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Anatomy of a Malpractice Debacle

Quick settlement in Zarkin case won't clear liability for New York hospital

Doctor carves initials in patient's abdomen

A physician in New York admits that he carved his initials in the abdomen of a patient who had just delivered a baby, leading to a $5.5 million lawsuit against him and the already troubled hospital where the incident occurred.

State officials have penalized the hospital severely, but some observers are saying the case raises questions about how the health care industry screens out dangerous providers and whether an investigation by the Joint Commission on Accreditation of Healthcare Organizations really leads to any meaningful changes.

Though the patient initially sued the hospital and the doctor, she soon dropped the suit against the hospital and accepted a settlement of $1.75 million from the doctor. From a risk manager's perspective, that outcome is perhaps the most surprising part of a truly bizarre case.

The case is so outrageous that even seasoned health care risk management professionals are dumbfounded. **Allan Zarkin**, MD, 61 years old and until recently a respected obstetrician, admits through his lawyers that he used a scalpel to carve the letters A and Z into the abdomen of a 31-year-old patient, directly above the cesarean incision he had just closed. The letters are 3 inches high by 1.5 inches wide.

Zarkin's attorneys say he suffers from a frontal

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lobe disorder that caused him to disfigure the patient. The Manhattan district attorney, Robert Sullivan, JD, charged Zarkin with felony assault and vowed to continue investigating Zarkin's treatment of other patients. At his arraignment, Zarkin pleaded not guilty to the criminal charge.

This is the second scandal at Beth Israel Medical Center in New York City since November 1997. In the first incident, a woman died following what should have been a routine hysteroscopy, and there were allegations that an equipment salesperson actually performed part of the procedure. **(See story, p. 32, for a recap of that incident.)**

The hospital underwent a major investigation and had to prove itself worthy of accreditation again. But as proof that lightning can strike twice in the life of a risk manager, the same facility is now facing a barrage of investigations and the real possibility that the public will forever associate Beth Israel Medical Center with outrageously bad treatment of patients. The hospital still was facing such problems from the hysteroscopy incident, with those issues far from settled, when the Zarkin incident occurred and compounded the damage exponentially.

Hospital gets off the hook financially

One risk manager who was troubled by the hysteroscopy incident now tells *Healthcare Risk Management* she is shocked and perplexed by the way this case was settled. **Margaret Douglass**, MPH, RN, director of risk management at FPIC, a physicians' insurance company based in Jacksonville, FL, says she expected a quick settlement, but one that included a huge payout by the hospital.

"This is a risk manager's nightmare," she says. "The only thing you could do is get them [the plaintiffs] in there and write them a check as quick as possible and try to get them not to talk to the press."

The $1.75 million settlement might be explained by the doctor's malpractice limits and everyone's desire to end the ordeal, she says. But she says she can't imagine how the hospital avoided paying damages. The doctor's reported friendship with the victim and her husband may have something to do with how the case ended, she says. The doctor was not employed by the hospital, but Douglass says she does not think that would help its case much.

"It's a very strange result," she says. "The hospital would have been an ideal deep pocket, and they had no hope of really defending themselves.

You'd never let this kind of thing go to trial. I can't understand why the patient would let the hospital off the hook unless there's something here that we just don't know about."

Even the amount of the doctor's settlement seems small for such an egregious case, she says. "We wouldn't have gotten away with a settlement like that in Florida," she says. "We may never know the truth. There really are a million stories in the Naked City, I guess."

The hospital won't get off scot-free, however. The carving incident could irreparably damage the reputation of Beth Israel, Douglass says. The incident goes far beyond any typical malpractice case, she notes. "It certainly will not be easy to save their reputation," she says. "That first incident made it hard for the public to develop a level of trust, and now this one is so outrageously bad."

Hospital had warning signs

The hospital's situation worsened when it became known that there were warning signs of Zarkin's strange behavior, that Zarkin immediately got another job after leaving the hospital, and that hospital officials were still working cooperatively with the doctor two months after the carving incident. Hospital officials met with him to discuss sending nurse midwives to work at a clinic where the doctor had gotten a new job, according to a hospital spokesman. Zarkin met with Daniel Saltzman, MD, chief of obstetrics at Beth Israel, and other hospital personnel in November to discuss setting up a midwives program with Choices Women's Medical Center, a clinic offering abortions and prenatal care.

''The chairman of our department of obstetrics and gynecology had one exploratory meeting with the clinic in question to discuss a possible clinical affiliation,'' according to a statement released by the hospital. ''For a variety of reasons, Beth Israel did not pursue this matter further.'' The hospital confirms that when the meeting became public knowledge, Saltzman resigned his position as chief of obstetrics. He remains on the medical staff at Beth Israel.

The incident occurred on Sept. 7, 1999, but only recently became known publicly when the patient and her husband filed a $5.5 million lawsuit against the hospital and the doctor. There is little or no dispute about what happened that day in September. The doctor's attorney, **Kenneth Platzer**, JD, says Zarkin did indeed carve his initials in the woman's abdomen after delivering a healthy baby girl, while the patient was still sedated and in the delivery room where the birth took place.

Platzer says the doctor realized he had done something terrible soon afterward, but that he was not in a normal state of mind at the time of the carving. "We have filed an affirmative defense, which states that any actions taken by Dr. Zarkin were not willful or malicious but that Zarkin is suffering from a medical dysfunction that resulted in his action," Platzer says. "It was terrible, but it was unanticipated."

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Platzer says Zarkin did not resist when officials revoked his privileges at the hospital, but that Zarkin did not know before this incident that he had a neurological disorder. "At the behest of family and consulting physicians, he underwent an initial work-up that shows he appears to have a disease process consistent with Pick's disease, a progressive form of dementia. He currently is under treatment to determine the prognosis."

Platzer stresses that Zarkin is not disputing the material facts of the case, only claiming that he harbored no ill will that would motivate him to disfigure the patient. Platzer says Zarkin had become socially friendly with the patient, 31-year-old dentist Liana Gedz, and her husband while managing her difficult pregnancy. When he realized what he had done to her, Platzer says, the doctor recognized the gravity of the situation and surrendered his privileges without a fight.

Zarkin's attorney says it is unclear whether the doctor realized at the time of the carving what he was doing. "He feels absolutely terrible about the entire situation and can't imagine what possessed him to do it," Platzer says. "He wasn't holding a grudge or being cute or wanting to do something on a conscious level. We're just now trying to sort out why he did exactly what he did, but we know it was his disorder that led to it."

The lawsuit was filed Nov. 8, 1999, against the hospital, Zarkin, and Zarkin's medical group, New York GYN / OB Associates. The first cause of action sought unspecified damages for medical malpractice, so whatever that amounted to theoretically could have been added to the $5.5 million total. The second cause of action was battery, an intentional tort for which the plaintiffs were asking $5 million. That figure includes punitive damages, Platzer says. The additional $500,000

was requested for the plaintiff's husband to cover derivative damages.

The hospital and the doctor still could face other disciplinary action and investigations. The Joint Commission in Oakbrook Terrace, IL, is aware of the carving incident and has begun a review of the allegations, says spokeswoman **Donna Larkin.** She tells *HRM* the carving incident is being reviewed as a sentinel event.

The Joint Commission's previous investigation, and the timing of this most recent problem, raises questions for some observers. Just before the carving incident, the Joint Commission had put its stamp of approval on Beth Israel once again after investigating the previous hysteroscopy incident. The November 1997 hysteroscopy incident was classified as a sentinel event, requiring the hospital to conduct a root cause analysis to find the cause. In addition, the hysteroscopy incident prompted the Joint Commission to conduct a survey of the hospital in December 1998. That survey led inspectors to cite a number of deficiencies and to call for these improvements in these areas before continuing accreditation:

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- patients' rights;
- initial assessment;
- anesthesia care;
- operative and other procedures;
- orientation, training, and education of staff;
- patient-specific data and information;
- credentialing.

"On Aug. 23, 1999, the Joint Commission informed Beth Israel that they had demonstrated compliance with those recommendations for improvement," Larkin says. The hospital was again fully accredited by the Joint Commission. Sixteen days later, Zarkin carved his initials in a patient.

The timing of the incident suggests that Beth Israel still is unable to properly screen out a dangerously incompetent provider, Douglass says. One would think that after such a serious investigation of a sentinel event and improvements required by the Joint Commission, the hospital's oversight would be tight enough to detect a physician who was a threat to patients for any reason, whether it is a neurological disorder or outright depravity, she says.

"It makes you wonder what they improved after the first incident," she comments. "If the Joint Commission called for improvements in credentialing, and this guy had any history of strange behavior, they should have caught it before he hurt someone."

The Joint Commission defends its oversight process by claiming that there is no way to prevent a single doctor from committing an outrageous act. The sentinel event investigation may reveal process shortcomings that made it possible for the doctor to carve on the patient, but Joint Commission vice president **Paul Schyve** says the previous Joint Commission investigation could not be expected to prevent any future act by a disturbed physician.

"An organization is made up of hundreds of people, and things will happen," he says. "We can't anticipate that incidents like this will occur, but organizations seek Joint Commission accreditation to reduce the risk as much as possible. The idea is that if a hospital is following these rules, the patients are more likely to get good care and bad things are less likely to happen."

JCAHO defends its oversight

Schyve denies any charges that the timing of the incidents and the Joint Commission accreditation indicate shortcomings in the oversight process. If the incidents were very similar, there might be more justification for doubting the value of the intervening Joint Commission investigation, he says.

"But if you do that [investigation] with one event and make the kind of changes the root cause analysis suggests would be necessary to make, you may not have addressed some sort of changes that would be helpful in avoiding some other type of event," Schyve says. "So the fact that you were successful in reducing the chance of one type of adverse event occurring does not mean that you have addressed all possible adverse events. That is why this is a continuing process."

In addition, Douglass says she is troubled by the fact that the doctor could be hired so easily as medical director at Choices Women's Medical Center in Long Island City, NY. State health department officials say the clinic did not check his credentials as required by state law, so the clinic is being investigated for that alleged violation. **(See p. 31 for more on the sequence of events and p. 30 for Beth Israel's expected liability.)**

The state health department investigated the incident and recently issued a scathing report

on the hospital's culpability. The department announced Jan. 21 that Zarkin had signed an "Order of Conditions" requiring him to cease the practice of medicine effective Jan. 7, pending resolution of disciplinary proceedings against him.

On Feb. 3, the health department released a report saying the hospital knew about aberrant behavior by Zarkin long before the carving incident and did not intervene, and that the hospital did not respond appropriately after the incident. **(See story at right for more on the health department's recent actions against the hospital.)**

Report says three patients were mistreated

The health department report says the investigation by the New York State Board for Professional Medical Conduct stems from Zarkin's mistreatment of *three* patients, including the woman who has his initials on her stomach. The three accusations against Zarkin are for "verbal abuse of one patient; negligent practice, and / or negligent supervision of another patient's care; and using a surgical instrument to create a scar in the shape of the letters A and Z on the body of a third patient without the patient's consent and for no medical or proper purpose."

Sources would not release information on the other two patients in the allegations, but *The New York Times* reported Jan. 27, that a woman contacted the newspaper claiming to be the patient who accused Zarkin of verbal abuse. She told the newspaper the doctor had been her gynecologist until he made lewd and sexually suggestive comments to her.

The attorney handling the case for Beth Israel Medical Center, **Laura Shapiro,** JD, of New York, says the hospital has issued a strict order not to comment on the case. **Jim Mandler**, a spokesman for the hospital, says no one else at the hospital is allowed to comment. ■

Sources

- **Kenneth Platzer**, 666 Third Ave., NY, NY 10017. Telephone: (212) 697-4090. **Margaret Douglass**, Director of Risk Management, FPIC, 1000 Riverside Ave., No. 800, Jacksonville, FL 32204. Telephone: (904) 354-5910.

Beth Israel fined $14,000 by NY health department

Hospital is warned to clean up its act

Pointing to repeat deficiencies related to quality assurance, provider credentialing, and incident reporting, the New York State Department of Health has cited Beth Israel Medical Center in New York City for seven violations, resulting in penalties of $14,000 against the hospital. The proposed fines amount to $2,000 per violation, the highest monetary penalty allowable under state law.

In announcing the action, state health commissioner **Antonia Novello**, MD, MPH, said the state investigation revealed that, no matter what motivated Allan Zarkin, MD, to mutilate his patient, the hospital bore responsibility. "I cannot and will not tolerate a situation in which an individual seeking health care is put in harm's way because of a facility's failure to monitor its medical staff and the failure to take prompt corrective action once it became aware of the incident," Novello said. "The violations cited against Beth Israel Medical Center are in reference to the lack of oversight of the hospital's department of obstetrics and gynecology and a failure on the part of administrators to appropriately report the seriousness of the incident once they became aware of it."

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In addition to the fines, the state health department imposed these sanctions:

- The hospital will be required to submit a "Plan of Corrections" describing how each of the identified deficiencies will be addressed and what corrective action will be taken. For a period of one year, the hospital must submit quarterly reports to the state health department detailing the corrective actions that have been implemented and assessing their effectiveness.
- The hospital must retain an independent consultant organization, acceptable to the state health department, to conduct an in-depth analysis of the management and oversight of Beth Israel's department of obstetrics and gynecology and provide a detailed report and recommendations for improvement within 60 days, with a particular focus on the department's quality assurance and provider credentialing.
- Beth Israel Medical Center must hire an

independent consultant to analyze and suggest hospitalwide improvements to quality assurance and credentialing within 120 days. Once the hospital receives either consultant's report, recommendations must be implemented within 30 days, providing they are acceptable to the health department.

Doctor will not practice medicine again

Also, the health department made final a disciplinary order under which Zarkin surrendered his license to practice medicine. "Dr. Zarkin's case is an example of what can go wrong in the medical field if reporting procedures are not adhered to and if prompt and decisive actions by health care facilities are not implemented to protect patients," Novello says. "As health commissioner, my top priority is to ensure that patients receive the best health care, and of the highest quality. Because Dr. Zarkin presents an imminent danger to patients under his care, I have done, and will do, everything within my power to ensure that he never again practices medicine in the state of New York."

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The health department cited seven violations of Article 28 of the Public Health Law and the New York State Health facilities code. Deficiencies were cited in the areas of governing body, medical staff, quality assurance program, patient rights, incident reporting, and medical records. The department's investigation focused not only on whether the hospital properly investigated and took appropriate action after the carving of initials incident, but also on the possible warning signs before the incident that Beth Israel failed to act on.

Specifically, the investigation determined that although the hospital conducted a prompt investigation and suspended Zarkin two days after the carving incident, Beth Israel officials did not file a required incident report through the New York Patient Occurrence Report Tracking System.

In a Sept. 28 report to the health department's Office of Professional Medical Conduct (OPMC), the hospital indicated only that Zarkin had been suspended because his actions toward an obstetrical patient were grossly inappropriate. No details of the carving incident were provided. The health department now reports that "such lack of specificity in reporting was at variance with previous reports submitted to OPMC by Beth Israel which provided explicit reasons for the suspension actions taken against other physicians."

"Despite clear indications a year before the carving incident that Dr. Zarkin's behavior was inappropriate, Beth Israel officials did not take necessary action," the report says. "There was no documentation of follow-up by the hospital when nurses and physicians first complained to their superiors of strange behavior by Dr. Zarkin."

In December 1998, Zarkin was sent to the hospital's occupational health service for evaluation, but counselors were not provided with full information about Zarkin, and the hospital subsequently disregarded its own plan to monitor the doctor's behavior, the health department reports.

The health department also noted the repeat nature of some of the deficiencies, since violations relating to the operation and oversight of Beth Israel's department of obstetrics and gynecology, as well as the hospital's quality assurance program, were cited following an investigation into an incident of patient harm in October 1998.

The hospital still faces likely sanctions from federal investigators and the Joint Commission on Accreditation of Healthcare Organizations in Oakbrook Terrace, IL. ■

Beth Israel is likely to be held responsible

Accreditation, Medicare/Medicaid are at risk

Pending investigations are likely to find that Beth Israel Medical Center in New York City is responsible for the incident in which a doctor carved his initials on a patient's abdomen, says one risk manager, even though the doctor clearly was acting in an unreasonable and unexpected manner. Another says the case should be a lesson in the importance of explicitly reporting problems to licensing authorities.

Like New York State Department of Health officials, investigators from the Joint Commission on Accreditation of Healthcare Organizations are likely to conclude that hospital officials should have foreseen the incident due to other disturbing behavior, says **Margaret Douglass**, MPH, RN, director of risk management at FPIC, a physicians' insurance company based in Jacksonville, FL. The investigation by the health department

concluded that the hospital had ample warning that something was seriously wrong with Zarkin but did not respond appropriately.

"They will get dragged in hook, line, and sinker," Douglass says. "If this was so egregious, there must have been some behavior patterns that they should have picked up on before. It doesn't sound like it would be an isolated event. You would think that if a practitioner did something as egregious as this, there would be other signals."

'They are as exposed as they can get'

Douglass was a nurse before she became a risk manager, and she says she occasionally saw "providers outside of the norm, with some quirky behaviors, but nothing even close to this. It's hard to believe anybody could do something this strange and you wouldn't see warning signs."

Another question regards the action, or apparent inaction, of the hospital staff and possibly other physicians nearby when the doctor was carving his initials on the patient. It is not clear who was around and who might have been close enough to see exactly what the doctor was doing, and it also is not clear whether anyone tried to intervene. But the doctor's attorney says the carving took place in the delivery room, immediately after the doctor closed the Cesarean incision, so that suggests that hospital staff may have been nearby.

"This is not just about the doctor and the actual moment he did the carving," Douglass says. "What were the people around the room thinking? How could they let him do this and nobody said anything? They are as exposed as they can get."

Clinic failed to check credentials

The doctor's immediate hiring at a women's clinic after leaving Beth Israel points to significant problems with the licensing system, says **Steve Johnson**, director of risk management for Wellstar Health System in Marietta, GA.

Johnson says the hospital may have erred by reporting "gross misconduct" to the state health department as the reason for Zarkin's departure, rather than explicitly saying what he had done. With something as egregious as mutilating a patient, an explicit report would prompt an investigation, whereas a more general comment might not.

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Dismissed doctor quickly hired by clinic

Recommended by friend; credentials unchecked

A spokesman for Beth Israel Medical Center in New York City, **Jim Mandler**, confirms that Allan Zarkin, MD, carved his initials in the patient in the delivery room and that staff members saw the mutilation immediately afterward. They reported the incident to their superiors without delay, he says, and the patient discovered the initials when she was in the recovery room.

The hospital's chief administrator visited the patient the next day to see the carving and suspended Zarkin's privileges a day later. On Sept. 17, Zarkin resigned his privileges.

Several sources confirm this sequence of events: Beth Israel Medical Center reported the incident to the New York State Department of Health, saying Zarkin would no longer practice there because of "gross misconduct," providing no details on the incident. At the same time, Zarkin's partners at his physician group dismissed him. On Nov. 1, 1999, Zarkin was hired as medical director at Choices Women's Medical Center in Long Island City, NY, by an old friend. On Nov. 4, 1999, Zarkin poorly performed a gynecological operation, according to a complaint filed with the state health department.

The lawsuit was filed on Nov. 9, 1999, and on Dec. 13, 1999, Beth Israel sent the president of Choices a letter saying Zarkin's privileges had expired. The letter did not detail why Zarkin left Beth Israel but suggested Choices' president call the hospital if she had further questions. She did not learn of the carving incident until Dec. 28, 1999, when the plaintiff's attorney sent a copy of the civil suit sent to the clinic. She fired Zarkin that day.

On Jan. 7, 2000, Zarkin volunteered to temporarily suspend his license at the request of the state health department. On Feb. 3, the health department announced that Zarkin's license was permanently revoked. ■

"When we've had bad situations with professionals, we try to give more details for the reason they were suspended than just a generic description," Johnson says. "I can think of one case where we had a physician who changed a medical record after the fact, and we reported it to the state in that manner, not just as a violation of policy. We gave them enough information to make a judgment."

"This should be a learning opportunity for all of us that we've got to work more closely with our licensing folks . . ."

Johnson notes that hospital officials often must walk a fine line between explicit disclosure and protecting a professional's right to due process and privacy, but he says the Zarkin case is one in which the hospital should have just told state authorities what happened as clearly as possible. The wrongdoing was so extreme and so clearly unacceptable that any sugarcoating would be a disservice to patient safety, he says.

"This should be a learning opportunity for all of us that we've got to work more closely with our licensing folks in certain situations we consider egregious to give them the information they really need," he says. "Give them enough information to know whether this is something they need to move on quickly or not so quickly."

As for the clinic that apparently hired Zarkin without checking his credentials, Johnson says that failing tempts any administrator who is personally familiar with a candidate, but it nevertheless is a failing.

"It happens all the time that we get referrals from close friends swearing this guy is a great doctor and would be an asset to our organization," he says. "That's great, but we do all the normal checks, go through the normal credentialing process, because we have a responsibility to due diligence." ■

Source

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Hospital sanctioned for death during hysteroscopy

Incident led to sentinel event investigation

The current problems at Beth Israel Medical Center in New York City come close on the heels of another incident at the hospital that also was remarkable for the extreme nature of the alleged malpractice. The incident involved a woman who died during what should have been a routine procedure. Investigators claim that the woman died because two gynecological surgeons made gross medical errors and that an equipment salesman actually performed part of the procedure. As in the Allan Zarkin case, there was evidence of long-known complaints against the doctors. One doctor's privileges to deliver babies had even been revoked.

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Even though the salesman's alleged participation in the procedure apparently was not the cause of the woman's death, observers say it greatly complicates the defense of the malpractice cases and creates extremely bad publicity for the medical center. The immediate fallout from the incident was a $30,000 fine imposed by state health officials. They concluded that a salesman of hysteroscopy equipment participated in the procedure, actually manipulating the new electrosurgery system because the doctors and nurses did not know how to operate it.

The woman's husband also filed suit against the hospital, both surgeons, the anesthesiologist, and Ethicon, the company whose salesman allegedly participated in the procedure. Ethicon is a division of Johnson & Johnson.

The incident also was investigated as a sentinel event by the Joint Commission on Accreditation of Healthcare Organizations in Oakbrook Terrace, IL. **Sam Bishop**, ARM, vice president of compliance and insurance services for Wellstar Health System in Marietta, GA, called the allegations "a nightmare, a massive failure of the system that is supposed to protect the patient. There's no way to make an excuse for this, to make this sound like anything better than what it is. You'd think these things just couldn't happen, but then they seem to pop up every once in a while."

The incident began in October 1997, according

to a report from the State Department of Health. Ethicon salesman David Myers reportedly met with Allan Jacobs, MD, chairman of the hospital's department of obstetrics and gynecology, to introduce an Ethicon product used for hysteroscopies, a minimally invasive procedure. The product, the Versa point Bipolar Hysteroscopy Electrosurgery System, allows the surgeon to cut and ablate with electrosurgery probes.

Jacobs made no commitment to buy the product but did not dissuade Myers from seeking the support of surgeons and other administrators, the report says. Myers arranged to have the product used in surgery about a month later with OB-GYN partners Marc Solar, MD, and Robert Linger, MD. The patient, Lisa Smart, 30, was a healthy accountant and financial analyst undergoing hysteroscopy for the removal of a benign fibroid tumor — a routine procedure with relatively little risk.

State health investigators say the OR nurses told the surgeons they were not familiar with the new electrosurgery system, but that the surgeons dismissed their concerns and said Myers would operate it. The salesman was scrubbed and did operate the electrosurgery system during the procedure, according to the health department report.

However, the report does not claim the salesman's actions led to the woman's death. In fact, it appears that he may have performed his task better than the actual surgeons. As a normal part of the procedure, the patient's uterus was filled with saline, and nurses monitored the fluid output closely to make sure that the patient was not overloaded with fluids. The salesman reportedly was operating the electrosurgery equipment and had no involvement in the fluid administration. The state report says that a nurse told the doctors several times during the surgery that the fluid output was too low, but her concerns were dismissed.

But immediately after the surgery, the patient appeared bloated from excess fluid. According to the state report, one of the OR nurses claims that Linger admitted to shutting off the fluid outflow so he could get a better view of the uterus, an action that could lead to fluid overload if not corrected quickly. Linger denied shutting off the flow or making the statement afterward, according to the report.

As a result of the fluid overload, the woman went into cardiac arrest soon after surgery and died in the emergency department. The autopsy determined she had died of "excessive infusion and absorption of normal saline." ■

Dialysis centers settle fraud suit for $486 million

Settlements will only get bigger, experts say

The largest health care settlement in the history of the U.S. Department of Justice (DOJ) has yielded $486 million from a national chain of kidney dialysis centers. One attorney involved in fraud litigation says the settlement "raises the bar as far as future settlements go," suggesting an upward trend in the amount of money awarded.

The settlement with the Massachusetts-based National Medical Care includes a criminal fine of $101 million for wide-ranging misconduct, according to a DOJ statement. The agreement also includes $385 million in civil fines, penalties, and restitution for fraud related to Medicare and other government health care programs, the statement says. Whistle-blowers will collect $65.8 million of the $385 million civil recovery.

'Landmark recovery' is a success story

The settlement includes allegations that company officials used Medicare and other government health insurance programs to pay for hundreds of needless tests for patients suffering from kidney disease, officials said. Company executives also obtained referrals of lab business by paying kickbacks, a violation of anti-kickback statutes, officials say. National Medical Care is owned by Fresenius Medicare Care AG (FMS), a German company that is the world's largest provider of dialysis products and services.

"Today's landmark recovery comes as one more example of success in our fight against health care fraud, which has been a priority at the Justice Department since 1993," said **Eric Holder Jr.**, deputy attorney general.

The government's involvement is a key point, says **Stephen Meagher**, JD, an attorney with Phillips & Cohen in San Francisco. The firm specializes in representing whistle-blowers in False Claims Act cases and is responsible for about two-thirds of the $1.3 billion the government has collected through whistle-blower lawsuits in the past five years. "This case sends the message that false claims cases in which the government intervened are likely to have a large outcome," he says. "The numbers are going up, and that's generally a good thing. This settlement raises the bar in terms of

what we might expect from future cases."

June Gibbs Brown, inspector general of the U.S. Department of Health and Human Services in Washington, DC, called the investigation and settlement "an excellent example of multiple law enforcement agencies working together on a long, complex Medicare fraud investigation. We are committed to working with our partners to investigate these complicated schemes, to hold the responsible parties accountable, and to return ill-gotten gains to the Medicare Trust Fund."

Brown notes that as part of the settlement, Fresenius has agreed to the most comprehensive corporate integrity agreement ever imposed on a company doing business with federal health care programs. The corporate integrity agreement requires Fresenius to conduct mandatory compliance activities, including special audits and training, to help prevent this kind of misconduct from recurring. Typically, corporate integrity agreements run for five years, but the Fresenius agreement will last for eight years and covers every aspect of the company's future business with federal health care programs.

Size of settlement could strike fear

The huge number could trigger fear among health care professionals who have been trying to anticipate paying on their fraud cases, Meagher says. National Medical Care had reserved $2 million for settling this case, so they got a big surprise when it came to the actual payout, he says. Others could experience the same shock.

"Columbia HCA has a billion dollars in reserve for their own fraud case, so you have to wonder if they're going to be covered or their own payout will be much bigger," Meagher says. "For those in the health care fraud community, the message is that the money you set aside is not necessarily what it's going to be. It can grow much larger."

Other than the huge settlement, Meagher says there was nothing especially novel about the case. "It's been known for a long time that end-stage renal disease was an area where the government was getting royally ripped off," he says.

Some attorneys are starting to worry that the government is going to start pushing for more criminal fines, he says, because the whistle-blowers don't share in that part of the settlement.

"I gather from what I'm told that the whole thing has been fraught with nastiness for a while, with people expecting the government to start leveraging the size of criminal fines in an attempt to keep more of that money for themselves," he says.

Though the settlement is the biggest to date in health care, a landmark for that reason alone, Meagher compares it to Dow Jones crossing the 10,000 mark. The number is significant, but it almost certainly will be surpassed, he says.

"We see other things in the pipeline that will continue the trend in big money for the government," he says. "The big one, of course, is Columbia. They've put aside letters of credit favoring the government to the tune of a billion dollars. Even if it doesn't go beyond that, that will be a huge settlement. And the other lesson is that even though these things take years, they do get settled eventually." ■

Source

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JCAHO issues reminder on survey process changes

Health care providers will see several policy modifications in 2000 under the Joint Commission on Accreditation of Healthcare Organizations' Accreditation Process Improvement (API) initiative, including some that will radically alter the way providers are accredited.

Most of the changes went into effect Jan. 1, 2000, and the Joint Commission recently issued a reminder that the new policies are in effect. These are the changes to the accreditation process:

• Advance notice for random unannounced surveys has been discontinued. Surveys may be conducted at any time between nine and 30 months following the triennial full survey.

• "Accreditation with Commendation" has been eliminated as an official decision category. Recent field research indicated that this decision category was leading organizations to place inappropriate emphasis on achievement of commendation and interfering with the consultative and educational aspects of the accreditation process.

• There are new guidelines for evaluation of peer review and credentialing processes. Surveyors will examine specific issues such as the organization's definition of the circumstances requiring peer review; the participants included in the review process; and the time frames in which the review must be conducted and results reported.

• Surveyors will receive an enhanced pre-survey information packet that will provide them with more information about the health care organization such as its recent complaint history, if any, and its ORYX data.

• The survey agenda has been revised to allow surveyors the time necessary to address in more depth organization-specific performance issues.

• Scheduled survey dates will be posted on the Joint Commission's Web site beginning in the first quarter of 2000.

• Pilot testing of the extension of the on-site survey activities to evening, night, and weekend periods, which began during the last quarter of 1999, will continue in the first quarter of 2000.

• A common identifier for all accredited organizations will be created and will be used to improve customer services.

• The focus of the unannounced survey also has been modified. In addition to five pre-selected standards-related performance areas, organization performance will be reviewed in areas indicated after an analysis of certain organization-specific information.

Organization-specific performance areas for review will be selected for review based on an analysis of the organization's last accreditation survey or any validated complaint or performance measurement data received since the last full survey. For some organizations, the extent of review required for the organization-specific elements of the survey may not allow the time needed to assess all of the pre-selected performance areas. In such cases, only the highest priority, pre-selected elements will be addressed.

The Joint Commission conducts random unannounced surveys for a 5% sample of accredited organizations. The percentage of random unannounced surveys has not changed. The first group of organizations eligible for a random unannounced survey under the modified policy are those that had their triennial survey between July 1997 and April 1999.

Random unannounced surveys will not be conducted for laboratories or health care networks in 2000. ■

Pharmacy group proposes system for error reporting

National system could reduce medication errors

The American Society of Health-System Pharmacists (ASHP) in Bethesda, MD, is proposing a national approach to reducing medication and other medical errors.

The ASHP, which represents 30,000 pharmacists who practice in hospitals and other components of health systems, is advocating the establishment of a national medical error reporting system and the strengthening of voluntary reporting systems.

"We need to move beyond the culture of blame that has traditionally surrounded the issue of medical error and begin to establish standardized reporting systems that take a 'lessons-learned' approach to the problem," says ASHP president **Bruce Scott**, FASHP.

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"The ideal system would allow sunshine into the processes that create error so that we can change those processes and protect patients," he adds.

The ASHP statement says a mandatory reporting system should only be applied when patients are seriously harmed or die as a result of error. "This system should focus on three primary goals: accountability, quality improvement, and enhancement of patient safety," Scott says.

Pharmacies play a role in error prevention

ASHP recommendations are in direct response to the Institute of Medicine's recent report on medical error, "To Err is Human: Building a Safer Health System," which highlighted the important role of pharmacists in preventing medication errors, especially through their work on patient-care teams.

ASHP supports a mandatory medical error reporting system at the state level with strong federal coordination, analysis, and oversight. That system would focus on improving health care processes; providing confidentiality to patients, health care workers, and institutions as long as the confidentiality doesn't compromise public accountability; and eliminating penalties for either the reporting of or involvement in a medical error that causes serious harm or death.

Standardizing reporting methods

The group also recommends the adoption of a definition of "serious harm" that focuses on incidents of long-term or irreversible patient harm. It also advocates that a mandatory system include national coordination and standardization of reporting methods and analysis, adequate resources for report analysis and quality improvement, and periodic assessment to ensure the system is working and not creating undesirable consequences.

ASHP also weighed in on the importance of maintaining and improving current voluntary reporting systems. The Society noted that the current Medication Errors Reporting Program operated by the U.S. Pharmacopeia in cooperation with the Food and Drug Administration's MedWatch program and the Institute for Safe Medication Practices could serve as a model for voluntary reporting of other types of medical errors. ■

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Failure to communicate need for cancer tests: $850,000

News: The plaintiff patient and her husband received a jury verdict of $850,000 against a physician who failed to communicate the need for a colonoscopy after an endoscopy showed no ulcer despite bleeding, and did not contact the patient when the preoperative blood work indicated anemia. Colon cancer was diagnosed a year later and had progressed significantly.

Background: The patient / plaintiff in this case went to her gynecologist for her annual checkup. The day before she had noticed blood in her stool and had experienced severe stomach pains, both of which she reported to her doctor. She was thirty-three years old and had given birth to her first child six months earlier. The blood in her stool was confirmed by the internist to whom her gynecologist had referred her, and the internist ordered an upper endoscopy that was performed one week later. The endoscopy showed mild gastritis for which over-the-counter medications were prescribed. The medical records from the procedure indicted that she was to be tested for anemia and based on the results she might need a colonoscopy. However, the potential need to seek further testing was not provided to her in her discharge papers from the endoscopy nor was she informed through any other means of the potential need for any follow-up tests.

Further, when the preoperative blood test results were made known to the internist the next day and indicated anemia, once again the patient was not contacted. Even though both the internist and a nurse initialed the medical records notation to "contact patient," neither the physician or nurse had actually contacted the patient. The physician believed that by initialing the results, the nurse would contact the patient; and conversely, the nurse acknowledged the abnormal results, but believed the practice to be that only the physician contacted the patient when abnormal results occurred. Accordingly, the patient was not notified at either point of the need for further testing.

After two months of using the over-the-counter medications for gastritis, her symptoms disappeared. When she returned for her annual physical one year later and complained of fatigue and pain in her right side, a subsequent blood test revealed severe anemia, for which she was hospitalized, during which time a colonoscopy was performed. The colonoscopy revealed colon cancer, which had advanced to a Dukes B2 tumor requiring chemotherapy. The plaintiff claimed that her chances for survival had fallen from 85-95% to 60-75% because of the one year delay in diagnosis of the cancer. Because of the chemotherapy, the patient suffered infertility and arthritis.

What this means to you: Cheryl A. Whiteman, RN, MSN, HCRM, a private health care consultant in Florida, says, "apparently, the preoperative blood work was reported to the internist the day after the endoscopy was preformed. Review of preoperative testing before beginning a procedure would be the expected standard of care. Also, although the internist and a nurse initialed the records notation to 'contact patient,' regarding her anemia, neither took responsibility to do so. Each assumed that this would be done by the other. Assumptions lead to errors and omissions. A written policy regarding patient notification and corresponding documentation could have prevented such an omission," notes Whiteman.

"Communication is critical to the provision of quality health care, regardless of the clinical setting. Accurate and complete information must be relayed among providers and between providers

and the patients and/or their families. This unfortunate example demonstrates how repeated failures in communication resulted in advancement of colon cancer in this young patient. Incomplete documentation and documentation without appropriate follow-up left a readily visible paper trail of errors," concludes Whiteman.

Reference

Lynda Figueroa and Melvin Figueroa v. Internal Medicine Associates, Orange County (FL) Circuit Court, Case No. 98-9503. ■

Negligent hiring, diagnostic failure: $600,000

News: Plaintiff alleged that the hospital negligently hired a pathologist against the recommendations of the hospital's internal quality improvement committee and that the physician's failure to read biopsy slides taken during an elective hysterectomy lead to an 11-month delay in the diagnosis of ovarian cancer.

Background: The plaintiff estate brought suit against the hospital where an elective hysterectomy had been performed. In the course of the procedure, biopsy tissue had been extracted and examined by the chairman of the department of pathology; however, he failed to notice that the slides of her ovary and fallopian tubes' tissues contained cancer cells. Eleven months later, she was diagnosed with ovarian cancer and claimed that the delay in diagnosis allowed for significant metastasis and reduced the chances for a possible cure. The plaintiff maintained that the hospital was negligent in its hiring of the pathologist.

Two years before the alleged missed diagnosis, the hospital's Ad Hoc Committee on Quality Improvement has decided not to endorse the pathologist's request for appointment to the medical staff and further noted that his work was not of acceptable quality for him to be qualified to lead the department of pathology. Despite the ad hoc committee's recommendation, the hospital's medical executive committee appointed the pathologist to the medical staff as chairman of the department.

While the ad hoc committee's actions are generally protected by state law, once identified as of potential interest through the discovery phase of the proceedings, after an in camera review by the judge, otherwise confidential material may be revealed. That occurred in this situation. The pathologist resigned from the position shortly after the case was revealed. It was settled out of court for $600,000 based on the theory of negligent hiring.

What this means to you: "This case demonstrates that corporate liability is alive and well as a legal means of imposing responsibility on a hospital for the acts of negligence committed by independently contracted physicians holding staff privileges as originally enunciated in *Darling vs. Charleston Community Memorial Hospital* by the Illinois Supreme Court in 1965 or under *Respondeat Superior* for negligently hiring an employee," notes **John C. Metcalfe**, Vice President, Risk Management Services, Memorial Health Services in Long Beach, California.

"When the trier of fact may gain access to information or documentation that staff privileges were granted or an employee was hired counter to a hospital or medical staff committee's recommendation, it should be expected that the trier of fact's evaluation will be quite critical and probably adverse to the hospital. After all, when the purpose of a committee is to evaluate quality and competency, its recommendation should not be taken lightly. When it is specifically noted that the staff member's work is not of acceptable quality, and that same staff member winds up injuring a patient, there is very little likelihood, even in the hands of the most competent and capable defense attorney, to successfully defend such a case," says Metcalfe. He suggests "that in the hospital environment, committees that review and evaluate quality and competency tend to error on the side most favorable to the staff member. Therefore, when a committee appointment to review quality and competency makes a recommendation not to endorse a staff member, a decision-making body needs to be warned of the legal ramifications of making a decision counter to the recommendations of the committee. The decision-making body needs to be specifically advised of all relevant aspects of corporate liability and the state's jury instruction on the issue should be taken into consideration."

Reference

Estate of Maria Isabel Tome v. Marvin Lessig and Christ Hospital, unknown New Jersey venue. ■