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Informed consent nightmares – Is it a dream that you won't have one?

Legal experts offer advice on how to avoid liability

A woman came in for breast implants and went under anesthesia. The silicone implants she had selected were not available; only saline ones were there. She was kept under anesthesia while the woman's fiance was told about the mistake and, according to the subsequent lawsuit, was pressured to make an immediate decision. He told the surgeon to go ahead with the silicone implants. The only problem? He wasn't legally authorized to make a decision for the patient.

The physician refunded $1,050 to the patient, apologized, and attempted to argue that saline implants were superior to silicone, the lawsuit says. The patient is seeking $300,000 for corrective surgery and for emotional and physical discomfort. The lawsuit accuses the surgeon of medical battery, medical malpractice, intentional infliction of emotional distress, and false imprisonment for allegedly keeping the patient unconscious longer than necessary.[1] The physician did not respond to a request for comment

In another case, a physician and his facility were found liable because the doctor documented "did not get consent form, because patient doesn't speak English."[2] Apparently the physician made no attempt to obtain an interpreter, which is mandatory under patient rights regulations from the

SPECIAL FOCUS ISSUE: HOW NOT TO GET SUED

In this special issue of *Same-Day Surgery*, we give you the most up-to-date advice on how to avoid liability in outpatient surgery. In our cover package, we tell you some horror stories involving informed consent and how you can avoid them. We tell you why vendor contracts can increase your liability, and what steps you can take to avoid that problem. Another story explains what areas are being targeted by federal and state governments as Stark Law violations. We also include the second part of our series on new guidelines on testing staff who are infected with HIV or hepatitis.

We hope you find this issue an essential addition to your risk management efforts!

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Centers for Medicare and Medicaid Services (CMS), says **Sue Dill Calloway**, RN, Esq., BSN, MSN, JD, a nurse attorney and medical legal consultant in Columbus, OH. Calloway recently presented an audio conference on "Informed Consent 2010: The Latest in CMS and Joint Commission Consent Requirements" for AHC Media, publisher of *Same-Day Surgery*.

Calloway has experienced her own issues with informed consent. When she tore her anterior cruciate ligament and went in for surgery, the registration clerk handed her a consent form and said, "Here you need to sign this that the risks, benefits, likelihood of achieving the results have all been discussed." "And I looked at her and I said, 'I'm extremely embarrassed because I'm a nurse, I teach this stuff, but you know I haven't talked to the doctor about the risks and benefits and alternatives,'" Calloway says. "And being very unsympathetic she looked at me and she said, 'Look, lady, if you don't sign this, you're not having surgery today.'"

Calloway's husband and mother had woken at 4 a.m. to take her to the hospital and were waiting with her, so she signed it. "If the surveyor had come to me and said, 'Oh, how was that informed consent process?' and I just repeated what happened, they would actually cite the hospital," Calloway says. "That registration person has now violated this requirement."

The reason? Informed consent is a process, not a piece of paper, Calloway says, "and when she knew that process had not been accomplished, just saying 'sign this form or you're not having it' is violating the standards." The Joint Commission and the Centers for Medicare and Medicaid Services (CMS) are emphasizing that informed consent is a process, she says.

Don't wait for a lawsuit to be filed before you develop a thorough informed consent process, Calloway warns. When she was doing medical malpractice legal work, she had three examples of what she considered to be the best informed consent. "I found out that they had all been sued before for informed consent, and that's when they got great informed consent," Calloway says.

Consider these suggestions:

- **Establish policies on intraoperative consents.** Ambulatory surgery programs should have

EXECUTIVE SUMMARY

If you don't have your informed consent process being properly executed, you can wind up with unhappy patients and ultimately, an expensive lawsuit.

- Ensure your policies cover intraoperative consents and the right to refuse treatment.
- Ensure the consent is on the record before surgery and that it includes the state law. Physicians performing surgery at hospitals often miss the correct name of the facility and the time.
- Because of increasing problems with electronic medical records, audit a number of charts every quarter and share the results.

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policies about how intraoperative consents are obtained and who may grant such consent, says **Patricia S. Calhoun**, JD, associate at Buchanan Ingersoll & Rooney in Tampa, FL.

"Emergencies are different, but ASCs frequently run into the argument that they could have stopped and asked the patient," Calhoun says. "Because elective surgery can always be rescheduled, I think juries are less likely to understand going forward with a decision like this [different type of breast implant] from someone not authorized to grant consent in an elective surgery." *(See story on what to include in informed consent, p. 76.)*

• Policies must address right to refuse treatment.

Ensure your policies and procedures address the right to request or refuse treatment, Calloway says. "...I need to know what all the risks and alternatives are so I can make an informed decision, so that's part of the informed consent process," she says.

• Have the consent on the chart before surgery.

CMS requires providers to have a consent form in the chart before patients go to surgery, except for emergencies, Calloway says. "You've got to have a policy to make sure it happens, so they should have had a process when that person knew I hadn't been given any information, that should have told her what to do," she says. The form must be signed before administration of medications/anesthetics.

If the consent form is signed outside the facility, then you have to include in your policy how you're going to get it into the chart, Calloway says. "Make this easy," she advises. "They can fax it in, they can e-mail it in, the patient can bring it with them, the doctor can bring it with him."

• Ensure thorough documentation.

From a medical malpractice perspective, the best defense is good documentation, say sources interviewed by *Same-Day Surgery*.

Calhoun says, "Documentation that the patient stated they had no questions, that they understood the risks and benefits, that they understood or that their physician had answered all their questions, are all helpful when the patient alleges that they did not give informed consent, because the basis of that allegation is that the patient just signed the paper."

The physician also should document the same information or even more, she says. "In addition, careful documentation any time a consent is changed in the pre-op holding room is very important," Calhoun says. "In particular, documentation about the patient's level of awareness and the timing of any medications can be key."

Anesthesia providers sometimes administer a small amount of medication for anxiety, but the exact time that medication is administered is frequently missed, she says. "Pre-op nursing can document that sedation was given per anesthesia and note the time, just in case the anesthesia provider doesn't," Calhoun says.

• Beware of electronic medical records.

Problems with electronic medical record documentation is increasing in frequency, Calhoun says.

"In order to make the charting easier and more complete, many facilities use a template," she says. "I've seen it be wonderful, but I've also found that complacency causes a template to end up with some really goofy results."

Staff might check the wrong boxes or forget to check the right boxes, Calhoun says. The end result can be a poor medical record, she says. "I'd recommend that facilities pull a sample number of the template records every quarter or so, and share the results with the staff," Calhoun says.

• Follow guidance from national organizations.

Several national organizations have developed informed consent guidance, including The American Congress of Obstetricians and Gynecologists (www.acog.org/from_home/publications/ethics/co439.pdf), the American Association of Nurse Attorneys (www.aana.com/practicedocuments.aspx), and the American College of Surgeons (www.facs.org/fellows_info/statements/stonprin.html), Calloway says.

RESOURCES

• The Queensland Government offers a site for consent forms that list the risks, complications, and alternatives of procedures including general surgery. Web: www.health.qld.gov.au/consent/html/for_clinicians.asp.

• Minnesota Alliance for Patient Safety. This web site focuses on informed consent forms for a population with lower literacy. Web: www.mnpatientsafety.org/index.php?option=com_content&task=view&id=85&Itemid=69.

• The National Quality Forum maintains a set of Safe Practices for Better Healthcare, including ones on informed consent. Web: www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=18338.

"So whatever area you're in, always be familiar with your organization's, because if you follow those you can use them in the court room, and if you don't follow them they can be used against you," she says. (*For hospital and ASC requirements, see below. For accreditation requirements, see p. 77.)*

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What to include in informed consent

When performing informed consent, there are several critical elements for hospitals, including a list of the procedures that your facility has compiled that require informed consent, says **Sue Dill Calloway**, RN, Esq., BSN, MSN, JD, a nurse attorney and medical legal consultant in Columbus, OH. Calloway recently presented an audio conference on "Informed Consent 2010: The Latest in CMS and Joint Commission Consent Requirements" for AHC Media, publisher of *Same-Day Surgery*.

This list is a requirement of the Centers for Medicare and Medicaid Services (CMS) and The Joint Commission. "You have to have a list of procedures that you do in the hospital, and you have to say 'yes' or 'no,'" Calloway says. "Make sure that all of the procedures that your physicians and your licensed independent practitioners are credentialed and privileged for are on that list."

CMS says that signed informed consent forms are needed for all hospital surgeries except in emergencies, she says. It "doesn't matter whether they're inpatients or outpatients," Calloway says.

Calloway supports individualized consent forms for each procedure, although she acknowledges that such forms take a lot of time and effort and they must be kept updated. "But I really think it's worth it, having been a defense attorney," she says.

CMS surveyors are told to confirm that the policy discusses state law and that the state law requirements are included on the consent form. They also are told to pull six medical records from the hospital. They also are told to ensure the consent forms have the minimal or mandatory elements, she says. Those elements are:

- **The name of the facility.** When a patient is having elective surgery and is receiving the consent form in a doctor's office, the doctor doesn't always think to put the name of the hospital on the form, Calloway says. "That's one of the two that the doctors miss," she says.
- **The procedure.**
- **Description of the surgery, plus risks and benefits.**

The description of the surgery should include the anesthesia to be used, Calloway says. You have the option of spelling out the risks, benefits, and alternatives, or simply saying on the form, "The risks and benefits and alternatives have been discussed with me," she says.

"And of course, having been a defense lawyer, I would really like to say `the risks include but are not limited to,' and that you specifically name the reasonably known risks," Calloway says.

- **The practitioner.**
- **Who is going to perform the surgery.**

The Centers for Medicare and Medicaid Services (CMS) requires that you list whoever is doing important parts of the surgery, even if the surgeon is in the OR supervising the entire time, Calloway says. Patients must be informed about staff who are assisting, such as the RN first assistant, surgical physician assistant, or surgical resident, she says. However, you aren't required to list the names of the assistants, Calloway says.

She says that one teaching hospital says in its consent form, "We are a teaching hospital, and as such we have surgical residents on most of our cases and they do help us with important parts of the surgery including helping make the decision, helping close up the incision," etc.

List all potential physicians

Be careful, Calloway warns. "If you're in a group where you cover for each other like gastroenterologists..., just say, 'Anyone in our group could be doing the procedure including A, B, and C.' Or 'Dr. A is going to be doing it, but often, the way that we're set up, any of the [doctors] can

fill in, and so you have permission for Dr. B, C, and D,'" she says. If you have one doctor listed, and another doctor performs the procedure, "you don't have any informed consent," she says.

• **Signature/date/time.** The time is the second element that physicians often miss, Calloway says. Representatives from CMS and The Joint Commission want everything timed: "every time of every order, time of every consult report, a time of everything in the progress note," she says.

• **The state law requirements.**

Recommendations for surgery centers

For ambulatory surgery centers, CMS officials say that a well-designed informed consent process would most likely include a discussion of the following:

• **a description of the proposed surgery, including the anesthesia to be used;**

• **the indications for the proposed surgery;**

• **treatment alternatives, including the attendant material risks and benefits;**

• **who will conduct the surgery and administer the anesthesia;**

• **whether physicians other than the operating practitioner will be performing important tasks related to the surgery.** Important surgical tasks include: opening and closing, dissecting tissue, removing tissue, harvesting grafts, transplanting tissue, administering anesthesia, implanting devices, and placing invasive lines;

• **whether, as permitted by state law, qualified medical practitioners who are not physicians will perform important parts of the surgery or administer the anesthesia,** and if so, the types of tasks each type of practitioner will carry out; and that such practitioners will be performing only tasks within their scope of practice for which they have been granted privileges.

Don't forget the implants

In addition, informed consent documentation should include details of the implant, legal sources say.

One option is to list the specific type and size of implement, such as 450 cc Mentor silicone implant, says **Patricia S. Calhoun**, JD, associate at Buchanan Ingersoll & Rooney in Tampa, FL.

"The physician should have already thoroughly discussed this information with the patient, but by putting it in writing, the [ambulatory surgery center] can have some additional assurance that the patient is truly informed," Calhoun says.

However, the physician might not know ahead of time exactly what size implant will be used, which would mean that the consent would have to include a list of the options or a range of possible options, she says. In addition, the facility might not have that information in advance and would have to wait for the physician to provide the information before the consent is signed, which could cause delays, Calhoun says.

"And there is the problem about what happens when the physician no longer wants to use the proposed size or style, based upon his or her surgical findings," she says. "Surgery is an art, not just a science, and decisions made based on the findings during surgery are well within the standard of care"

Managers will have to weigh the options and determine if adding that information to the consent improves their outcomes and/or the quality of care, Calhoun says. ■

Know your accreditation, regulatory requirements

Health care facilities, depending on their individual circumstances, might be required to follow the following group's requirements with their informed consent policies: Centers for Medicare and Medicaid Services (CMS), The Joint Commission, The Accreditation Association for Ambulatory Health Care (AAAHC), and state law.

If you are at an ambulatory surgery center that is a joint venture with the hospital, then you most likely will have to follow the CMS Conditions for Coverage, says **Sue Dill Calloway**, RN, Esq., BSN, MSN, JD, a nurse attorney and medical legal consultant in Columbus, OH. "And then if your hospital decides to get in a joint venture with the physicians, you decide to get it accredited by one of the ambulatory accrediting organizations, then you have to follow those guidelines," Calloway says. "So that's what makes it so confusing in this country, is that first you just have to figure out what standard applies to you." Calloway recently presented an audio conference on "Informed Consent 2010: The Latest in CMS and Joint Commission Consent Requirements" for AHC Media, publisher of *Same-Day Surgery*.

If you accept Medicare and Medicaid patients, then you must follow those standards for every patient, she says.

For its part, The Joint Commission defines informed consent as the "agreement or permission accompanied by full notice about the care, treatment, or service that is the subject of the consent." The agency says that patients must be apprised of the nature, risks, and alternatives of a medical procedure or treatment before the physician or other health care professional begins. After receiving this information, the patient consents to or refuses the procedure or treatment (Joint Commission Standard RI.01.03.01).

The standards don't say who should witness and sign the document, but the document clearly has to denote that there is a mutual understanding between patient and independent licensed practitioner about the care, treatment, and services the patient will receive, says **Virginia McCollum**, MSN, RN, associate director of the Standards Interpretation Group at The Joint Commission. However, some state laws spell out that the physician or a physician designee has to witness and sign the informed consent, McCollum adds.

For its part, AAAHC standards call for specific informed consent for the surgical procedures (10.1.T) and if anesthesia is used (9.E), according to **Frank J. Chapman**, MBA, chief operating officer of Asheville (NC) Gastroenterology Associates and a member of the AAAHC board.

AAAHC standards also call for informed consent for situations such as observation by non-medical staff, including medical students, and for non-medical interventions such as dental or mental health services, Chapman says.

"The process is designed to facilitate two-way communication between the patient, or the patient's legal representative, and the provider," he says.

Some providers use video presentations as part of the informed consent process, Chapman says. However, "the video is only one component of the process and cannot replace the process of open communication between the patient and the provider," he says. "In all cases there must be a formal written consent signed by the patient, or the patient's legal representative in the patient's chart prior to the procedure."

Always have the current manuals for your regulatory and accreditation requirements, Calloway emphasizes. *(Editor's note: Medicare manuals are available at /www.cms.gov/manuals/downloads/som107_Appendicestoc.pdf.)* State hospital associations are excellent resources for requirements, as are state departments of health, she says. ■

Avoid liability with your contracts

Horror story points to need to investigate

[Editor's note: This is the first part of a two-part series on avoiding liability in contracting. In this month's issue, we tell you about how you can end up contracting with the wrong company and what your liability can be. In next month's issue, we give you specific steps to investigate vendors, and we suggest items to watch for in the contract.]

A hospital has a disagreement with its anesthesia group and decides not to renew its contract, which is set to expire.[1] Negotiations are undertaken with a new group. At the last minute, the group requests that a different name be used on the contract, which the negotiators claim is a new affiliate of their group.

After the contract is signed, the president of the former anesthesia group posts a video on YouTube that says the newly signed company has a business address in a strip mall. He questions the hasty credentialing of the new anesthesiologists. "We are very, very concerned about the safety of our patients," the president says.

Representatives of the company that hospital officials thought they had negotiated with says they have no affiliation with the group named in the contract. Although the "affiliate" claimed to have had more than 25 years of experience managing anesthesiology services, the company didn't officially exist until February 2010. The hospital was its first contract. The lead negotiator for the contract is determined to be the son of the founder

EXECUTIVE SUMMARY

Ensure you don't end up signing a contract with a different vendor than the one you negotiated with, or with a vendor that has a questionable reputation.

- You can be held liable for the services of your contractor, depending on the contract you signed.
- Your contract might not be covered by your insurance.
- Investigate the people doing the negotiating, and conduct due diligence on their company.

and head of the company that the hospital thought it was negotiating with.

Articles in the local newspaper and letters to the editor accuse the hospital administrator of putting patients' safety and health in jeopardy. Open-heart surgeries are on hold while a cardiac anesthesiologist is sought.

Just nine days after the contract is signed, the hospital drops the new group and replaces it with an in-house medical group as manager. The hospital said its reason was that it "refused to go from one unacceptable management situation ... to the potential for another ...."

Situations in which a facility ends up signing a contract with a company different from the one with which it intended are not unheard of, says **Richard Bays**, RN, MBA, CPHQ, CLNC, health care consultant with R Bays Consulting, Houston, TX. "I've seen some things, such as a company domino onto the reputation of another company," Bays says. "Or they'll use another, similar name, so it looked like a subsidiary." The end result? "I've seen people get burned," Bays says.

Be forewarned: You can be held liable for the services of your contractor, depending on the contract you signed, say sources interviewed by *Same-Day Surgery*. **John Schario**, MBA, CEO of Nueterra Healthcare, part of a U.S. holding company in Leawood, KS, says, "In the end, if you are the party that is being paid for the service or your place of business provided a component of the service, you can be held responsible for anything that is provided. It can be very difficult to place blame, especially if the vendor claims your staff used a product wrong or played some role in the claim."

Your contract might not be covered by your insurance, Bays says. Notify your insurance company that you are entering into an agreement, he advises. Determine if your contractor will be covered as an "insured contract," Bays says. If it is, then ask the vendor you are contracting with to also cover you with their insurance, he says.

To avoid liability, thoroughly investigate the company, experts advise. Start with the people doing the negotiating, advises **Stephen Trosty**, JD, MHA, CPHRM, ARM, president of Risk Management Consulting Corp. in Haslett, MI. Verify their positions, Trosty says. Confirm that these persons have the right to negotiate contracts on behalf of the company and to hold the company responsible and liable for the contacts, he says. Document the negotiations, sources say.

In the case with the newly introduced "affiliate" company, "that should have been a red flag, when at least minute you suddenly have a new corporation that is signing the contract, and not the corporation you've been dealing with," Trosty says. In such a situation, don't sign the contract until you've thoroughly checked out the newly named entity, he says.

Contracting decisions should be based on more information than answers to a request for proposal (RFP), Schario says. "Providers should conduct due diligence on anyone they plan to subcontract with, especially those who will come in contact with patients whose care is entrusted to you," he says.

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Engage surgeons to protect selves, patients

[Editor's note: This is the second part of a two-part series on a new guideline from the Society for Healthcare Epidemiology of America (SHEA) regarding the management of providers who are infected with hepatitis B virus (HBV), hepatitis C virus (HCV) and human immunodeficiency virus (HIV). In last month's issue, we gave you an overview of the guideline, which procedures are at greatest risk of transmission, and the recommendations for infected staff. In this issue, we further explain the new guidelines and discuss how to decide which workers to test.]

The new Society for Healthcare Epidemiology of America guideline is embedded in a long, detailed, and heavily referenced document, says **Janine Jagger**, PhD, MPH, director of the International Health Care Worker Safety Center at the University of Virginia in Charlottesville.

"Without going into excruciating detail, the main difference between the previous guideline and this one is that the number of cases in which patients have been infected by providers has

grown," Jagger says.

There is one paragraph embedded in the 29-page document that sums up the philosophy neatly, Jagger says: "The accumulated experience and data provide reassuring evidence that the magnitude of risk for provider-to-patient transmission of HIV, HCV and HBV, although not zero, is exceedingly small. At the same time, the burdens of certain restrictions that have been placed on healthcare providers out of concern for patient safety have been disproportionately high. ... These burdens, associated with highly personal and stigmatizing diagnoses, seem unjustified in the face of an extremely low risk . . ."

She says, "In other words it is better to sacrifice the patient's health — possibly life — in order to protect health care providers from discriminatory restrictions than to protect the patient's health at the expense of the health care worker's right to practice his or her profession."

The guideline are on the side of the health care worker, Jagger says. "Although the philosophy underpinning the new guideline remains unchanged, we are in a very different situation today than when the guidelines were first introduced almost 20 years ago," she says. "We have an effective vaccine for hepatitis B, effective treatments for hepatitis C, and effective treatments and post-exposure prophylaxis for HIV."

Health care provider-to-patient transmission of bloodborne pathogens is limited to a narrow scope of health care, Jagger says. "This is an issue affecting surgeons, and only those performing procedures that involve hands in a body cavity in proximity to sharp objects," she says. "We do not need a scattershot policy encompassing all health care workers. This issue needs to be worked out with surgeons."

It is in surgeons' best interest to know their bloodborne pathogen status, "although some may still need to be convinced of that," Jagger says.

Scientific and medical advances have not yet been fully incorporated into policies, she says. "We have the knowledge and resources to create new policies that are not based on a choice of whom to sacrifice, whom to protect," Jagger says. "There is no time like the present for surgeons to engage in this discussion and put forward some enlightened policy proposals that protect their patients as well as their own interests. I believe they are up to the challenge, and the goal is within reach." ■■

Facilities must decide which workers to test

At the Infected Health Care Worker Program in the Minnesota Department of Health, nurse specialist **Stephen Moore,** RN, MPH, has a case load of 150 health care workers who have HIV, hepatitis B, or hepatitis C. Some are administrators not involved in patient care. Only about 20 are nurses, doctors, or dentists who perform invasive procedures that are considered exposure-prone, according to a 1991 guideline from the Centers for Disease Control and Prevention.

The new guideline of the Society for Healthcare Epidemiology of America (SHEA) provides some updated approaches to monitoring but also presents challenges, says Moore. Since the guideline was released in March, health care managers have been determining how or whether they will adapt their policies. Many states have laws relating to health care workers infected with HIV or HBV, and facilities must adapt any changes to those statutes.

"For the 15% of the licensed health care workers I deal with who have some chance of transmitting [a bloodborne pathogen], it probably has some benefits to raise awareness and send a message to the public that we do look out for this," Moore says. "We work hard with health care workers in modifying their practices to make sure people don't lose their careers. When we work with people, we treat them as if they have honor and ethics and they're good at what they do — they just happen to have this disease."

Bi-annual testing of viral load would add a new wrinkle to the monitoring. It also will raise the question of cost: Who pays for the testing? Physicians and even some surgical techs might be independent contractors and might perform procedures at more than one facility. Moore plans to meet with infection diseases experts and the state attorney general to consider policy changes. "I plan to seek input on the SHEA guidelines from infection preventionists, governing boards, and other state agencies," he says.

The Joint Commission expects health care facilities to consider national guidelines related to health care workers infected with a bloodborne pathogen. But they don't necessarily have to adopt the monitoring protocol recommended by SHEA, says **Robert Wise**, MD, vice president of The Joint Commission's Division of Standards. "We would expect the organization to have thought through

how to handle a situation," he says. "We don't demand that they use the SHEA guideline, but we would expect some sort of pronational guideline be used to direct their policy."

A recent review of state laws and guidelines found that only one addressed hepatitis C, and 15 required notification of patients before an invasive, exposure-prone procedure if the worker was infected with a bloodborne pathogen. None of them addressed the issue of viral burden, said **Sarah Turkel**, MPH, an investigator with the National Institutes of Health Clinical Center in Bethesda, MD, who presented the findings this year at the Fifth Decennial International Conference on Healthcare-Associated Infections. In 19 states, the issues of possible practice restrictions are handled at the hospital level, her review found.

How often should you test HCWs?

A recent HBV transmission from an HBV-positive orthopedic surgeon to patients forced the University of Virginia (UVA) Health System in Charlottesville to reconsider issues of testing and restrictions. The surgeon had been a nonresponder to HBV vaccination. He discovered that he had hepatitis B infection — with a viral load of 17 million international units per ml of blood — in baseline testing after a reported sharps injury.

The health system then tested patients in 237 procedures and discovered two HBV-positive cases that were linked to the surgeon and four that were likely cases of transmission, says **Kyle Enfield**, MD, MS, assistant hospital epidemiologist, who presented the findings at the Fifth Decennial International Conference. After treatment, the surgeon was allowed to resume performing procedures, with restrictions, says Enfield. He must double-glove and must report any potential exposures. He must have a non-HBV-infected surgeon with him in the operating room. He is also restricted from performing the most exposure-prone procedures, such as total hip or total knee replacement. The health system does not require him to reveal his HBV status to patients prior to surgery.

"The risk of transmission with a low viral load is infinitesimally small," says Enfield. UVA now conducts further testing of nonresponders to the HBV vaccine to determine if they are HBV-infected, says Enfield. The health system does not require routine testing of surgeons who perform invasive, exposure-prone procedures.

That is in keeping with the new SHEA guideline, which calls for "voluntary confidential testing" but not mandatory testing of providers.

Facilities will need to make a determination about testing of providers, says **Neil Fishman,** MD, director of health care epidemiology, infection prevention, and control at the University of Pennsylvania Health System in Philadelphia, an author of the guideline and president of SHEA. "At the least, every institution should offer confidential and readily available testing to providers," he says. "Then it's up to each institution to decide whether that should be mandatory if someone is going to perform these exposure-prone procedures." At the University of Pennsylvania, for example, Fishman says, "we make testing readily available and strongly recommended. We're considering whether to make it mandatory."

For physicians, testing could take place when their credentials are periodically renewed, he says. ■

Government targets physician self-referral

Are you certain you are compliant?

In the past 10 years, there have been about 100 settlements of self-referral and kickback between the Office of Inspector General (OIG) of the Department of Health and Human Services and health care facilities. Twenty of these cases occurred in the past two years.

In one recent case, a hospital faces nearly $45 million in damages for Stark Law violations.[1] The hospital, Tuomey Regional Medical Center in Sumter, SC, was found to have provided part-time employment arrangements which violated the provisions of the Stark law to induce referrals. The OIG had sought $277.5 million for fraudulent Medicare claims (False Claims Act) against Tuomey Regional. The hospital was found not to have violated the False Claims Act.

Such cases are cropping up more frequently as health care facilities seek closer alignment with physicians, and those alignments are coming under increasing scrutiny by the federal government, legal experts say. And it's not just the federal government getting involved. In New Jersey, the Codey Law places restrictions on physician owner-

EXECUTIVE SUMMARY

As more health care facilities are looking to closely align themselves with physicians, the federal government and states are cracking down on violations of the Stark Law, the False Claims Act, and other regulations.

- Use legal consultants who are familiar with anti-kickback, self-referral, and other regulations. Don't keep shopping for a favorable opinion.
- Look at physician/facility relationships as a whole, rather than focusing on individual physician's relationship with the facility.

ship of surgery centers and limits construction of new physician-owned centers.

"In reality, a lot more of these violations come up, state and federal government are being more vigilant and aggressive in looking for them and going after them," says **David M. Johnston**, JD, associate with Bricker & Eckler in Columbus, OH. Through pilot projects, OIG is "being very aggressive regionally," Johnson says. Additionally, the recently passed health care reform law has several provisions that strengthen enforcements for the False Claims Act and for violations of the Stark Law, he says.

Hospitals and ambulatory surgery centers don't always strictly follow the Stark Law exceptions, To avoid violations, obtain solid legal advice, say experts interviewed by *Same-Day Surgery*. The Stark law is a strict liability statute, Johnston says. "That means you don't have to have intent to do wrong, just technicalities put you in violation," he says.

The law is quite detailed and has several parts that require compliance, Johnston points out. Health care facilities need knowledgeable legal advice about relationships their facility is planning with physicians, he says. "They particularly need to get good valuations advice, to make sure the contract is for fair market value for whatever services are being provided," Johnston says.

Compensation arrangements must meet fair market value standards and must be commercially reasonable, without regard to volume of referrals, to meet the requirements of the Stark Law, says **Sandra Miller**, Esq. a partner in the Greenville, SC, firm of Womble Carlyle Sandridge and Rice. Miller represented the physician relator who originally brought the federal lawsuit. The government intervened and took over the lawsuit after investigating the original complaint.

The lesson to be learned? You can't shop for legal opinions or appraisals, Miller says. In other words, if you have an arrangement that you feel is very outside the norm, and you have a reputable firm or reputable group that tells you `there is a problem with this,' you can't keep going to people until you get someone who tells you it's OK, she says.

Ensure you're using reputable consultants and legal counsel who are familiar with the Stark law and regulations, Miller advises. Make sure you are compliant on the front end, she says. "It's much easier to correct contractual relationships before anyone has billed anything, than to find a problem on back end and have to engage in repayment," Miller says.

Look at individual/group relationships

As collaborations grow between physicians and health care facilities, one significant concern is the need to avoid examining each individual physician relationship in isolation, Miller says.

For example, consider the example of a joint venture that involves a physician group with a medical director. Those physicians might have "problematic relationships" in which they manage other programs, product lines, or research for the hospital, Miller says. "Each by itself may be OK, but you have to look at the whole too and make sure it all fits together," she says. The Medicare program requires that when a business venture impacts multiple contracts with one physician group, they should cross reference each other. The same requirement goes for lease arrangements.

"If you have a large medical practice group, you could have 12-15 arrangements between one group and one hospital," Miller says. The solution? "Look at them individually and in their totality," Miller says. ■

Same-Day Surgery Manager

A look at trends in outpatient surgery

By **Stephen W. Earnhart**, MS
CEO
Earnhart & Associates
Austin, TX

Well, this is a fine mess all us health care providers are all getting into isn't it? I mean, we have oil spills, the earthquakes, and volcanoes and

various other sundries out there to make our lives more complicated and miserable. On top of those disasters, at press time it just had been announced that Medicare is cutting reimbursement to physicians by 21% starting in June. It is no wonder so many surgeons want to do their own surgery center — just to break even!

It is so frustrating for everyone dealing with this uncertainty. I normally focus on revenue and not expenses, and I still will, but with a slight turn of direction. I know that the paperwork under that new reform is not quoted as being "significant," but I have seen so many things change that were not going to change either that I am skeptical of just about all of it.

It is time to consolidate as much work effort as possible at our facilities, be they hospital or freestanding. Consider rolling everything into one package and letting one business handle it: custom packs, billing, revenue cycle enhancement, electronic medical records (EMR), staffing, you name it. Outsourcing of billing is probably cheaper now than doing it in-house. Even if it is breakeven, it is still a better deal to outsource it as the prices have come down. Having one company to handle transcription, insurance verification, and other stuff I don't even understand, "uncomplicates" the process.

Speaking of EMR, how many of you are making the transition? We have found that most facilities are holding off until they have a better idea of how health care reform is going to be handled. There's too much confusion right now for lots of people to deal with it.

Other thoughts on trends in health care:

I am really getting disgusted with the human billboards of people advertising some company's product or logo. I mean it would be different if they were paying you to wear their product on your T-shirt or hat, but you are paying them! This is really starting to irk me, and it is a practice that must stop.

In terms of dental procedures, how many of you are doing them? The facility fee from Medicare is about $675 for the smallest of procedures. Look into it.

Do you know the reimbursement for many of the urological cases? They have risen nicely over the past couple years. Call those urologists and talk with them.

In-vitro fertilization (IVF) is hot (Goggle it), and you should be doing these procedures at your facility. It offers nice private pay revenue.

If you are expanding your hospital suites or surgery center, put windows in your operating rooms. The natural light is a hit with the surgeons, and rooms that have full-length windows are the most sought after by the docs.

Make sure you insist on your business office manager taking vacations regularly. I am hearing more and more horror stories about embezzlement from centers where the manager insists upon not taking time off. Have someone oversee them frequently. Don't think it can't happen to you. It did to me more than once. *(For more information on avoiding embezzlement, see package of stories in the September 2009* Same-Day Surgery.)

Want to shorten your patient recovery time? Turn off the recovery room TVs.

Increase your "time outs" to two per case. Don't rely on just one. In addition to the one timeout just before the case starts, add another one just before the patient is taken into the room. *[Earnhart & Associates is a consulting firm specializing in all aspects of outpatient surgery development and management.]* ■

CNE/CME INSTRUCTIONS

Physicians and nurses participate in this CNE/ CME program by reading the issue, using the references for research, and studying the questions. Participants should select what they believe to be the correct answers, then refer to the answers listed in the answer key to test their knowledge. To clarify confusion on any questions answered incorrectly, consult the source material. After completing this semester's activity with the **December** issue, you must complete the evaluation form provided and return it in the reply envelope to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you.

COMING IN FUTURE MONTHS

- Avoid lawsuits over CRNA supervision
- OSHA's new role in infection prevention
- Award-winning secrets for patient satisfaction
- Where do you with an accreditation question?

CNE/CME QUESTIONS/ OBJECTIVES

- **Identify** clinical, managerial, regulatory, or social issues relating to ambulatory surgery care.
- **Describe** how current issues in ambulatory surgery affect clinical and management practices.
- **Incorporate** practical solutions to ambulatory surgery issues and concerns into daily practices.

1. According to Sue Dill Calloway, RN, Esq., BSN, MSN, JD, a nurse attorney and medical legal consultant, when a registration clerk says that if a patient doesn't sign an informed consent form, there won't be any surgery, which of the following is true?
   A. The registration clerk is correct.
   B. The registration clerk should notify the surgeon that the patient doesn't feel informed.
   C. The clerk violated the Medicare informed consent requirement.
   D. None of the above.

2. What are the two elements that physicians often miss on informed consent forms, according to Calloway?
   A. The name of the facility and the time.
   B. The name of the facility and the procedure.
   C. The procedure and the time.
   D. The time and who is going to perform the surgery.

3. According to Frank J. Chapman, MBA, chief operating officer of Asheville (NC) Gastroenterology Associates, which is true of video presentations as part of the informed consent process.
   A. The video can replace open communication between the patient and the provider.
   B. The video can replace open communication between the patient and the provider, as long as the patient is given the opportunity to ask questions.
   C. The video cannot replace open communication between the patient and the provider.

4. What is the tip from Stephen W. Earnhart, MS, CEO of Earnhart & Associates, to shorten patient recovery time?
   A. Tell patients at check in what time you expect them to be discharged.
   B. Turn off the recovery room TVs.
   C. Confirm patient's ride home before surgery.
   D. Have patients sit in recliners.

Answers: 1. C 2. A 3. C 4. B.