not disclosed to the government that, taken together, are misleading.

Additionally, the court breathed new life into the materiality requirement and narrowed the broad definition in the text of the statute and the plaintiff-friendly broad interpretation that lower courts routinely had adopted, Wrabley says. The materiality requirement is based on the legal system's acknowledgment that heavily regulated companies, such as healthcare organizations, cannot be expected to comply perfectly with the thousands of applicable laws, regulations, and guidelines. With that requirement in mind, courts have developed a mechanism known as "materiality" to differentiate which violations actually go to the heart of a claim for federal money and which violations are inconsequential to a federal funding decision.

In this decision, the Supreme Court emphasized the need for materiality by describing the burden as "demanding materiality," Wrabley notes. The court also emphasized that the "demanding" materiality requirement is susceptible to disposition pre-trial through dismissal and summary judgment motions.

Furthermore, the court clarified that materiality under the FCA is an objective test that does not rely on artificial characterizations such as "condition of payment" and "condition of participation," explains **Cleveland Lawrence**, JD, an attorney with the law firm of Sanford Heisler in Washington, DC. Lawrence is chair of the firm's whistleblower practice and former co-executive director of Taxpayers Against Fraud, also in Washington, DC.

The overall message, however, is a stern warning to healthcare organizations that they are expected to know when they are noncompliant and, therefore, unable to bill Medicare, he says. Lawrence says the ruling returns the FCA to its intended purposes: providing a strong remedy and deterrent to combat fraud on government funds. The Supreme Court emphasized that when a contractor delivers a good or provides a service to the government, the contractor cannot seek payment while omitting material information from the government.

"Doing business with the government while failing to disclose underlying statutory, regulatory, or contractual violations that are key to the government's payment decision will lead to FCA liability," Lawrence says. "Contractors must turn square corners." ■

SOURCES

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Supreme Court Rules on Implied False Certification

In *Universal Health Services Inc. v. United States et al. ex rel. Escobar et al,* the U.S. Supreme Court addressed a case involving Yarushka Rivera, a teenage beneficiary of Massachusetts' Medicaid program who received counseling services for several years at Arbour Counseling Services, a satellite mental health facility owned and operated by a subsidiary of petitioner Universal Health Services.

Rivera had an adverse reaction to a medication that "a purported doctor at Arbour" prescribed after diagnosing her with bipolar disorder, the Supreme Court's decision says. She eventually died of a seizure related to the medication. Her parents later discovered that few Arbour employees were licensed to provide mental health counseling or authorized to prescribe medications or offer counseling services without supervision.

They filed a *qui tam* suit and alleged that Universal Health Services had violated the False Claims Act, which penalizes anyone who "knowingly presents ... a false or fraudulent claim for payment or approval" to the federal government. They based their claim on the theory of "implied false certification theory of liability," which treats a payment request as a claimant's implied certification of compliance with relevant statutes, regulations, or contract requirements that are material conditions of payment and treats a failure to disclose a violation as a misrepresentation that renders the claim "false or fraudulent."

If an organization was not in compliance, then it would not submit the bill for payment because compliance is a prerequisite, the theory says. By billing the federal government for services, the

organization implies that it is in compliance with all requirements, even if it does not say so outright. "Specifically, respondents alleged, Universal Health (acting through Arbour) defrauded the Medicaid program by submitting reimbursement claims that made representations about the specific services provided by specific types of professionals, but that failed to disclose serious violations of Massachusetts Medicaid regulations pertaining to staff qualifications and licensing requirements for these services," the court decision says.

Universal Health Services thus allegedly defrauded the program because it "knowingly misrepresented its compliance with mental health facility requirements that are so central to the provision of mental health counseling that the Medicaid program would have refused to pay these claims had it known of these violations."

The District Court granted Universal Health Services' motion to dismiss and said the "implied false certification" theory of liability did not apply because none of the regulations violated by Arbour was a condition of payment. The First Circuit reversed that part of the decision and said that every submission of a claim implicitly represents compliance with relevant regulations. It said that any undisclosed violation of a condition understood to be required for payment — even if it is not specifically stated as a "condition of payment" — renders a claim "false or fraudulent."

Justice Clarence Thomas wrote the opinion. "We first hold that, at least in certain circumstances, the implied false certification theory can be a basis for liability," the decision says. "Specifically, liability can attach when the defendant submits a claim for payment that makes specific representations about the goods or services provided, but knowingly fails to disclose the defendant's noncompliance with a statutory, regulatory, or contractual requirement. In these circumstances, liability may attach if the omission renders those representations misleading."

The decision goes on to say that the False Claims Act liability for failing to disclose violations of legal requirements "does not turn upon whether those requirements were expressly designated as conditions of payment. Defendants can be liable for violating requirements even if they were not expressly designated as conditions of payment."

On the other hand, the court also said that even when a requirement is expressly designated a condition of payment, not every violation of such a requirement gives rise to liability. "What matters is not the label the Government attaches to a requirement, but whether the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision," the decision says. ■

'Perfect Compliance' Impossible, Attorneys Argue

Perfection is unattainable when it comes to the myriad regulations that healthcare organizations must follow, according to an amicus brief in the case of *Universal Health Services Inc. v. United States et al. ex rel. Escobar et al,* on behalf of the National Association of Criminal Defense Lawyers.

The brief notes that it is a fundamental prerequisite of due process that one have fair notice of conduct that might be unlawful. That explanation means that a provider should not be guilty of violating the False Claims Act (FCA) unless it knew it was violating a condition of payment, the brief argues. *(The brief is available at http://bit.ly/299dkwH.)*

"Imposing a broad duty to disclose noncompliance with a contractual, regulatory, or statutory obligation that the government might later deem, for litigation purposes, to be "material" — and then imposing the FCA's draconian penalties for the failure to disclose such noncompliance — does not come close to providing the sort of fair notice the Constitution requires," the brief says. Such a standard leaves contractors or program participants to guess at what violations might, or might not, affect the government's decision to pay a claim and what they have to disclose to avoid an FCA violation.

"In that decidedly unpredictable environment, where the government is incentivized in litigation to elevate any instance of noncompliance to a 'material' one that can support FCA liability, only perfect compliance — or complete disclosure of all noncompliance — can ensure against a potentially annihilating FCA award of civil penalties and treble damages," the brief says. "But in the present regulatory climate, perfect compliance is a virtual impossibility for most contractors — the scope and complexity of one's legal obligations are often both expansive and inscrutable." ■

How Risk Managers Should Conduct an Adverse Event Investigation

When the phone rings and you learn that a patient has died from a medication error, are you prepared to implement your investigation protocol immediately? Or are you caught unprepared and wondering what to do first?

Having an action plan for that moment will greatly improve an adverse event investigation, says **Edwin G. Foulke Jr.**, JD, partner with the law firm of Fisher Phillips in Atlanta. Foulke was the head of the Occupational Safety and Health Administration from 2006 to 2008 and directed more than 300 workplace fatality investigations. Exactly how you carry out the investigation can determine how and what crucial information is obtained and, potentially, the course of future litigation.

"You cannot do this on the fly. You have to have an accident investigation process in place before anything happens," Foulke says. "When you have situations in which someone has died and there may be governmental inquiries, you need to be able to act quickly to gather information before it disappears or becomes spoiled. There can be evidence that you need to isolate and protect, and you may need to get to witnesses before they are influenced by others or forget key details."

An investigation's primary focus should be preventing a recurrence of the adverse event, but the potential legal liability cannot be set aside, Foulke says. That potential liability means that one of the first steps should be notifying legal counsel of the event and noting that the investigation is being conducted in anticipation of litigation. That step will provide a basis for asserting an attorney work product privilege to the investigation, Foulke says.

It may be necessary to have counsel direct the investigation in order to provide the most protection to the resulting documents, witness statements, and reports, Foulke says. *(See the story in this issue for more on the role of privilege in an adverse event investigation.)* Issuing a document hold also is an immediate concern, including the preservation of electronic documentation such as emails.

Expertise Needed?

Determining the right people to involve in the investigation will depend on the particular situation, particularly with clinical matters. If the adverse event involved an area of medicine or type of procedure that is beyond the understanding of counsel and, perhaps, even a risk manager with a nursing background, it will be necessary to draw in a staff member who is knowledgeable, but not involved, to guide the investigation.

Securing the scene is another immediate concern. After an injury or death, there often is an urge among those involved and their managers to clean up the area right away, almost as a subconscious desire to make the bad situation go away, Foulke says. Valuable evidence can be lost. Plaintiffs' attorneys will argue adverse inferences and say you must have destroyed the evidence because it was detrimental to your case.

"Sometimes people are more interested in interviewing witnesses right away and, before they realize it, housekeeping has gone in and cleaned up the area, tossed evidence in the garbage, and you can never get that evidence back or rely on its validity," Foulke says. "That room should be locked down, [with] no one allowed to enter or do anything to it until you've investigated and documented the scene."

Don't Let Witnesses Talk

Identifying and interviewing witnesses comes next. Risk managers should consider the nature of the incident and the role of privilege when determining who should conduct witness interviews, notes **Amy Hampton**, JD, partner with the law firm of Bradley Arant Boult Cummings in Nashville, TN.

For example, the interview of a witness who is potentially subject to employment action as a result of the incident should be managed with

EXECUTIVE SUMMARY

Risk managers should be prepared to conduct an investigation immediately after an adverse event. There are specific strategies that can help you gather the most valuable information.

- How you question people influences what kind of information they provide.
- Gather important documents immediately.
- Consider how privilege may pertain to your investigation.

human resources or counsel.

Risk managers should avoid concurrent or group interviews in favor of individual interviews, Hampton suggests, and they should caution witnesses to avoid the natural tendency to discuss the event or the investigation among peers. Explain the reasons for this warning, she advises. First, it insulates the witness' memory of the event, and it avoids influence of another witness over the witness' memory. It also helps avoid a claim that witnesses collaborated on a story to cover up misconduct. Talking among witnesses and with uninvolved people also opens up the possibility of criminal conspiracy charges, Foulke notes.

"If you have a doctor and nurses standing around talking about what happened, the doctor might say, 'Well, remember I did this and then I did that,'" Foulke says. "The nurses don't want to contradict the doctor, and so that becomes part of the nurse's story when she's interviewed. She doesn't really remember him doing that, but he said he did, so she passes it on as part of her memory."

In addition, keeping witnesses quiet helps avoid drawing in individuals who did not observe the incident and who would not otherwise be involved in the investigation.

"When a witness is questioned or deposed regarding an incident, the examiner inevitably will inquire with whom the witness has spoken about the event," Hampton explains. "The otherwise uninvolved individual now becomes a potential witness because of the shared information."

From his experience in hundreds of accident investigations, Foulke learned how easy it is for people to jump to conclusions and find fault. He warns risk managers to avoid that tendency and keep the investigation focused on "why" for as long as possible. Conduct a thorough root cause analysis even when the answer seems obvious, he says.

"We saw it all the time where people would think right away that they knew what went wrong and who did it, then the investigation would come to a halt," he says. "They stopped asking the 'why' questions that could eventually lead them to the real explanation."

The Oregon Patient Safety Commission also offers advice on how to best gather information from adverse event witnesses, and the Agency for Healthcare Research and Quality has debriefing tips and a new toolkit for responding to adverse events. *(See the stories in this issue for more on those resources. Foulke's advice for some of the hard questions to ask witnesses also is included in this issue.)*

Some sensitivity is required when interviewing witnesses, especially those who are emotionally upset by the event, Foulke notes. Having one person to conduct the interview and a second taking detailed notes is good, but avoid having several investigators interview the witness at once, which can be overwhelming and intimidating. The investigator should explain the purpose of the investigation and emphasize that it is not to place blame on individuals, he says.

Urge the witness to speak up if a question is not clear or to ask what the investigator is seeking, and offer to take breaks or go as slowly as the witness wants. The goal is to put the witness at ease so that you can obtain as much information as possible, rather than the witness feeling on guard and careful about every word, Foulke says.

It will be necessary to ask some specific questions, including difficult ones, but start with letting the witness tell the story from beginning to end, Foulke advises.

"Ask the person to recount what happened, from the earliest point in the day all the way through what happened and the aftermath. Encourage even the smallest details that seem unimportant, and then just let them talk," Foulke says. "The hardest thing for interviewers is to just let people talk uninterrupted. Let them pause and think, gather their thoughts, and continue. That's how you get the whole story." ■

SOURCES

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Protect Privileged Information in Adverse Events

Carefully consider the role of privilege in an adverse event investigation, says **Amy Hampton**, JD, partner with the law firm of Bradley Arant Boult Cummings in Nashville, TN.

Assertions of privilege often are met with skepticism, and risk managers must not blindly assume that information collected during the investigative process will be protected from future disclosure by summarily claiming "peer review privilege" or "attorney-client privilege," she says.

Before beginning an investigation,

the risk manager should determine whether the investigation is purely for ordinary business purposes or, in whole or in part, for a quality improvement, legal, or other purpose for which privilege may apply. Conduct the investigation accordingly.

Even thought it might seem apparent to the drafter, "notes, reports, and data prepared for purposes of the investigation should be marked as privileged at the time they are prepared to demonstrate the intended purpose and to avoid inadvertent disclosure," Hampton says. "Risk managers should be aware that privilege may be waived and should avoid conduct that might constitute a waiver of the privilege."

For example, it is not appropriate to record investigation notes and findings in the patient medical record. Doing so almost certainly would constitute a waiver of privilege. Similarly, sharing findings or analysis with parties outside of the investigative process might constitute a waiver of privilege, not only as to the shared information, but potentially as to all findings or analysis related to the investigation, Hampton says.

That advice can create a tricky situation when talking with the patient or family members after an adverse event. Although transparency and full disclosure are valid goals, risk managers must be careful not to discuss privileged information, Hampton says.

Because challenges to assertions of peer review and attorney-client privilege are more commonplace today, Hampton says even experienced risk managers should consider including counsel at the outset of an investigation.

"At a minimum, the risk manager should have a working knowledge of applicable state or federal quality improvement privileges and a basic understanding of when a legal privilege applies," she says. ■

Tips on Interviewing Witnesses, Debriefing

The Portland-based Oregon Patient Safety Commission offers tips on interviewing adverse event witnesses. The following is some of the advice:

- Be prepared to respond to questions the patient or family may have about the event and what is being done to improve care for future patients.
- Use plain language, avoid jargon, and check for understanding throughout.
- Actively listen and respond with empathy.
- Start with broad, open-ended questions, and then narrow them down to clarify your understanding of what has been shared.
- Practice "humble inquiry": drawing someone out by asking questions to which you do not already know the answer, using curiosity and interest to build a relationship.
- Designate a contact person whom the patient or family can reach with questions or if they remember additional information. *(For more information, readers can go online to http://bit.ly/298HJgX.)*

In addition, the Agency for Healthcare Research and Quality (AHRQ) offers advice on how to debrief clinicians involved with adverse events. AHRQ notes that all forms of debriefing have a shared structure that involves setting the stage followed by three phases, including description or reactions, analysis, and application. The following is some of the advice from AHRQ:

- **Setting the stage:** To be effective, a debriefing must be conducted in a manner that supports learning. Thus, the purpose is not to identify error and assign blame, but to understand why actions and decisions made sense to clinicians in the moment. This step requires establishment of psychological safety for participants regardless of the type of debriefing conducted. Whether engaged in a clinical debriefing lasting three minutes or a simulation debriefing lasting 30 minutes, the tone set by the leader and the leader's management of the discussion are critical to maintaining psychological safety.
- **Description or reactions:** During this phase, the leader generally elicits perspectives from team members about how events unfolded in the clinical situation or simulation scenario and asks them to describe their reactions. Participants should be requested to identify the important issues to address, and the sequence of events should be clarified.
- **Analysis:** The leader should develop the priorities for discussion with the participants. The leader should balance participant priorities with any other critical safety concerns that were noted during the event. The goal is to explore clinicians' rationales for observed behaviors, identify and close performance gaps by discussing pros and cons of chosen actions, and determine any modifiable systems issues that may have interfered with performance.
- **Application:** This phase of debriefing is designed to identify

and summarize the main learning points and consider how they can be incorporated into future practice. Explicitly summarizing lessons learned from the scenario or clinical event may help team members recall and apply these lessons in the future. *(The AHRQ advice on debriefing is available at http://bit.ly/29oyrx4.)* ■

Ask the Hard Questions After an Adverse Event

Even when the cause of the adverse event is identified, investigators should drill down further to identify other factors that may have played a role, says **Edwin G. Foulke Jr.**, JD, partner with the law firm of Fisher Phillips in Atlanta and former head of the Occupational Safety and Health Administration.

Rather than just asking witnesses to recount the event, ask more probing questions such as the following:

- Was there anything unusual or different about the working conditions at the time?
- Were you or anyone else multitasking at the time? Was your attention diverted by something else?
- Were you surprised that this happened? Did you worry beforehand that this could happen at some point? What made you think so?
- What did you first think when this happened? Did you know right away why it happened or have a suspicion?
- Were the proper procedures being followed? Were any steps skipped?
- Did someone voice concerns before this happened? What was the response?
- How long had it been since you had a break? Were you or anyone else particularly fatigued for any reason?
- Were the people involved competent for their jobs? Did you have any concerns before the event?
- Was the equipment insufficient in any way?
- Was there any disagreement or any personal issues between people involved?
- Do you regret anything you did or didn't do? Do you regret not speaking up about something?
- Can you explain this inconsistency in what you said? You said this at one point, but then you said that, so can you help me understand?
- What do you think would prevent this from happening again? If you could go back in time and stop this, what would you do?

"These are questions that people usually don't ask because some of them are not comfortable, like asking if your colleagues are competent and sufficient for their tasks or if they have any regrets," Foulke says. "But they need to be asked, and people usually won't volunteer this kind of information if you just ask them what happened and leave it at that." ■

CANDOR Toolkit Helps After Adverse Events

After an adverse event, prompt and honest communication with the patient and family members has become the best practice in healthcare over the past decade, and the federal government is supporting that effort with a new toolkit from the Agency for Healthcare Research and Quality (AHRQ).

The Communication and Optimal Resolution (CANDOR) Toolkit provides a process that healthcare institutions and practitioners can use to respond when unexpected events cause patient harm. The toolkit is based on expert input and lessons learned from AHRQ's $23 million Patient Safety and Medical Liability grant initiative launched in 2009. The CANDOR Toolkit was tested and applied in 14 hospitals across three healthcare systems in the United States.

The CANDOR Toolkit contains eight modules, each containing slides with facilitator notes. Some modules also contain tools, resources, or videos. Generally, the CANDOR process begins with identification of an event that involves harm. This step activates initiation of coordinated post-event processes.

The CANDOR Toolkit is intended to help hospitals save money on malpractice litigation while encouraging more robust scrutiny of what went wrong and a full disclosure to the patient or family. In addition to supporting patients' families, CANDOR also acknowledges that an adverse event can be traumatic for clinicians and provides ways to assist them.

CANDOR calls for a prompt response after an adverse event, with specific actions to take. When a case involving patient harm is identified, trained hospital staff members tell victims or their families what happened within one hour. They also contact the clinicians involved and offer assistance. The hospital also puts an immediate hold on the billing process so the patient or family is not

stressed by a bill for the very services that may have injured or killed the patient. Hospital leaders stay in touch with patients and relatives during the investigation, which should be completed within two months. The results of the investigation are shared with the patient or family, along with a discussion of how to prevent such adverse events in the future.

When the investigation concludes that harm resulted from a breach in the standard of care, CANDOR calls for the hospital to negotiate financial compensation.

The CANDOR Toolkit is available online for readers at http://1.usa.gov/1P2A17C. ■

Feds Offer Best Practices Response to Ransomware

After a spate of attacks in which hospital computer systems were seized and held for ransom, the departments of Homeland Security, Justice, and Health and Human Services have issued technical guidance summarizing existing "best practices" to prevent and respond to ransomware incidents.

Ransomware is the fastest growing malware threat, the guidance notes. Recommended actions include educating personnel and implementing certain preventive and business continuity measures. If infected, organizations should report incidents immediately to their FBI Field Office Cyber Task Force or Secret Service field office for assistance, and to the FBI Internet Crime Complaint Center, the agencies advise. The guidance can be accessed by readers online by going to http://bit.ly/2966w4T. ■

National Fraud Takedown Nets 301 People And $900 Million in False Billing

The recent arrest of 301 people for healthcare fraud brings the campaign against fraudulent billing to another level and illustrates that licensed professionals are as vulnerable as everyone else.

Attorney General Loretta E. Lynch and Sylvia Mathews Burwell, secretary of the Department of Health and Human Services (HHS), recently announced an unprecedented nationwide sweep led by the Medicare Fraud Strike Force in 36 federal districts. The sweep resulted in criminal and civil charges against 301 individuals, including 61 doctors, nurses, and other licensed medical professionals, for their alleged participation in healthcare fraud schemes involving about $900 million in false billings.

In addition, CMS is suspending payment to several providers using its suspension authority provided in the Affordable Care Act. This coordinated takedown is the largest in history in terms of the number of defendants charged and loss amount, HHS says.

The defendants are charged with various healthcare fraud-related crimes, including conspiracy to commit healthcare fraud, violations of the anti-kickback statutes, money laundering, and aggravated identity theft. The charges are based on alleged fraud schemes involving medical treatments and services, including home healthcare, psychotherapy, physical and occupational therapy, durable medical equipment, and prescription drugs.

A significant difference from previous fraud investigations is that more than 60 of the defendants arrested are charged with fraud related to the Medicare prescription drug benefit program known as Part D, says **Mark Hardiman**, JD, a partner with healthcare law firm Nelson Hardiman in Los Angeles. He specializes in representing and advising healthcare providers with respect to criminal investigations and charges, civil False Claims Act allegations, and fraud lawsuits. Part D is the fastest-growing component of the Medicare program overall.

These arrests should alert the healthcare community that no one is immune from prosecution, Hardiman says.

"While DOJ [the Department of Justice] has announced a grab-bag of healthcare fraud cases across the country, the charging of more than 60 physicians and other licensed healthcare professionals is noteworthy," Hardiman says. "Historically, licensed professionals have been more difficult to prosecute for healthcare fraud because they have significant leeway in practicing medicine and also have the resources to aggressively defend themselves. Clearly, DOJ is sending a message that healthcare professionals who engage in fraud will be aggressively prosecuted."

Court documents allege that the defendants participated in schemes to submit claims to Medicare and

Medicaid for treatments that were medically unnecessary and often never provided. In many cases, patient recruiters, Medicare beneficiaries, and other co-conspirators allegedly were paid cash kickbacks in return for supplying beneficiary information to providers. Collectively, the doctors, nurses, licensed medical professionals, healthcare company owners, and others charged are accused of submitting about $900 million in fraudulent billing.

The Medicare Fraud Strike Force has charged more than 2,900 defendants who collectively have falsely billed the Medicare program for more than $8.9 billion. ■

SOURCE

- **Mark Hardiman**, JD, Partner, Nelson Hardiman, Los Angeles. Telephone: (310) 203-2800. Email: mhardiman@nelsonhardiman.com.

Patient Shot by Security Officer Sues Hospital

A patient who was shot by an off-duty police officer working security at St. Joseph Medical Center in Houston, TX, is suing the hospital, its parent company, the city of Houston, and four police officers.

Alan Pean was having a severe panic attack when he checked himself into St. Joseph Hospital Aug. 26, 2015, according to a CMS report of the investigation after the shooting. Pean grew confused during his hospital stay and repeatedly left his room naked. His actions prompted nurses to call hospital security, which was two off-duty Houston Police Department officers.

Pean attacked the officers with a piece of furniture when they came to his room, which prompted the officers to first use a conducted electrical weapon and then shoot the patient. The lawsuit seeks more than $1 million for Pean's pain and suffering as well as legal and medical expenses, and it claims the officers were not properly trained to de-escalate a mental health crisis.

The lawsuit follows a harsh blow from CMS at the end of 2015. After investigating the shootings and other compliance issues, CMS notified St. Joseph Medical Center that it would be terminated from the federal government programs. The hospital was out of compliance for six months, with the shooting and other issues putting patients in "immediate jeopardy," CMS reported. ■

CNO Says Hospital Fired Her for Criticism of Electronic Medical Record

A former nursing executive at Sonoma West Medical Center (SWMC) in Sebastopol, CA, says she was fired for raising concerns that the facility's electronic medical record (EMR) was a threat to patient safety. The EMR was developed by one of the hospital's board members.

The lawsuit says Autumn AndRa, RN, was serving as chief nursing officer (CNO) of the hospital when she approached CEO Ray Hino and said the EMR was unsafe.

AndRa was terminated from her CNO position April 14, 2016, and was offered a demotion to a position in the ICU, the lawsuit claims. She refused the position and left the hospital. She cited harassment.

In addition to the hospital, the lawsuit also names Dan Smith, the developer of the EMR software, called Harmoni, as a defendant. Smith "has engaged in retaliation against [AndRa] and other employees who have voiced concerns that Mr. Smith's electronic medical records system, his self-dealing, and his management of medical and financial decisions are not in the best interests of SWMC and pose life-threatening risks to patient care," the lawsuit says.

A key problem with the software is that it mixes up patients' records, the lawsuit alleges. The lawsuit also alleges the EMR has difficulty tracking and updating patient medications, displaying patient code status information, and advising providers of patients' desired medical interventions.

Smith is a significant financial

COMING IN FUTURE MONTHS

- How to respond to a subpoena
- 15-minute walk-around improves safety
- Risks with newborn identification
- Facility removes fall protection gear

supporter of the hospital. A 2015 report from *The Press Democrat* newspaper said Smith and his wife have contributed nearly $9 million to the hospital in donations and forgivable loans, and that he plays a role in "every major decision" regarding the hospital. Smith is on the hospital's board of directors. ■

$53 Million Award for Birth Brain Injury

In what is believed to be the biggest birth injury verdict ever in Chicago's Cook County, a jury has ordered the University of Chicago Medical Center to pay $53 million in a case involving a 12-year-old boy who was born with a serious brain injury.

The award to Lisa and Isaiah Ewing includes $28.8 million for future caretaking expenses, according to information provided by their lawyers, Geoffrey Fieger, JD, of Detroit and Jack Beam, JD, of Chicago. The boy has severe cerebral palsy and is in a wheelchair.

Lisa Ewing had arrived at the hospital when she was 40 weeks into the pregnancy, and she was concerned that the baby was not moving as much as before. The lawsuit filed in 2013 alleged 20 errors by doctors and nurses at the hospital, including failures to carefully monitor mother and baby, perform a timely cesarean section, follow a chain of command, obtain accurate cord blood gases, and be aware of abnormal fetal heart rate patterns that indicated distress to the baby, including hypoxia, or a drop in the supply of oxygen.

At a news conference after the verdict, Fieger said the University of Chicago had been "completely unapologetic, and even though the evidence was overwhelming that they caused Isaiah's brain damage, they refused to accept responsibility."

Attorneys for the hospital argued that the child's injuries resulted from an infection and that he was born with normal blood oxygen levels. Fieger said at the news conference that the hospital's medical records showed that the baby suffered hypoxia, "yet the University of Chicago and its lawyers came to court and tried to tell the jury that their own records were false, that their own records were mistaken, and that Isaiah really had a phantom infection that infected his brain that they could never have known about."

Hospital spokeswoman **Lorna Wong** issued a statement saying the hospital had "great sympathy" for the family but disagreed strongly with the jury's decision. The hospital had filed for a mistrial and complained that Fieger's "closing argument shattered the line between zealous advocacy and improper prejudicial comments, rendering it impossible for defendant to receive a fair trial. He also prejudicially argued that the defendant's case was built on a falsehood and proceeded to equate defendant's conduct and testimony of its witnesses with the propaganda techniques notoriously and unmistakably associated with Nazi Germany." ■

Changes to Conditions of Participation Proposed

CMS has proposed changes to the Conditions of Participation that the agency says will improve patient safety and quality.

The rule proposes to reduce overuse of antibiotics and implement comprehensive requirements for infection prevention.

Kate Goodrich, MD, MHS, CMS director of the Center for Clinical Standards & Quality, said the proposal requires Medicare and Medicaid hospitals to have designated leaders in charge of specialized programs to prevent infections, improve antibiotic use, and follow nationally recognized guidelines. The proposed rule also advances protections for traditionally underserved and often excluded populations based on race, color, religion, national origin, sex (including gender identity), age, disability, or sexual orientation.

More information about the proposed rule is available online at http://go.cms.gov/1YzEvEQ. ■

CE/CME OBJECTIVES

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

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

HEALTHCARE RISK MANAGEMENT™

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To earn credit for this activity, please follow these instructions:
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CE/CME QUESTIONS

1. **What was a key part of the U.S. Supreme Court ruling in *Universal Health Services Inc. v. United States et al. ex rel. Escobar et al*?**

   a. An organization can violate the law if it relied on "implied false certification" when billing the government for services.
   b. A hospital must violate an "express condition of payment" to violate the False Claims Act (FCA).
   c. Implied false certification has no bearing on whether a hospital violated the FCA.
   d. Contractors will be required to certify compliance with regulations each time they bill the government.

2. **What is one way to summarize the meaning of the U.S. Supreme Court ruling in *Universal Health Services Inc. v. United States et al. ex rel. Escobar et al*?**

   a. The onus is on the government to ensure compliance of contractors with appropriate regulations.
   b. The government shouldn't have to remind a contractor or seek an affirmative confirmation of compliance each time it bills the government.
   c. The government can claim fraud only if a contractor explicitly declares it is in compliance with appropriate regulations.

3. **What does Edwin G. Foulke Jr., JD, partner with the law firm of Fisher Phillips, say should be one of the first tasks for a risk manager after an adverse event?**

   a. Issue a statement to the media.
   b. Notify the board of directors.
   c. Cancel computer access to people involved.
   d. Notify legal counsel.

4. **Which of the following is true regarding privilege and adverse event investigations?**

   a. It is not appropriate to record investigation notes and findings in the patient medical record; doing so would almost certainly constitute a waiver of privilege.
   b. Investigation notes and findings always should be a part of the patient medical record to ensure they are protected by privilege.

LEGAL REVIEW & COMMENTARY
EXPERT ANALYSIS OF RECENT LAWSUITS AND THEIR IMPACT ON HEALTHCARE RISK MANAGEMENT

Relying Exclusively on Family for Medical History Breaches Standard of Care, Yields $4.58M Verdict

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News: On June 8, 2012, a 33-year-old woman drove to the hospital and was complaining of severe head pain and other symptoms. She told doctors that she had a history of brain swelling that was caused by a pre-existing condition known as lupus and was being monitored by a neurologist. The hospital diagnosed the woman with a migraine, administered a "migraine cocktail," and then discharged her without providing a neurological consult, performing diagnostic imaging of her brain, or reviewing her past medical history. The next day, the woman died.

The woman's estate and her husband sued the hospital, the medical corporation that employed the hospital's ED physicians, as well as the attending physician responsible for the woman's treatment. The plaintiffs' attorneys argued that the defendants did not meet the appropriate standard of medical care and treatment by failing to review the woman's medical history, order diagnostic testing, or perform a neurological consult. The plaintiffs' attorneys also said that the defendants failed to consider a neurological disorder or recognize and treat symptoms of a serious neurological illness, despite the fact that the woman had history of brain swelling. The jury agreed that the standard of care had been breached and awarded the plaintiffs $4.58 million.

Background: In 2010, a woman required emergency hospitalization and treatment for chronic headaches, in addition to nausea and vomiting. After a neurologist and rheumatologist examined the woman, the hospital ordered a CT scan and MRI of the woman's brain. The imaging tests revealed cerebral edema, or brain swelling, caused by excessive fluids in the brain. As a teenager, the woman had been diagnosed with lupus, which can cause brain swelling.

The hospital administered medication that would reduce the woman's brain swelling by draining excess fluids from her brain. Four days later, the woman's headaches and nausea subsided, and she was discharged from the hospital.

In 2011, the woman once again experienced a chronic headache caused by her lupus and returned to the hospital for treatment. The hospital again determined that the woman had brain swelling and administered steroids intravenously to reduce the swelling. When the swelling resolved, the woman was discharged and returned to her normal life.

On June 8, 2012, the woman awoke at 3 a.m. to the sudden onset of a severe headache. The woman and her husband arrived at the hospital, where the woman complained of severe head pain, nausea, vomiting, and excessive sweating. The woman informed the doctors that the onset of her head pain had been sudden and that her pain was a 10 on a scale of 1 to 10. She also communicated to doctors that her lupus previously had caused her to experience brain swelling that now was being monitored by her neurologist.

After the woman was admitted, the hospital diagnosed her with a migraine headache and administered a migraine cocktail that included Dilaudid, Zofran, and Toradol. After the medication was administered, the woman indicated that her head pain had decreased to a 7 on a scale of 1 to 10.

The hospital then discharged the woman without providing her with a neurological consult, performing diagnostic imaging of her brain, or administering medications that reduce brain swelling. More importantly, the hospital failed to review the woman's past medical history that detailed how she had been treated successfully for brain swelling within the past two years.

On June 9, 2012, the woman experienced the same chronic headache upon waking and soon became unresponsive when her husband tried unsuccessfully to rouse her. The woman was transported by ambulance to the hospital, where doctors determined that she could not sustain significant neurological function. She was pronounced brain dead due to herniation caused by untreated brain swelling. After life-sustaining measures were removed, the woman died shortly thereafter.

The woman's estate and her husband sued the hospital, the medical corporation that employed the hospital's ED physicians, and the attending physician responsible for the woman's treatment. The plaintiffs' attorneys argued that if the doctors had reviewed the woman's medical history, it would have revealed that she had been treated successfully for brain swelling in the past and that her symptoms on June 8, 2012, were indicative of similar neurological swelling.

Attorneys for the hospital argued that doctors believed that the woman's headache was a normal continuum of the patient's chronic condition, which were her headaches.

The jury found that the hospital and treating physicians breached their duty to provide appropriate standards of medical care and treatment for the woman and awarded the plaintiffs $4.58 million.

What this means for you: This case illustrates the importance of a healthcare provider's role in making the ultimate decisions regarding a patient's medical care and treatment. It is standard practice for physicians to review a patient's chart, perform a history and physical examination of the patient, and then draw assessments about the patient's condition from this information. This information then is validated using the appropriate diagnostic testing.

It is equally common for physicians to consult the patient and/or the patient's family about the patient's symptoms and past medical history to obtain a more comprehensive picture of the patient's condition. However, in doing so, healthcare providers must bear in mind that simply because a patient and his or her family are knowledgeable about the patient's condition does not mean that they are responsible for making decisions regarding medical treatment and care, are sufficiently knowledgeable to provide qualified medical opinions, or even know what additional information they need to volunteer. These issues are the sole responsibility of the physician.

In this case, one of the ED physicians who treated the woman brazenly testified that the woman knew herself and her condition well enough that if she had wanted a CT scan, then the hospital would have considered ordering one. The jury rightly rejected this line of argument. It is not the patient's responsibility to request standard diagnostic tests.

In addition, when gathering a patient's medical history from a patient or a family member, healthcare practitioners must be mindful of the fact that these individuals may inadvertently provide incorrect medical information. For example, in this case, the woman's husband informed doctors that the woman experienced "migraines" frequently. Although the woman had never been diagnosed with migraines, the husband mistakenly used this term to describe the woman's past and present medical condition. This description, in turn, led to assumptions by the physician that resulted in the physician choosing to administer a "migraine cocktail" without first examining other possible sources for the woman's head pain. What may seem to be the simplest or most obvious diagnoses and treatment must be confirmed diagnostically, each and every time. Consulting with specialists, a neurologist in this case, also meets the standard of care and might have saved the woman's life.

While it is important to ascertain from the patient the reason why he or she has come to the hospital, healthcare practitioners must refrain from basing their decisions regarding patient treatment and care on this information alone. Healthcare providers are responsible for determining what is in the best interest of the patient because they alone possess the requisite level of training and skill and ultimately will be held to such a standard of care in a medical malpractice lawsuit.

Here, the woman's doctors testified that because the woman stated that she was at the hospital for pain relief and seemed comfortable with being treated, medicated, and then reassessed for head pain, the doctors did not consider ordering diagnostic imaging such as a CT scan or an MRI. The jury determined that the hospital breached the appropriate standards of medical care and treatment required under the circumstances by failing to obtain the woman's past medical records from the very same hospital or talk to any

of the doctors who had treated her in the past. ■

REFERENCE

Summit County Court of Common Pleas, Ohio, Case No. CV-2013-11-5404 (May 19, 2016).

Radiologist's Failure to Diagnose Breast Cancer Results in Jury Verdict of $6.9 Million

News: In 2008, a 39-year-old woman underwent a mammogram. The doctor who reviewed the results reported that the calcifications, or calcium deposits, found in the woman's right breast were benign. Although a prior mammogram screening in 2003 revealed no such calcifications, and the woman's medical records reported a family history of breast cancer, the doctor did not order further diagnostic testing of the woman's right breast. Instead, the doctor recommended that the woman undergo annual mammogram screenings. However, the woman did not elect to undergo a mammogram screening in 2009. In April 2010, the woman was diagnosed with Stage III invasive duct carcinoma, or breast cancer. Despite undergoing extensive treatment, the woman's cancer metastasized, and her prognosis was deemed terminal by 2013. The woman and her husband sued the doctor and the radiology practice, and they argued that they breached the appropriate standard of medical care and treatment by failing to order additional testing or recommend that the woman undergo another screening within three to six months. They also argued that the improper reading of the 2008 screening and the lack of further testing resulted in the untimely diagnosis of the woman's cancer more than two years later, with a significantly worse prognosis. After a jury trial returned a $6.9 million verdict in favor of the plaintiffs, the plaintiffs received $625,000 in accordance with a settlement agreement entered into during the trial.

Background: In 2008, a woman underwent a digital mammogram screening at a hospital. The doctor who ordered and subsequently reviewed the mammogram results reported that there were dystrophic-type calcifications, or calcium deposits that appear as white spots or flecks, in the upper portion of the woman's right breast. The doctor rated the woman's screening as a Breast Imaging Reporting and Data System (BI-RADS) 2, which means that he believed the calcifications found in the woman's right breast were benign. He also noted that there were no suspicious microcalcifications, which can be an early sign of breast cancer.

The woman had undergone a mammogram screening on Nov. 13, 2003, that did not reveal the dystrophic-type calcifications found in the 2008 screen. Furthermore, the woman's medical history provided that her mother had been diagnosed with breast cancer. Although the doctor recommended that the woman undergo an annual mammogram screening by April 2, 2009, he did not order any additional studies, diagnostic testing, or follow-up appointments with regard to the calcifications.

The woman did not have a mammogram screening performed in 2009. In April 2010, the woman sought medical treatment for a hard mass in her right breast, which had been present for about a month. On April 23, 2010, the woman was diagnosed with Stage III invasive duct carcinoma, or breast cancer. Although the woman underwent radiation, chemotherapy, and a mastectomy, by April 2013 the woman's cancer had metastasized and spread to her sternum, pelvis, and spine. At age 44, the woman was diagnosed with Stage IV breast cancer and given a terminal prognosis.

The woman and her husband sued, and plaintiffs' legal counsel argued that because the calcifications found in the 2008 mammogram screening were new and not present in the 2003 screen, the doctor should have rated the screen as a BI-RADS 0, or incomplete, and recommended additional screening, such as spot compression or spot magnification imaging. They further argued that this additional screening might have revealed pleomorphic features in the calcifications, which in turn would have required a biopsy of the woman's breast and a recommendation of additional mammographic surveillance in three to six months. Thus, the attorneys asserted that the foregoing breached the standard of care by failing to timely diagnose and treat the woman, which allowed the woman's cancer to progress to a greater stage before it was diagnosed in 2010 and resulted in a much worse prognosis.

The defense attorneys argued that the woman's cancer was of a type that is very difficult to diagnose and can grow so fast that it could have developed within a six-month period. They further argued that the calcifications found during the

2008 screen were not cancerous and did not indicate cancer. Finally, they alleged that it is difficult to determine when the woman's cancer developed because the woman did not undergo a screening in 2009 and that a natural disease process caused the woman's injuries or damages.

After a jury trial, the jury returned a $6.9 million verdict in favor of the plaintiffs. However, the court later vacated the verdict and instead implemented a settlement agreement that was entered into by the parties during the trial. According to the agreement, if the jury returned a verdict in favor of the woman, the plaintiff would receive $625,000 10 days after the jury verdict.

What this means for you: This case is an example of the critical importance of diagnosis and early detection of serious conditions, such as breast cancer.

Legal counsel for the plaintiffs built their entire case on the theory that had her cancer been detected sooner than 2010, her condition would have had a different, more favorable outcome. Healthcare providers should use every resource available to them in the treatment and care of patients, including the patient's medical history.

The woman's attorneys emphasized the fact that the woman's medical records, which note that the woman's mother was diagnosed with breast cancer, were available during the woman's 2008 mammogram screening. The woman's medical history also indicated that her screening in 2003 did not reveal calcifications. Accordingly, the plaintiffs' attorneys argued that the change in the woman's mammogram results from 2003 to 2008 should have warranted additional testing of the calcifications.

This case had many circumstances that pointed to reasons to perform further diagnostic testing. Another important point is that the doctor also had an opportunity to consult with competent peers. Supporting opinions from experts before an adverse outcome can serve a defendant well if litigation occurs. Taking this step not only supports the decision-making process, but it also demonstrates the physician's concern for the patient's health and long-term prognosis.

Note also that the familial tendencies of breast carcinoma have been researched for years, and countless publications, available to physicians and the public, emphasize the importance of placing patients with family histories of breast cancer into the high-risk category. Some women even elect to remove breast tissue to avoid developing the disease. This doctor chose to put his patient and his career at risk by ignoring basic warnings.

It is equally important to employ proper patient follow-up procedures, polices, and protocols. Healthcare professionals should explain to patients the significance of a doctor's recommendation for further diagnostic testing to ensure the likelihood of the patient actually following the recommendation. Additionally, hospitals should ensure that each patient's condition is surveilled and monitored according to the individual facts and circumstances that are presented to healthcare personnel. Here, the woman presented new calcifications not previously detected in a prior mammogram screening and had a family history of breast cancer, which should have warranted mammographic surveillance every three to six months rather than on an annual basis.

This case also illustrates the frequently staged battle between expert witnesses in establishing the appropriate standard of medical care and treatment that a healthcare provider will be held to during a trial. Medical experts for the woman asserted that the standard of care for patients who present the type of calcifications found in the woman's 2008 mammogram screening required that the patient should be advised to undergo screenings every six months for at least two years. Conversely, medical experts for the defense opined that even increased surveillance of the calcifications found in the 2008 screening would not have improved the woman's prognosis. Rather, they believed that the woman's cancer was so aggressive that the woman's dismal prognosis was caused by the natural progression of her cancer and not anything that the doctor did or failed to do. Ultimately, the jury believed the plaintiffs' expert more.

Finally, this case also is a good demonstration of an effective use of the "high-low" settlement strategy to limit exposure. In a "high-low" settlement, the parties agree that the plaintiff promptly will recover something, but almost always specify a procedural trigger and limit the top-end recovery. By agreeing to such a mechanism at some point short of the revelation of the jury's actual verdict, the defense saved itself well over $6 million. Strategic negotiation strategies can be employed even in the middle of trial, so always work with your counsel on parallel tracks, litigation, and settlement. ■

REFERENCE

Charleston County Court of Common Pleas, South Carolina, Case No. 2013CP1005902 (Jan. 21, 2016).