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INSIDE

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Patients, Staff Using Cellphones in ASCs Could Cause Major Trouble

Lawsuits have resulted from insults — and worse

An anesthesiologist preoccupied with sending text messages didn't notice a patient's oxygen level dropping until it was too late. An ambulatory surgery patient's cellphone was left on in the operating room, and the patient later sued after hearing the anesthesiologist speak badly about him. A nurse's aide and anesthesiologist put stickers on an unconscious surgery patient and snapped a photo — also resulting in a lawsuit.

Each case involved physicians and others getting into legal trouble because either patients or staff carried cellphones in patient care areas. In the case of the doctor who made fun of a patient while he was unconscious, the mistake cost her $450,000.[1]

> EACH CASE INVOLVED PHYSICIANS AND OTHERS GETTING INTO LEGAL TROUBLE BECAUSE EITHER PATIENTS OR STAFF CARRIED CELLPHONES IN PATIENT CARE AREAS.

These are just some of the legal reasons why ambulatory surgery centers (ASCs) should prohibit all patients and staff from bringing cellphones into operating rooms and other areas used for patient care.

"If you have a cellphone in the [ASC], then you could be recording things in the pre-op area with other patients and hear protected health information from them," says **William A. Miller**, JD, partner and chair of the healthcare group at Higgs, Fletcher & Mack in San Diego.

Other reasons to prohibit cellphones:

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infection control and the potential for phones to create a distraction — as in the case of the texting doctor.

ASCs should be very concerned about potential breaches of privacy and HIPAA, says **Gil Cabrera**, JD, principal with The Cabrera Firm in San Diego.

It's a mistake to give staff and patients full access to cellphones, which easily can violate patients' privacy, he says.

"Even in waiting rooms, you'll have people taking selfies," Cabrera says. "You need to have policies that say, 'Please do not take photographs in the waiting room.'"

Here's the privacy risk: Suppose a patient takes a selfie and inadvertently captures a photo of another patient in the background of the picture. That additional person has just had his or her privacy breached.

"You've just told the world what that person is doing now," Cabrera explains. "People do not often think about these things, but especially in those groups of settings, where you might be comfortable telling people in your world what is going on with every moment in your life, but that doesn't mean other people are comfortable with it."

Most people rely on their cellphones for video and photos, and this makes the ubiquitous devices a potential hazard.

"As the technology has improved, it also makes it easier for people to record without the knowledge and consent of other people," Miller says. "I'm not saying the [ASC] staff or physicians are doing anything wrong, and we're not trying to prevent people from seeing what they're doing behind the scenes because we all want the best care for patients, but you can't always prevent complications."

Infection control also is important, and cellphones are microbe zoos.

"From the risk management side, these devices have a frightening amount of bacteria," Cabrera says. "There are contamination issues."

Staff will find it difficult to check their phones in a locker, but that is the safest strategy, he says.

"From a contamination standpoint, you don't want staff checking their phones and handling biomatter," Cabrera says.

Cellphone rules for staff also should apply to doctors in the ASC.

Miller has represented ASCs, including one in which the lawsuit was about whether an anesthesiologist had given the patient the wrong medication because of cellphone use.

EXECUTIVE SUMMARY

Cellphone use in ambulatory surgery centers (ASC) has led to high-profile legal snafus in recent years. Why allow patients and staff to carry cellphones in patient care areas?

- The most common concern involves patient privacy. Patients and staff inadvertently could photograph, videotape, or audio-record other patients, violating their privacy under HIPAA.
- Another problem is infection control. Cellphones are germ factories.
- Cellphones create potential legal problems for surgery centers when physicians are recorded talking or acting unprofessionally.

"The surgery center was dismissed from the case because anesthesiologists are independent contractors, and we had a consent form that said the physicians are independent contractors," he says. "The case went to trial, and the verdict was rendered against the anesthesiologist."

ASC administrators and owners should ask this question: "What benefits are we getting by letting patients and patient representatives carry their phones in these areas?" Miller suggests.

Miller and Cabrera offer the following strategies for handling the issue of cellphones in the ASC:

• Implement a written policy. Write policies and procedures (P&Ps) that make cellphone use rules clear to all staff and physicians, Miller says. A separate policy can explain the cellphone ban to patients.

"Explain the rationale behind the policy," he says.

For example, an ASC could state that the cellphone ban in patient areas is for the protection of patient privacy rights, as well as for infection control purposes. ASCs also could reference electronic interference and that cellphones distract healthcare providers, Miller offers.

Employees and patients can store their phones in safe areas, such as in the patient's personal bag and in employees' purses or lockers.

• Direct patients to sign the cellphone policy notice. "Put it in writing and have patients sign off on it," Cabrera says. "Give yourself some kind of defensive position in case anything is used inappropriately."

It's not a perfect shield. If a patient captures something that is completely inappropriate, then the signed policy will not matter, he notes.

"But if they use the recording for any inappropriate purposes, then at least you have the position that you had made it clear that the ASC does not allow electronic devices in the room, and the person breached that policy," Cabrera says.

• Tell patients about the electronic device policy prior to surgery. When surgery centers call patients prior to the surgery to remind them of what they need to do to prepare, the person making the call can address the policy.

"In the pre-op call, say, 'We want to let you know that you are welcome to bring your cellphone with you to the lobby area, but you cannot bring your phone back with you. We just wanted to give you a heads up, so you can plan accordingly,'" Miller says.

Then, when patients arrive for surgery and question the policy, ASC staff can respond, "Sorry, but we have this policy. We told you on the phone that you cannot bring your phone back with you," Miller adds. "If on the day of surgery this becomes an issue, then you can say to the patient, 'This is our policy and procedure. If you don't want to follow it, we're not going to proceed with your case.'"

The important thing is for ASC directors, physicians, and staff to be aware that cellphones can be a problem, Cabrera says.

"It's everywhere. That's what people don't understand — video is endemic," Cabrera says. "Wherever you are, as long as there are people around you, there are odds it will be captured on video." ■

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Will Congress Pass the ASC Quality and Access Act?

A Republican Congress and president might be the combination that will result in success for a bill that has long received bipartisan support, only to go nowhere. U.S. Reps. **Devin Nunes**, R-CA, and **John Larson**, D-CT, in March reintroduced The Ambulatory Surgical Center Quality and Access Act of 2017 as a solution to a flaw in current ASC Medicare reimbursement policy.

"Similar legislation has been introduced in the past — not the exact version," says **Kristin Murphy,** MBA, assistant director of legislative affairs for the ASCA.

There's a widening disparity between what CMS pays ASCs and hospital outpatient departments (HOPDs), Murphy says.

"In 2003, ASCs received 86% of what HOPDs were paid; now, ASCs receive 49% of what HOPDs are paid on average," she explains. "The bill does a couple of things, but one of the primary components addresses how ASCs are measured in terms of inflationary rates."

HOPD payments are updated based on the hospital market basket, which measures costs of prescription drugs, nursing, and other healthcare-related goods and services.

ASC payments are updated based on the consumer price index for All Urban Consumers (CPI-U), which reflects the prices of items such as bread, milk, and gasoline, Murphy explains.

"The fact that HOPDs and ASCs are updated on different inflationary factors has contributed significantly to this widening disparity over time," she says.

Using CPI-U to estimate inflationary trends is the default setting the government uses. Either Department of Health and Human Services (HHS) Secretary Tom Price can use his authority to move ASCs from the CPI-U to the hospital market basket, or Congress can pass legislation requiring such a move.

Such a change is good for healthcare patients and the healthcare industry, Murphy argues.

A recent analysis found that ASCs saved the Medicare program $7.5 billion between 2008 and 2011, according to the University of California, Berkeley, Nicholas C. Petris Center on Health Care Markets and Consumer Welfare.[1]

In the last Congress, the bill that would have fixed this problem received 93 bipartisan cosponsors, yet the bill still didn't make it through the two-year congressional window.

The current bill also has received bipartisan support, with more than two dozen sponsors in the House.

"The Ambulatory Surgical Center Quality and Access Act will make sure patients continue to receive access to high-quality, cost-efficient care," Murphy says.

> "THE AMBULATORY SURGICAL CENTER QUALITY AND ACCESS ACT WILL MAKE SURE PATIENTS CONTINUE TO RECEIVE ACCESS TO HIGH-QUALITY, COST-EFFICIENT CARE."

The bill has been referred to the House Energy and Commerce and the Ways and Means committees. Similar legislation is expected to be introduced in the Senate soon.

"Although the legislation didn't pass last year, there were some provisions in the past that have been adopted by CMS, so we're happy about that," Murphy says.

ASCA has seen how patience and years of work can result in necessary changes. For example, in 2006, the organization and its community of ASCs asked CMS to establish a uniform quality reporting system to allow ASCs to publicly demonstrate their performance on set quality measures. CMS implemented the Ambulatory Surgical Center Quality Reporting Program six years later, on Oct. 1, 2012.

If the ASC Quality and Access Act passes, it will equalize the inflationary updates between ASCs and HOPDs. It also would require ASCs to share quality reporting information in a format that makes sense to patients, Murphy says.

The bill would give ASCs a seat on the HHS Advisory Panel on Outpatient Hospital Payments. The panel is influential in determining how hospitals are paid, Murphy adds.

"When CMS is deciding whether a procedure should be performed in an ASC setting, this legislation would require CMS to disclose which of those criteria they are using to deny those procedures," Murphy says.

ASCs then would have information that could be helpful in engaging in a dialogue with CMS about the decision.

"We could respond to CMS with studies, saying, 'Here's the data that show it allows us to provide this procedure safely and effectively,'" Murphy explains. "This enables us to engage in data-driven dialogue." ■

EXECUTIVE SUMMARY

The Ambulatory Surgery Center Association has learned over time that it requires patience to achieve regulatory and legislative goals. The group is trying again to convince Congress to pass the Ambulatory Surgical Center Quality and Access Act. The 2017 version would correct the unbalanced Medicare reimbursement formulas for ASCs and hospital outpatient departments (HOPDs).

- In 2003, ASCs received 86% of what HOPDs were paid.
- Now, ASCs receive 49% of what HOPDs are paid.
- The cause of the difference is that ASC payments are updated based on the consumer price index for "All Urban Consumers" and not on the hospital market basket.

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App Seeks to Improve Doctor-Patient Communication

Early results are promising

The idea for an app that would improve physician-patient communication came from a surprising source: hospital infection control checklists.

"Checklists are a great tool because they make you focus on work processes," says **Peter Pronovost**, MD, PhD, senior vice president of patient safety and quality and director of the Armstrong Institute for Patient Safety and Quality at Johns Hopkins Hospital.

"We built on this idea to see if we can enhance physician communication, especially around patients having surgery," Pronovost says. "They're frightened, confused, get ambiguous information beforehand, and leave confused about a variety of things."

For example, patients pre-surgery often are confused about when they can shower. Also, patients sometimes receive conflicting instructions.

"One patient told me they had bowel preparation instructions in the mail that differed from what the doctor told them to do," Pronovost says. "So, even if you read the instructions, it often is quite complex."

Pronovost and colleagues built an app called Doctella to improve communication and family-centered care. The app provides each patient with pre-op information and can put specific instructions on the patient's electronic calendar with an automatic reminder and notification.

Any person can download the app for free, but there is a fee for healthcare providers.

"We're in the pilot testing," Pronovost says.

Researchers are learning what users like about the app and how easily patients can use it. They're also studying its effect. Early, unpublished outcomes data suggest the app is producing positive outcomes, reducing surgery cancellations by 60%, Pronovost says.

Pilot testing includes a partnership with the online health education website Krames. The education site's platform is easy for patients to use, and now its content is embedded on the app's platform.

"Our vision is that some people want written material, some want a checklist, some want to watch a video or podcast," Pronovost says.

> "THE POINT REALLY IS TO GET THE DOCTOR AND PATIENT FOCUSED ON INFORMATION THAT IS IMPORTANT FOR THE PATIENT."

"Once you have this platform, we can impart any content you want, but, most importantly, give it to patients so they access the format that's most meaningful to them."

The piloting phase is expected to conclude by fall. But so far, it appears that the app would work well in an ASC setting. Also, it is a time-saver for physicians and office staff. The redundant patient instructions no longer must be given orally. The app gives patients the necessary pre-surgery information and contains built-in reminders for when they need to act on the information, Pronovost says.

The app provides a generic checklist for various procedures. The generic checklist would give patients information to discuss with their surgeon prior to surgery, and it tells them what they might worry about after surgery. Physicians can customize the checklist, Pronovost notes.

"Doctors then can make their own specific checklist because everyone has a different way of doing things," Pronovost says. "The specific checklist can give much more details."

For example, it could tell patients precisely when to stop eating and explain what they need to do. It can provide them with education and suggest questions to ask their surgeons.

The app also can be interactive, giving patients a forum in which to write down questions for their surgeons.

"The app has secure texting, so you can text your doctor a question," he says. "And if the doctor sends you a text, it automatically goes on your calendar."

Then, patients will receive a cellphone alert that tells them to take their pre-op medication or what they need to do next to prepare for surgery.

When surgeons use the app to communicate specific instructions, they also receive feedback about when a patient took the action.

"The point really is to get the doctor and patient focused on information that is important for the patient," Pronovost says. ■

Spine Surgeries Moving to Outpatient Facilities with 23-hour Observation

Concerns about safety are an issue

The healthcare industry's focus on greater efficiency and cost-effectiveness is moving more surgeries to the outpatient setting, including spine and joint replacement procedures. But what, exactly, is the trend for surgeries that previously required several-day hospitalizations?

Researchers studied spine surgery trends to see how often spine surgery is performed in an outpatient hospital setting vs. a true ambulatory setting. They found that a greater proportion of spine surgeries are moving to the outpatient hospital setting, but not quite as many are moving to ASCs.[1]

"The reason we did this study was, in the recent past, as we get more efficient with healthcare and more cost-effective, we are naturally moving more toward an outpatient model for a lot of procedures, decreasing length of stay, and we've seen this trend in spine surgery and joint replacement surgery," says **Michael J. Lee**, MD, associate professor of orthopaedic surgery and co-director of the Operative Performance Research Institute at the University of Chicago Medical Center.

Outpatient surgeries can vary according to the setting and state regulations. The term can be used to connote same-day admission and discharge, or it can refer to surgery and discharge that take place within a 23-hour window, allowing for a longer observation period, Lee says.

Although most outpatient surgeries feature safety profiles that work with a same-day admission and discharge, spine surgeries typically do not, he explains.

"Post-surgical hematomas for many surgeries can cause pain and wound healing difficulty," Lee adds. "However, after spine surgery, post-operative hematomas, if not identified and treated in a timely fashion, can literally cause paralysis and airway obstruction."

So, many spine surgeons prefer outpatient surgery at medical centers, where there is the capacity for prolonged monitoring, if needed. They can convert a patient's status to inpatient without much difficulty in that setting, he says.

"But if I do the surgery at an ASC and the patients need to be monitored beyond 23 hours, the patient needs to be physically transferred to an inpatient facility," Lee says.

Many ASCs can handle 23-hour observation periods, but this practice is limited by state regulations. For example, six states define ASCs as requiring discharge on the same calendar day of admission and not as a 23-hour stay, Lee explains.

"So, in this study, we looked at states that defined ASC as the same calendar day discharge to see whether rates of outpatient spine surgery were the same as for outpatient spine surgery elsewhere," Lee says. "We found that the rates for ASCs were way below the rates for outpatient spine surgery at non-ASCs."

This difference could reflect the fact that there aren't as many ASCs in the same-day surgery center states, but researchers interpreted the data differently. "We suspect that because of complications unique to spine surgery, most spine surgeons prefer to perform their outpatient surgery at facilities with capacity for prolonged monitoring, if needed," Lee says.

In states in which ASCs are not defined as same-day surgery, there were two-to-seven times greater rates of spine surgery at ASCs than in the other states, he adds.

"We're seeing a push where some surgeons may perform surgeries at a facility where they can stay for 23 hours," Lee says. "The majority of time, it will probably work out, but if you require that patients be discharged the same calendar day as admission — I suspect that is a threshold of risk that most spine

EXECUTIVE SUMMARY

Spine surgery trends show that a greater proportion of spine surgeries are moving to an outpatient hospital setting, but fewer are moving to ASCs, according to a new study.

- Spine surgery typically does not feature a safety profile that works with a same-day admission and discharge.
- Also, many spine surgeons tend to prefer outpatient surgery at medical centers, where there is the capacity for prolonged monitoring.
- Some surgeons believe that a minority of spine surgeries can be performed at ASCs when they involve otherwise healthy patients who present with minimal risk factors.

surgeons may not be willing to assume."

Spine surgeries moving to outpatient surgical settings include microdiscectomy, which is performed for a herniated disc; lumbar laminectomy surgery for spinal stenosis, which is performed to alleviate pain from neural impingement; and anterior cervical discectomy and fusion, which is a type of neck surgery that removes a damaged disc, Lee explains.

"These are surgeries that increasingly fall within the parameter of outpatient surgery," he says. "The question among spine surgeons is whether they can be done safely at true [ASCs], and should they be done there."

There is a growing belief that these types of surgeries can be performed at ASCs when they involve otherwise healthy patients who present with minimal risk factors. "But a very small minority of cases are being done at true ASCs," he says.

"In the course of achieving optimal cost-effectiveness, we can't lose sight of patient safety," Lee cautions. "That threshold for complications for surgeries at ASCs has not been defined in our industry."

The emphasis always must be on patient safety, Lee adds. ■

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Know Insurance Coverage Pitfalls to Prevent Gaps, Problems

Consider full cyber coverage

The main insurance issue for ASCs is making sure they have appropriate coverage and structure. This includes an alignment of insurance limits by ASCs and surgeons.

"Make sure physicians and surgeons have appropriate coverage in place and adequate limits," says **Sarah Logue**, MSM-RMI, RPLU, CPCU, AU, ASLI, senior vice president and medical facilities division leader for OneBeacon Healthcare Group in Richmond, VA.

Here's an example of how a surgeon's inadequate coverage can affect a surgery center: "Suppose you have a surgeon doing orthopedics in the surgery center, knee replacement surgery, and the center is in a state or place where the surgery center is more conservative in its tolerance for risk and carries a $2 million limit on personal liability. But the surgeon only carries a $1 million limit," Logue offers.

Then, there's a mistake and complications that lead to a patient injury. The patient files a claim against the surgeon and ASC. During discovery, the plaintiff's attorney learns that the surgeon had a $1 million limit, while the surgery center had a $2 million limit, she says.

"They'll keep both in the claim, but target the surgery center more, to go after the higher dollar amount," Logue explains.

It's understandable that surgery centers are dependent on surgeons using their facilities, and they don't want to be difficult, but they still must protect themselves from liability, and the best way to do that is to ask surgeons to have the same limit in coverage, she adds.

One way surgery centers can exert influence over surgeons' insurance coverage is through the credentialing process. They can review physicians' insurance claim history and create best practices that encourage obtaining a certificate of insurance with certain limits and deductibles in place, she says.

"The claims history is a good

EXECUTIVE SUMMARY

ASCs must make sure they obtain appropriate insurance coverage and structure.

- They should ensure physicians and surgeons obtain appropriate coverage and adequate limits.
- Review physicians' insurance claim history and best practices.
- Consider punitive damage coverage and how the deductible will be structured.

indicator," Logue says. "They can make recommendations based on what they prefer to see, including, number one, having the surgery center and surgeons carry the same limits."

This means that if the surgery center has a $2 million limit per occurrence and a $4 million limit per year aggregate coverage, then the surgeon also has those limits.

Alternately, surgery center leaders might ask for those matching limits for surgeons in higher risk specialties, such as spine and orthopedic surgeries, Logue suggests.

Other insurance issues to consider are coverage for punitive damage, which is necessary in certain states, and coverage for sexual misconduct and physical abuse, she says.

ASCs should assess whether their deductibles are the right fit.

"Many centers carry zero deductible plans and some have $25,000 or $50,000 deductibles, and there are options where you can do indemnity only," Logue says. "Look at the amount and how it is structured."

Also, ASCs should pay attention to their insurance plan details. For instance, if their coverage offers legal defense coverage outside of the policy limits, that means they won't use up their $1 million or $2 million policy limit on huge attorney bills.

"You could spend $250,000 on attorney fees and then only have $750,000 left to pay the claim," Logue says. "If the defense is outside the limit, then the $250,000 in legal fees is paid outside the $1 million claim."

ASCs also should request a certificate of insurance from their contracted anesthesiology group, she notes.

Sometimes, it's the unexpected issue that causes the most problems. For example, Logue has seen claims in which surgeons brought their own type of product for a procedure, and the product wasn't vetted by the ASC. In some cases, the product might not even be FDA approved, which could result in an insurer denying coverage in the event of an injury and lawsuit, Logue says.

"A LOT OF STATES HAVE MANDATES ON HOW TO NOTIFY PEOPLE, AND YOU HAVE TO DO THIS FOR EVERY INDIVIDUAL WHO COULD BE AFFECTED, AND THAT COULD ADD UP PRETTY QUICKLY IF THERE ARE HUNDREDS OF THOUSANDS OF PEOPLE IMPACTED."

"Some policies will say that if something is not approved by the FDA, then it's excluded in the policy," she says.

ASCs might find financial benefits to requiring a single insurer cover all or most of their insurance needs. This also could protect the ASC from insurance gap vulnerabilities, whereby neither policy will handle the claim.

"We do see situations where they separate out the general liability coverage from the medical professional liability of the surgery center," Logue notes. "The general liability is when someone trips or falls in the parking lot."

But when these two types of coverage are separated between two different carriers, they can produce gaps in coverage, she adds. "It's a good plan to place them together and not split them out. You need a good broker who can make all of the comparisons."

Another potential gap area involves insurance to cover cyberattacks.

"Consider having cyber coverage in place," Logue recommends. "Medical malpractice insurers do offer that, and that's one area where there's a potential gap."

When surgery centers carry cyber coverage, they should make sure they have enough coverage to handle all cyberattack expenses — not just the first $25,000 or $50,000, which might be offered in supplemental coverage, she suggests.

True insurance for cyberattacks should cover the cost of providing credit monitoring to everyone potentially affected by the attack. It should cover notification calls and letters about the breach.

"A lot of states have mandates on how to notify people, and you have to do this for every individual who could be affected, and that could add up pretty quickly if there are hundreds of thousands of people impacted," Logue explains.

Cyber insurance also can pay for forensic tracking expertise to identify how the breach happened and what was affected. It also can pay for the cost of retrieving any lost information.

"Time is money in responding to a breach," Logue says. "Usually, it is referred to as cyber coverage, and it's very specialized, so you will want to consult with an agent or broker who specializes in cyber coverage." ■

Develop an Outcomes-based, Survey-proof QAPI Program

The ASC director called in a panic. CMS sent a surveyor, who said the facility would be shut down tomorrow unless they sought immediate help from a consultant.

That scenario happens more times than most people imagine, says **John Goehle**, MBA, CPA, CASC, chief operating officer of Ambulatory Healthcare Strategies in Rochester, NY.

The smarter ASCs seek help before it gets to that point. They create policies and procedures (P&Ps), train staff on how to follow them, and ask experts to review both written policies and the actions employees take to follow the organization's P&Ps, Goehle says.

CMS looks for written policies and wants to see proof that managers are teaching employees, and that employees are following those procedures. Healthcare organizations that experience problems with the survey often are plagued by policies that are not well-followed.

At the very least, ASCs should create a quality assurance performance improvement (QAPI) program that tackles the most common problem areas and the low-hanging fruit, he suggests.

The following are Goehle's suggestions:

• Focus on governance and oversight. "Make sure your governing body is showing appropriate oversight of the operation," Goehle says.

Red flags occur when organizations don't conduct enough board meetings or are not documenting in the minutes what happened in those meetings.

"I'm passionate about governance because I've seen so many problems with it," Goehle says. "Ultimately, everything becomes a governance issue. When the nursing staff is not doing handwashing, it's the governance not overseeing and following up."

The surveyor's chief information about how well an ASC's ownership is watching the facility is to look at the minutes. If the minutes lack important details, surveyors will notice.

"The administrator needs to make sure the governing body gets together, and that proper minutes of the meetings are written down," Goehle says.

One problem area Goehle often sees involves documentation of quality improvement processes.

"We've seen places that might or might not have a great quality improvement program that are not reporting the results to their governing body," he explains.

Anytime an ASC conducts a QI project, this must be documented and shared with the governing board. The board's minutes should reflect that information, and the minutes should show whether the board approved the changes that occurred because of the QI process.

"Maybe the ASC has to make changes in its fall prevention program," Goehle says. "They need to report it to governing body because they're responsible."

"I do not necessarily believe the governing body needs to approve of changes that are appropriate and consistent with providing higher quality healthcare," **Steven A. Gunderson**, DO, medical director and CEO of the Rockford (IL) Ambulatory Surgery Center, offers. "However, I do think that the changes should be brought to a governing body meeting and presented to the board. It does not take board permission for the nursing staff to implement changes that improve patient care."

• Stay current with credentialing. "There are a couple of different areas where ASCs can get into trouble," Goehle says. "One, is they need to remember to credential all physicians, allied health professionals, and residents."

Sometimes, administrators forget that residents' credentials must be checked before they can see patients in an ASC, he notes.

"Check with the institution where the resident is being educated," he says. "Double-check the resident's medical license, and go to a primary source, such as a school."

Also, make sure the governing body approves, Goehle adds.

"Have a credentialing chart for every doctor who works in your facility," he suggests. "They are granted privileges for a period of time, and then you need to make sure those doctors re-credential themselves."

ASC directors sometimes forget to check credentials after the first time, or there might be lag time between when one credential expires and another one begins, he says.

For nurses who are ASC employees, credentialing is conducted through their employment process.

• Address infection control and sterilization. "This is the hottest topic right now," Goehle says. "There can be a lot of different issues, including not handling drugs properly."

For instance, when handling multidose drugs, the ASC's staff should make sure drug labels read multidose. These drugs must be drawn outside of patient care areas.

"Say you're drawing up lidocaine

for a patient," Goehle explains. "This has to be drawn up into the syringe, outside of the patient area."

Drawing multidose drugs near a patient can create a risk of cross-contamination, he adds.

"These are logical things, but if something is labeled single-use, you can't give it to multiple patients," he says. "Or sometimes someone will not label syringes after they draw them up."

Surveyors are cautious about observing a facility's cleaning processes, to make sure it's conducted properly.

"This past week, we walked into a place where they were doing what they thought was sterilization," Goehle says. "But they were taking the pan out of the operating room and dropping it into the ultrasound cleaner without disinfecting it ahead of time."

The staff did not know they were supposed to wash it first with disinfectants.

"I walked into the room and saw the sink with all the disinfectants in it, and the sink was clean," he says. Another place was washing tools with fluids that were not certified as disinfectants. "We said, 'You have to make sure that any fluid you are using for cleaning is known by the infection control nurse, and the nurse has to sign off on them,'" Goehle says.

As a best practice strategy, ASC staff should read the manufacturer's instructions for cleaning fluids and all instruments and equipment they're using.

"Surveyors will come in and observe and ask, 'What are the instructions for this?'" Goehle explains. "You will want to pull out the instructions right away to show what you're doing."

• Follow up with training. Training is something many ASCs want. Goehle says he's often asked the following questions:

- How do we train staff?
- How do we retrain them?
- How do we train new people?

ASCs sometimes experience high turnover, and administrators say they don't have time to train new staff, Goehle says. But this is one area where management cannot cut back.

"You don't have time to fix the problems that occur because you didn't train them in the first place," he says.

Training programs should include as-needed inservices and mandatory, annual training sessions. The mandatory sessions should cover the things that must be part of staff's annual training.

"I'm finding that organizations are getting confused about what's mandatory and what's an inservice," Goehle says. "They forget the mandatory training has to be done every year."

Inservices should be held to cover processes whenever the organization sees that something is not performed correctly. ■

SDS Manager

Complacency: The Business Killer

By Stephen W. Earnhart, MS
CEO
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Austin, TX

Healthcare, in particular outpatient surgery, is aflutter right now. I have been working with hospitals and surgery centers for 30 years and this is the busiest we have ever been. I suspect that much of it is driven by foreseeable action on the Affordable Care Act, although any changes to that are still in the works as of this writing. However, it seems likely that something is going to change, hopefully for the better.

Much of our new business right now is focused on developing hospital outpatient departments (HOPDs) for hospitals, which allow them to run a lower-cost facility for outpatient surgical cases. Developing and managing freestanding surgery centers is second. Expansion of existing facilities is third. The time is right for all three. If you are not considering one of these options, you could be in trouble. Doing nothing is dangerous.

Hospitals understand the need to off-site their growing outpatient surgery into its own facility to allow for lower operating costs. This gives the hospitals the opportunity to bundle procedures such as total joint replacement, advanced shoulder procedures, and spine surgery that is going to the freestanding ASCs with escalating speed as payors see the opportunity to cut their costs.

The need for segregation of inpatient and outpatient cost structure is here to prevent further erosion to cost efficiency and the high customer satisfaction found in ASCs. Employing a staff that is dedicated to fast-tracking patients and cost control is paramount to hospitals' success in this growing market. Another benefit of outsourcing this class of patients is the elimination of costly in-hospital expansions of new surgical suites.

The number of freestanding ASCs

is rising as well, mostly because hospitals are joint-venturing with the doctors where they can (where they cannot is mostly in the Certificate of Need states). Of note, 100% of all the new ASCs and HOPDs we are working on right now have expanded patient recovery areas and expanded instrument processing sterilizers and space for total joint replacement.

Several hospital initiatives have to do with their employed surgeons, something that in the past hasn't been necessary because of the binding effect of employment with the surgeons. However, with the lure of the lucrative growing total joint market, even employed surgeons want to share in the facility fee with the hospital. With more surgeons becoming employees of hospitals, this is very telling of where the market is going.

Existing ASCs that are not willing to carry out a physical expansion of their surgery centers are essentially saying, "I am OK with losing my orthopedic and spine cases to someone else." Many ASCs are not taking orthopedic cases anyway, so it is not necessarily a high risk for them not to expand. However, for those that are performing a few arthroscopies and count on that revenue, do not get comfortable in keeping them in your budget as more orthopedic groups move from existing ASCs into facilities that will allow their surgeons to perform higher-end joint replacement and basic ortho cases in one facility with which the group has entered into an equity position. The same goes for spine procedures: Don't underestimate the tight bond between spine and ortho groups.

One must constantly expand or run the risk of being left behind. Surgery centers and hospitals' basic business model has remained the same for the past couple of decades. Not now. Settling for what you have in the past is going to kill many hospitals and surgery centers who cannot see the future and respond accordingly. Complacency is the worst place you can be tomorrow. The worst thing you can do is not make a decision today.

Earnhart & Associates is a consulting firm specializing in all aspects of outpatient surgery development and management. Earnhart & Associates can be reached at 5114 Balcones Woods Drive, Suite 307-203, Austin, TX 78759. Phone: (512) 297-7575. Fax: (512) 233-2979. Email: searnhart@earnhart.com Web: www.earnhart.com ■

Latest ASC Data Highlight Ambulatory Surgical Trends

The latest data about ambulatory surgery shows that more than half of such surgeries are covered by private insurance, and 53% were performed in hospitals vs. 47% in ASCs.[1]

There were 48.3 million ambulatory surgery procedures performed in 2010 — the year of the study data. Of these, 70% involved operations on the digestive tract, eye, musculoskeletal system, integumentary system, and nervous system.[1]

Other findings in the report include the following:

• Thirty-nine percent of procedures were performed on people in the 45-64 age group.

• Nineteen percent of procedures were performed on people in the 65-74 age group, and 14% involved people who were 75 years of age or older.

• About 2% of ambulatory surgery patients were admitted to the hospital as inpatients.

• Endoscopy of the large intestine, including colonoscopies, was performed 4 million times, and endoscopy of the small intestine was performed 2.2 million times. There were an additional 1.1 million performances of endoscopic polypectomy of the large intestine.

• There were 2.9 million extraction of lens operations on eyes, and 2.6 million prosthetic lens insertions.

• Nervous system operations included 2.9 million injections of agent into spinal canal, including pain relief injections.

• About 1.3 million musculoskeletal procedures included operations on muscle, tendon, fascia, and bursa.

• There were 1.2 million integumentary system operations that included excision or destruction of lesion or tissue of skin and subcutaneous tissue.

• The average ambulatory surgery operating room time was 57 minutes, with 33 minutes spent in surgery.

• Ambulatory surgery in hospitals took significantly more time than surgeries performed at ASCs: 63 minutes vs. 50 minutes.[1] ■

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SAME-DAY SURGERY

CME/CE INSTRUCTIONS

To earn credit for this activity, please follow these instructions:

1. Read and study the activity, using the provided references for further research.

2. Log on to AHCMedia.com then select My Account to take a post-test. *First-time users must register on the site.*

3. Pass the online tests with a score of 100%; you will be allowed to answer the questions as many times as needed to achieve a score of 100%.

4. After completing the test, a credit letter will be emailed to you instantly.

5. Twice yearly after the test, your browser will be directed to an activity evaluation form, which must be completed to receive your credit letter.

CME/CE QUESTIONS

1. **Which of the following is a good reason for banning cellphones in an ASC's patient care areas?**

   a. Cellphone recordings and photos could breach patient privacy under HIPAA.
   b. Cellphones pose infection control risks.
   c. Cellphones can record unprofessional words and actions by ASC doctors or staff.
   d. All of the above

2. **The Ambulatory Surgical Center Quality and Access Act of 2017 would fix a widening disparity caused by ASCs and hospital outpatient departments (HOPDs) updating Centers for Medicare & Medicaid Services payments based on different inflationary factors. What is the disparity between ASCs and HOPDs in payments now?**

   a. ASCs receive 75% of what HOPDs are paid.
   b. ASCs receive 49% of what HOPDs are paid.
   c. ASCs receive 38% of what HOPDs are paid.
   d. HOPDs receive 86% of what ASCs are paid.

3. **A new study shows that spine surgeons prefer outpatient surgery at medical centers over ASCs for which of the following reasons?**

   a. Spine surgery complications can result in paralysis, so surgeons prefer using surgery centers where there is capacity for prolonged monitoring and the opportunity to convert a patient's status to inpatient without much difficulty.
   b. Spine surgery is reimbursed at a higher rate in hospital surgery center settings.
   c. Most states require spine surgery to be performed at a hospital-based surgery center.
   d. All of the above

4. **When ASCs review their insurance coverage, they should consider cyber coverage because:**

   a. they'll need access to ready funds in case of cyber ransomware attacks.
   b. of the need to cover the costs of providing credit monitoring to everyone potentially affected by the attack, forensic tracking, and information retrieval.
   c. they'll need to cover the costs of retraining staff on how to prevent cyberattacks.
   d. None of the above

SDS ACCREDITATION UPDATE

Covering Compliance with TJC, AAAHC, AAAASF, and Medicare Standards

Federal Officials Ramp Up Healthcare Fraud Violation Investigations

When in doubt, ask for advisory opinions

Federal enforcement of the anti-kickback statute and other laws has increased over the past decade. In the 2016 fiscal year, the Department of Justice (DOJ) opened 930 new civil healthcare fraud investigations and had 1,422 civil healthcare fraud matters pending.[1]

Healthcare providers paid the federal government more than $2.5 billion in fraud judgments and settlements. Federal investigations also resulted in 765 criminal actions and 690 civil actions, including false claims and unjust enrichment lawsuits. The Department of Health and Human Services (HHS) prohibited 3,635 people and organizations from participating in Medicare, Medicaid, and other federal healthcare programs.[1]

The trend of increased healthcare fraud enforcement will continue, according to experts.

"The anti-kickback statute is as wide as it is long. It is so broad that the government has recognized that certain business arrangements may constitute a technical violation of the statute, but may not represent a significant risk to the Medicare Trust Fund as long as certain requirements are met," says **Robert W. Liles**, JD, MS, MBA, managing partner with Liles Parker in Washington, DC. Liles previously worked as a federal prosecutor in healthcare and was the first national healthcare fraud coordinator. He now represents healthcare providers and is asked to speak regularly about healthcare fraud issues at national conferences.

"The statute is so broad that practically anything you might consider to be standard business courtesies could run afoul of the anti-kickback statute," Liles says. "Whenever you are dealing with Medicare, Medicaid, and other federal and state health benefit programs, you have to be careful. It's not business as usual, and things have gotten a lot more complicated because of the Affordable Care Act [ACA] and the significant changes they've made to the anti-kickback statute."

> "THE STATUTE IS SO BROAD THAT PRACTICALLY ANYTHING YOU MIGHT CONSIDER TO BE STANDARD BUSINESS COURTESIES COULD RUN AFOUL OF THE ANTI-KICKBACK STATUTE."

The ACA contains provisions that strengthen federal fraud and abuse laws in healthcare, and these provisions likely will continue, even if lawmakers eventually dismantle the ACA, according to **Scott Grubman**, JD, partner with Chilivis, Cochran, Larkins, & Bever in Atlanta. Grubman was a federal prosecutor, focused on healthcare fraud, and served on a healthcare fraud task force for the DOJ. Now, he speaks about healthcare fraud and abuse and represents healthcare organizations, including ambulatory surgery centers (ASCs).

The old version of the anti-kickback statute required someone to have specific knowledge that their actions violated the statute, and they had a specific intent to violate the law. The new version took out "specific" knowledge and intent wording, making it easier for

federal prosecutors to allege a violation, Liles says.

"Fraud and abuse enforcement in the healthcare space skyrocketed under the previous administration, and all indications thus far are that this will not change under the new administration," Grubman says. "Confirmation hearings for Attorney General Jeff Sessions and HHS Secretary Tom Price showed that both of them have a strong commitment to continuing strong enforcement in healthcare."

That said, there are additional safe harbors to the anti-kickback statute, as amended in December 2016 and effective on Jan. 2, 2017. These include a change that protects certain cost-sharing waivers that pose a low risk of harm.[2] *(See anti-kickback statute table below.)*

What many ASC administrators and surgeons might not understand is that there is no "de minimis" amount that must be met for the anti-kickback statute to be triggered. Technically speaking, sending a Christmas fruit basket to a referral source, or receiving one from a vendor of supplies that are reimbursed by Medicare, can be a violation, Liles says.

"To be clear, it is highly unlikely that such a gift would be pursued as a criminal violation by a federal prosecutor, but you need to be aware that such a practice is problematic," Liles says.

"Don't confuse OIG's [Office of Inspector General's] 2002 guidance on the 'Offering of Gifts and other Inducements to Beneficiaries' with the general prohibition against providing anything of value to a party in an effort to induce Medicare referrals," Liles adds.

Under the 2002 OIG guidance, the agency indicated that it would permit Medicare and Medicaid providers to offer beneficiaries inexpensive gifts or non-cash or cash-equivalent items that are valued at no more than $10 individually and not more than $50 total in a year. That OIG guidance was aimed at beneficiaries, not at providers, who are actual or potential referral sources. ASCs should not assume that they're immune from prosecution simply because their services save Medicare money, Liles warns.

"ASCs are created as a cost-saving measure, making it cheaper to do outpatient surgeries when appropriate," Grubman says. "So, the government has encouraged the use of [ASCs] and the safe harbor dealing with ASCs. But like everything else, it's prone to potential fraud and abuse."

Another change under the ACA is that the government can pursue violations of the anti-kickback statute as violations of the False Claims Act, which can result in high-dollar civil penalties and pays whistleblowers.

"There are a lot of cases where the government might run across examples of technical violations that aren't safe harbors, but the government doesn't want to pursue it criminally," Liles says. "Anti-kickback violations under the ACA can qualify as False Claims Act violations, which are civil, not criminal."

The False Claims Act raised the amount of penalties twice in the past 12 months, from $10,957 to $21,916, plus treble damages in some cases, Liles says. *(See story on False Claims Act, page 4.)*

"That's how you see these multimillion-dollar cases under the False Claims Act," Liles explains. "When you apply penalties of at least $10,957 per false claim, plus treble damages, the potential exposure for a healthcare provider can be enormous in a False Claims Act case."

Grubman says that one area of government scrutiny that he has

More Details About Anti-kickback Statute

The federal anti-kickback statute (Section 1128B(b) of the Social Security Act) provides criminal penalties for people or entities that knowingly and willfully offer, pay, solicit, or receive remuneration to induce or reward the referral of business reimbursable under federal healthcare programs.

According to the statue:

- the offense is a felony, punishable by fines up to $25,000 and imprisonment up to five years;
- remuneration can include kickbacks, bribes, and rebates;
- prohibited conduct includes payment intended to induce or reward referral of patients and to induce or reward the purchasing, leasing, or ordering of, or arranging for any good, facility, service, or item reimbursable by any federal healthcare program;
- Congress created safe harbor provisions, specifying payment and business practices that would not be treated as criminal offenses;
- the ACA includes provisions that could affect liability under the anti-kickback statute, including a protection of drug discounts provided for under the Medicare Coverage Gap Discount Program.

For more information, please visit: http://bit.ly/2ocbnpr. ■

seen involving ASCs focuses on relationships between ASCs and anesthesia providers.

Anesthesiology groups are entirely dependent on referrals, so the industry is highly competitive. They compete in providing value to ASCs, which can cause issues. All it takes is for a service going in one direction and an extra value going in the other, Grubman says.

"It means the statute is implicated, and you're in dangerous territory," he explains. "It doesn't mean the statute has been violated, but it can raise eyebrows."

One strategy for avoiding an anti-kickback violation is to seek an advisory opinion from OIG prior to any contractual arrangements.

"You can write to them and say you're thinking of doing this thing, creating this venture or arrangement," Grubman says.

But it doesn't always work out in the healthcare organization's favor.

"Unfortunately, the government takes a very aggressive view," Grubman says. "Often, there's a situation where the government looks at something suspiciously, and we don't necessarily agree that's the case."

The OIG publishes advisory opinions online, including one published on Dec. 5, 2016, in which OIG addressed whether labeling test tubes and specimen collection containers at no charge to dialysis facilities constituted a violation of the anti-kickback statute. OIG ruled that the proposed arrangement "could potentially generate prohibited remuneration under the anti-kickback statute."[3]

In a 2007 advisory opinion, OIG ruled again that a proposed arrangement potentially could violate the anti-kickback statute. In this case, orthopedic surgeon investors in an established ASC proposed selling a 40% ownership interest to a local hospital. The investors would receive a profit from the sale. The hospital would be in a position to make or influence referrals directly or indirectly to the ASC or its physician investors.[4]

One key to determining a statute violation is whether remuneration for the service or product is fair market value.

"Is it commercially reasonable and not taking into account the value of referrals?" Grubman asks. "Any amount of money paid should be a reflection of work provided and fair market value. So, if an ASC is getting reimbursed by Medicare for something provided by an anesthesiology group, the government will take a negative view of that.

> "THERE'S NOT MUCH CREATIVITY IN HEALTHCARE LAW. THE BEST THING FOR AN [ASC] TO DO IS TO HIRE A HEALTHCARE LAWYER BEFORE THEY TRY ANYTHING NEW."

"If the anesthesia group is providing monitors to the ASC, the government will likely take the view that the ASC is double-dipping, and it's not true reimbursement," he continues. "And if it's not true reimbursement, then the government will likely take the view that it's more likely to be an incentive to encourage referrals, and that's what the anti-kickback statute is designed to prevent."

Another arrangement that could violate the statute is if an anesthesia group brings its own employees to the ASC to cover for a receptionist, who is at lunch from noon to 1 p.m.

"The government will view that suspiciously because it is something of value, and if the anesthesia group didn't provide it, then the ASC would have to pay someone else to do that job," Grubman explains.

OIG sometimes decides in organizations' favor. One example is an advisory opinion related to an ASC that was jointly owned by a hospital and group of physicians. The ASC also leased some space from the hospital. The anti-kickback statute contains a safe harbor related to lease agreements — so long as the lease is in writing, the rent is fair market value, and other specific requirements are met.

"There's not much creativity in healthcare law," Grubman notes. "The best thing for an [ASC] to do is to hire a healthcare lawyer before they try anything new."

An attorney can tell them how they could add safeguards to their plan to make it work or how to structure things in a way that will protect against potential liability. ■

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Watch Out for False Claims Act Violations

Powerful incentive for whistleblowers

Most False Claims Act cases are brought by whistleblowers who can receive up to 30% of the government's recovery in a successful investigation under the act.

"They have broadened the scope of the False Claims Act and anti-kickback statute, so we're starting to see more and more of these cases being brought forward," says **Robert W. Liles**, JD, MS, MBA, managing partner with Liles Parker in Washington, DC.

Always Report Overpayments

The ACA contains changes to the anti-kickback statute and the False Claims Act, including making it a violation if a healthcare organization receives an overpayment that is not reported, and the money returned, within 60 days.

The final rule, published in 2016, eased the 60-day timeline by saying that the clock starts once an organization investigates the overpayment and assesses the extent of the problem and amount owed, Liles says.

"The purpose of that is if you have a situation where you realize you've been doing something wrong, you can go back six years, figure out how much money you owe, and then you pay it back," Liles says.

Anyone Can Be a Whistleblower

Some recent examples of ASCs that ran afoul of the False Claims Act include the case of a company that employed a managing surgeon who performed unnecessary procedures on patients and also billed for services not rendered, Liles says.

"Two whistleblowers filed under the False Claims Act against the ASC," he adds. "The government got $4 million, and the whistleblowers got $900,000."

ASCs must stay on top of any overpayments and problems to avoid this type of situation.

"THE GOVERNMENT DOESN'T EXPECT YOU TO BE PERFECT. BUT THEY DO EXPECT YOU TO TRY, AND IF YOU MAKE A MISTAKE, THEY WANT YOU TO PUT SYSTEMS IN PLACE TO MAKE SURE IT DOESN'T HAPPEN AGAIN."

"Say you know about overpayments and you don't report it and return it within 60 days," Liles says. "I can guarantee that you're not the only one in your organization who knows about the problem."

Anyone in an organization who knows about services and billing is a potential whistleblower, he adds.

"You're supposed to have compliance policies and training, auditing, and monitoring," Liles notes. "Do a gap analysis of what you're doing right and what you need to do to fix your problems."

In another False Claims Act case, an ASC operator sold a minority interest to physicians at less than fair market value. It was a disguised kickback, and the government pursued it under the False Claims Act. The ASC paid $5.1 million, Liles says.

Private Payers are Not Immune

There is one other aspect of False Claims Act violations: If the federal government goes after an organization, private payers soon could follow.

"They follow in the wake of what the federal government is doing," Liles says. "When I was with the [DOJ], I never saw a case where someone was only ripping off Medicare. If they were doing something wrong, they were doing it across the board."

The best practice and policy is to prevent these problems from occurring by assessing the ASC's compliance with billing and coding best practices.

"So many providers don't want to take this step because it's like they're putting their blinders on," Liles says. "But don't you want to find out now vs. letting it get worse and owing more money later? Sit down, and do a gap analysis."

Other best practice strategies include ensuring the ASC's compliance plan is in place and training staff to comply.

"The government doesn't expect you to be perfect," Liles says. "But they do expect you to try, and if you make a mistake, they want you to put systems in place to make sure it doesn't happen again." ■