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Stakes High Regarding False Claims Act Compliance

ASCs could spend millions to defend and settle a case

Healthcare professionals have paid millions in fines, gone to prison, and lost their licenses over violations of the False Claims Act (FCA), Anti-Kickback Statute, and Stark Law in 2017. Collectively, False Claims Act violations resulted in more than \$3.5 billion in total settlements and judgments in 2015 and close to \$6 billion in 2014.

In one recent \$4 million settlement, a New York health system and its hospitals were sued by a whistleblower physician, who alleged the hospitals had engaged in improper financial relationships with physicians making referrals. *(Read more about the case at: <http://bit.ly/2yvcfBu>.)*

In another case, a South Carolina hospital paid more than \$7 million in an FCA settlement in which the health system billed for services while not following regulations. For instance,

the hospital billed for radiation oncology services for Medicare patients when a qualified practitioner was not available, as required by regulations, to provide assistance and direction during the procedure.

(Read more about the case at: <http://bit.ly/2zuBOg5>.)

“Everyone obviously understands that if you submit a bill for something that didn't happen, or you lie about whether a doctor did the procedure, or you bill a higher-level service than what was

COLLECTIVELY, FALSE CLAIMS ACT VIOLATIONS RESULTED IN MORE THAN \$3.5 BILLION IN TOTAL SETTLEMENTS AND JUDGMENTS IN 2015 AND CLOSE TO \$6 BILLION IN 2014.

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provided, you can't do that," says **John G. Martin, Esq.**, partner with Garfunkel Wild in Great Neck, NY.

"But surgery centers, because of their corporate structure, relationships, and applicable laws and regulations, have a particular vulnerability that is not necessarily apparent," Martin says. "Many have fairly complex business arrangements with a wide range of third parties." For example, surgery centers frequently engage in business relationships with anesthesiologists, medical device/supply vendors, and other physicians. Making certain these business arrangements do not violate federal and state laws can be challenging, he explains.

ASC owners and directors must understand that when they form their centers and enter into business transactions, they could be exposed to FCA liabilities if they run afoul of the applicable laws and regulations, says **Robert Del Giorno, Esq.**, partner with Garfunkel Wild.

A business arrangement that does not comply with federal regulations could be enough to trigger an FCA liability, even if the ASC provides medically necessary care and services, Del Giorno says.

"When your ASC structure and business relationships violate laws like the Anti-Kickback Statute or Stark Law, you can have False Claims

Act liability regardless of whether or not you are appropriately providing services that are medically necessary to patients," Del Giorno notes.

The stakes are high. If an ASC's business relationship with referring and practicing physicians runs afoul of the Anti-Kickback Statute, FCA, or Stark Law, then claims submitted to Medicare could be considered false claims — if the claims were submitted during the period in which the ASC is in violation.

"Even if you bill the patient accurately, if your ownership structure or referral relationships violate the regulations, then that could result in a violation," Martin warns.

The best solution is prevention. ASCs should seek legal advice about their business arrangements and referrals relationships from lawyers who specialize in healthcare law, Martin suggests.

"When we see people get into trouble, it's when they try to figure this out themselves or when they use the same lawyer that they use for personnel matters, and that lawyer tries to figure it out," he says. "That's where we often see people end up as defendants in False Claims Act cases."

Most ASCs will hire healthcare legal experts when they land in trouble, but that is an extraordinarily

EXECUTIVE SUMMARY

Ambulatory surgery centers (ASCs) are vulnerable to False Claims Act violations because of their corporate structures and relationships.

- False Claims Act violations resulted in more than \$3.5 billion in settlements and judgments in 2015.
- It can be challenging for ASCs to make certain their business structure and relationships do not violate federal laws.
- When an ownership structure is legally problematic, the ASC could bill for procedures properly and still be in violation.

expensive delay. “Once you are in court, the costs can quickly become prohibitive. FCA cases are complex, and, with liberal rules of discovery, can take years to resolve. Plus, you are going up against the government, who has unlimited resources,” Martin says.

Both Republican and Democratic administrations like prosecuting healthcare fraud because they see fraud and abuse settlements as a way to reduce healthcare costs. So, the federal government, generally regardless of who’s in power, regularly increases the resources to investigate and pursue fines, Martin adds.

ASCs that have not seen their business relationships scrutinized by healthcare legal experts should take their contracts to an expert and ask him or her to review the contracts for problems before the government knocks on the door.

“If the answer is ‘there is a problem,’ then fix it right away, and you might have to disclose it to the government and pay back money,” Martin says. “If you don’t fix it or disclose it and pay back [the appropriate fine], you raise your risk and exposure considerably.”

The government created a disclosure program in which organizations that voluntarily disclose

problems typically will not face the heaviest penalties, such as treble damages and per-claim penalties. While they must pay back any money gained related to the problem, the penalties for the violation can be considerably less, Martin notes.

The key to avoiding FCA violations is to make sure the ASC is structured right and offers a compliance program as well as appropriate policies and procedures, Del Giorno says.

“Detecting these types of issues and mitigating them results in less risk and consequences than if it blows up in a whistleblower suit,” he adds. ■

Tips for Avoiding Huge False Claims Fines

Watch out for referral landmines

ASCs can run into regulatory trouble by simply creating a poorly structured business ownership agreement or by paying one owner physician more than another. Two health law experts highlighted common mistakes healthcare professionals make regarding the FCA, Anti-Kickback Statute, and Stark Law.

• **Make or receive improper referrals.** The Anti-Kickback Statute and Stark Law apply to patients referred to an ASC for services and to any business in which they own an interest or from which they take money for referrals. Issues can arise regarding paying for referrals or referring patients to an ASC which one owns. These are broad and sometimes confusing laws with complicated exceptions that are called exceptions and/or “safe harbors,” says **John G. Martin**, Esq., partner with Garfunkel Wild.

“If you fit within one of those exceptions, the government has said that even if it sounds like you are doing what you otherwise can’t do, you are not generally subject to liability,” Martin says.

An ASC should obtain expert legal help to determine whether it meets a safe harbor or exception. “If you don’t fit into a safe harbor, there is a risk,” Martin warns. “It doesn’t mean you are violating the Anti-Kickback Statute, but you don’t have that safe harbor protection.”

If the federal government investigates the ASC, then investigators will scrutinize any excessive compensation paid to doctors, including owners, which appears to be a payment in exchange for a referral. The rules are complicated, arcane, and might even come down to calculating how much of an ASC’s doctor/owner’s business is referred to the ASC, Martin says.

“If you’re a general practitioner and you don’t do any kind of surgery or procedures that are generally done in an ASC, but you refer all your patients to the ASC you own, then you’re profiting off the ASC getting your referrals, and that relationship can run afoul of the laws and regulations,” Martin explains.

ASC owners and management should focus on their business relationships to make sure they comply with referral and other requirements under the Anti-Kickback Statute and Stark Law, Martin adds.

In July, a federal jury convicted a Houston physician who paid illegal kickbacks to a healthcare group in exchange for patient referrals. The physician also was convicted of engaging in a scheme to defraud Medicare of \$1.5 million in fraudulent claims for unnecessary home healthcare services. (*Read*

more about the case at: <http://bit.ly/2grX1mf>.)

• **Deviate from standard physician compensation.** The government generally understands that it's not feasible for each surgeon to create his or her own ASC. It's expected that ASCs will be owned by a group of doctors and/or other healthcare individuals, hospitals, or companies, Martin says. The problem is determining how the owners invest in the ASC, as well as how they are compensated, explains **Robert Del Giorno**, Esq., partner with Garfunkel Wild.

"You can get into serious trouble when providers who bring more referrals pay less for their shares, are 'loaned' money by other owners of the ASC to buy their shares, and/or receive a higher return on their investment," Del Giorno says.

For instance, ASCs will be out of compliance if they reward the harder-working surgeon owners.

"There is a problem if one owner says to another, 'I bring in 10,000 cases, and you bring in 1,000 cases, so I should pay less for my shares or get a greater return on investment,'" he explains. "If you structure your ASC in that way, you will likely end up in hot water and at significant risk."

In May, two Missouri providers agreed to pay \$34 million to settle FCA violations that stemmed from an improper relationship with referring physicians. Here, the oncologists based their compensation, in part, on a formula that took into account the value of their referrals of patients to the infusion center operated by the defendants. (*Read more about the case at: <http://bit.ly/2x6MO1z>*.) The bottom line is that ASCs cannot reward co-owners based on who refers the most business, Martin says.

Some organizations have attempted to structure these rewards in a less obvious way, such as appointing the rainmaker as medical director and then paying the medical director an exorbitant salary that is not commensurate with the person's actual job duties or fair market value, Martin notes.

"That's problematic," he says. "The requirement is that you pay fair market value for necessary services that are actually provided. The best way to do that is to get an expert to evaluate the salary."

"IN THE MEDICAL INDUSTRY, THE GOVERNMENT FROWNS ON REWARDING PEOPLE BASED ON REFERRAL VOLUME, OUT OF CONCERN THAT IT WILL RESULT IN EXCESSIVE OR UNNECESSARY TREATMENTS."

This is counterintuitive because in most businesses, it makes sense for the person who puts in the most time and produces the best results to receive a better payout, Martin says.

"But in the medical industry, the government frowns on rewarding people based on referral volume, out of concern that it will result in excessive or unnecessary treatments," he says. "So, if you pay these doctors based on which one brings in the most cases, then each has an incentive to maximize their cases."

The danger for ASCs is that if the organization has created a poorly structured referral relationship with its physician owners and one or more members are paid in excess of their ownership, then there is risk that those physicians' referrals could be viewed as tainted and subject to the FCA.

"There's the potential for liability there, and the government could go back a minimum of six years of claims," Martin warns.

• **Engage in improper relationships with anesthesiologists.** Anesthesiology services are profitable, with high rates of reimbursement, so some ASC owners have tried to find creative ways to capture some of this revenue, Del Giorno says. But, for the most part, they can't do this legally without absorbing real risk.

"If we're talking about a garage owner, and someone comes in and is doing work in my garage, then the owner could charge the mechanic 20 bucks for the use of the garage," Martin says. "But you can't do the same thing in an ASC."

The ASC bills a facility fee for the service, which includes certain anesthesia costs, and the anesthesiologists separately bill patients directly for the professional component. As a result, there is generally no quid pro quo for the payment to the ASC. As with any similar relationship, the government wants to make sure the ASC is not picking the anesthesiologists who pay the ASC for the privilege of providing services in the ASC.

The Office of Inspector General (OIG) has responded negatively to two different arrangements in which an ASC would capture revenue generated by anesthesiologists. One proposed arrangement included charging an anesthesiologist group

a management fee for certain space, assessments, and billing documentation assistance. The OIG rejected this because the ASC's Medicare reimbursement already included payment for these items "and the ASC would be getting paid twice under that arrangement." The OIG also rejected the creation of a separate company by the ASC owners, which would then contract with the anesthesiology group to effectively provide all the services. The OIG viewed this as a vehicle to capture some of the revenue otherwise paid directly to the anesthesiologists rather than a bona fide anesthesiology practice. (*Read more at: <http://bit.ly/2yFjwKK>.)*

"The OIG made clear that you can't do indirectly what you can't do directly," Del Giorno says.

• **Engage in an improper relationship with medical supply distributors.** "There are plenty of examples, outside of the ASC context, where physicians have set up inappropriate relationships with medical supply companies," Del Giorno offers. "Just yesterday, I read a recent case about a physician who had his fiancée set up a company to be an intermediary with the medical device distributor, saying

to the device company, 'This is the distributor I work through, so if you want me to buy and use your device, I'm not going to do it unless it comes through here and you pay this person a commission,'" he recalls.

This type of violation could result in a fine and/or a prison sentence.

• **Assume the government is too busy to check every ASC's business relationships.** Government regulators might not have the time to check out every ASC or healthcare organization, but the law solves that problem by providing whistleblowers with windfall rewards.

"The truth is there are resources out there looking for these violations," Martin says. "A fast-growing area is 'relators' — whistleblowers, who, under the False Claims Act, can sue you on behalf of the government."

If they're successful, such whistleblowers can earn a lot of money. Some recent cases involved relators who received millions of dollars. Whistleblowers can be almost anyone who learns about a violation. One often finds current or former employees, owners, and/

or competitors who have learned of a potential violation.

"Anyone who knows how contracts are written, or maybe one doctor is talking to a friend and mentions how he gets paid," Martin says. "Anyone can bring this action, and they share in whatever the recovery is."

The government can join the individuals in the action, which is called "intervening," but even if the government doesn't intervene, the whistleblower still can move forward with litigation and potentially recover some of the money.

"There are professional relators who look for certain things they know that providers or hospitals or ASCs tend to do a lot, and they search this out," Martin explains. "They may have no connection to the practice, but if they can figure out what's happening, they will file a lawsuit, and it can be like having a winning lottery ticket."

Be aware that the government and/or whistleblowers could discover any improper dealings or arrangements any time. Competent healthcare counsel should scrutinize relationships between referral sources and recipients before the government does so. ■

A Quick Look at 2018 for ASCs

Experts advise administrators to adapt like Netflix, not Blockbuster

What is the biggest issue ASCs will face in 2018? They will be challenged to sustain growth at a time when administrators are focused on lowering costs and raising quality during an era of mergers and acquisitions.

"How do they stay relevant and maintain their contracting ability, and how do they maintain

an infrastructure with decreasing reimbursement rates?" asks **Michael J. Patterson**, RN, MSN, FACHE, president and CEO of Mississippi Valley Health in Davenport, IA. "ASCs are, by nature, pretty lean operations."

As the ASC industry matures and ages, there are more challenges related to new services and increased growth

and demand. Healthcare claims data, including 24 billion records dating back to 2002, show that ASC procedures have been on the rise over the past decade, says **Robin Gelburd**, JD, president of FAIR Health in New York. A nonprofit, FAIR Health provides an independent, national database of healthcare claims and a public website that

educates consumers about healthcare insurance and costs. FAIR Health's data include more than 150 million privately insured individuals and more than 55 million people enrolled in Medicare.

"There's an uptick in terms of utilization nationally," Gelburd says. "We're starting to see increasing claims associated with services performed."

The nonprofit's ASC and benchmark modules provide cost comparisons among peers and offer a look at the ASC market in other regions. "What we tend to track are the most common procedures performed in an ASC," Gelburd explains.

FAIR Health's data can track common procedures for a window into how a segment of the healthcare market is evolving. For ASCs, the national procedure codes most often used in 2016 included endoscopic procedures and cataract removal. These include colonoscopy and esophageal endoscopy, Gelburd notes.

"ASCs play a certain and valuable role in the healthcare ecosystem," she says. "When FAIR Health was created, it was clear that ASCs were emerging on the scene with their own strategic and operational needs."

Technological improvements make it possible for increasingly complex procedures to move to an ambulatory setting. Medicare is

approving additional surgeries in an ASC setting each year. These trends suggest brisk growth for ASCs.

Regulatory scrutiny increases with Medicare-covered procedures, notes **Lori Callahan**, director of Algonquin Road Surgery Center near Chicago. (See story on making your ASC more efficient, page 142.)

"Medicare now is shifting dollars toward ASCs, so they'll want to see more data," Callahan says. "Regulatory scrutiny is not ever going to stop."

Increased Opportunities Raise Other Issues

"How can ASCs continue to invest in facilities and infrastructure and have the ability to meet rising demand over the next decade for services that haven't traditionally been provided in surgery centers, like total joint replacement and cardiology?" Patterson asks. "The value proposition they can make to providing safe, quality services is pretty compelling."

On the other hand, hospitals will face economic problems without their bread-and-butter procedures in orthopedics and cardiology. "As hospitals see more of those things turn to outpatient, how will they survive without those services?" Patterson asks.

This prospect will continue to propel health systems to partner with

surgery centers to maintain some of their lost revenue stream and to provide care in the lowest cost setting, Patterson adds.

Both ASCs and hospitals must learn from the Blockbuster vs. Netflix battle that ended badly for the company that did not adapt to changing times.

"Fifteen to 20 years ago, we all went to Blockbuster video if we wanted to rent a movie," Patterson says. "Then, the emerging companies of Netflix and Hulu said there was an easier way to do it, and it was less costly and more efficient."

Surgery centers could be the metaphorical Netflix in this scenario, unless they also do not adapt as technology and medicine changes.

"If Blockbuster had learned from Netflix, things would have been different. But Blockbuster said, 'No, never going to do that,'" Patterson says.

For instance, ASCs must learn from hospitals about how to take care of a larger patient population. ASCs have not evolved as quickly as hospitals away from the fee-for-service mentality.

"We're still a fee-for-service type of organization, but that's changing, and ASCs need to learn from hospitals how to do bundled payments and manage care beyond the date of service," Patterson says. "Hospitals will change, and ASCs will have to also."

Some of the cost pressures ASCs face concern major costs of which they have little to no control, including implant and cath lab equipment expenses, he notes.

"How do we find a balance?" Patterson asks. "You partner with a hospital, and say this book of business belongs in the surgery center. But how do we steer payers and patients?"

EXECUTIVE SUMMARY

Next year's big challenge will be to lower costs and raise quality, even as surgery centers face merger and acquisition pressure.

- ASC procedures have been on the rise over the past decade.
- Medicare is sending more dollars to ASCs, but also is increasing regulatory scrutiny of such facilities.
- ASCs are fee-for-service entities, but their mission is evolving and will be different in coming years.

For these reasons, ASCs might find that their biggest opportunities for growth are to partner with hospitals and others, learning how to treat patients with the type of care and service that is appropriate

for each person, Patterson offers.

As accountable care organizations and bundled payments become more prevalent in ASCs, surgery centers must learn to help patients become as healthy as possible prior

to surgery and better educate patients post-surgery to contain hospital readmissions, Patterson says.

“That’s the context of the greatest opportunity for ASCs in the next decade,” he adds. ■

Cutting Higher-hanging Fruit to Improve ASC’s Financials

Most ASCs have cut costs in all of the easier areas. What’s left is challenging.

“The low-hanging fruit has already been plucked, and you’re moving to the top of the tree, and it’s more difficult,” says **Stephen Blake**, JD, MBA, CPA, CEO of Central Park ENT & Surgery Center in Arlington, TX.

For further cuts, ASCs must focus on standardization, he says.

“The more you can minimize variation, the better it will be in efficiency and cost,” Blake says.

Any financial strategy also should include increasing cases through negotiations with payers and maintaining cost competitiveness, he says.

“But we have to be smart about it,” Blake stresses. “If we’re staying proficient in these areas, then they can be cost competitive in those areas, as well as price competitive in those areas, and we’ll ultimately be successful.”

Keys to Efficiency

These same competitive pressures have contributed to health systems purchasing ASCs. Health systems make the pitch that ASCs will receive more per case in a collaborative arrangement, but as patients increasingly pay higher deductibles, this can be self-defeating.

“You go to a higher price deliverer of care and not get any increase in value,” Blake warns.

The key to running an efficient operation is to standardize purchases, maintain competitive pricing, and increase cases and services. The following are some strategies for shaving costs and increasing cases:

- **Show physicians what their peers are spending on supplies.**

“Physicians are very competitive,” Blake says. “One of the things we’ve done at strategic planning retreats is set up a table with supply items and their associated costs.”

The cost labels will read “Surgeon A, B, C, D, E” to avoid using real names while clearly showing how much each surgeon spends on an item. A physician will see that a colleague has been using a less expensive product, which causes the doctor to wonder about switching to a less costly product. Standardizing product/supply purchases can help an organization cut costs, but it can’t happen with surgical supplies unless the physician is aware there is a way to cut costs and maintain quality.

“We let the physicians’ competitiveness take over, and we found in most cases physicians don’t like to be outliers, especially when it comes to cost,” Blake says.

Physicians would mill around the product tables at the strategic planning retreat, comparing their \$3 supply item with someone else’s \$1 item. A surgeon might decide he or she was OK with the \$1 item and switch.

The price cards forced everyone to ask questions. “Are we getting better results by using a \$150 blade, versus the cheaper one we had used in the past? Are we seeing patients are prepared quicker?” Blake notes. “We have that discussion, knowing the cost difference.”

The key is to show and not tell. When ASC leaders tell physicians to

EXECUTIVE SUMMARY

Minimizing variation is one strategy that can help ASCs improve efficiency and cost.

- Use physicians’ inclination toward competitiveness to show them how their supply costs stack up against peers.
- Challenge vendors to find an equal quality, lower-cost option.
- Grow existing business through price transparency and focus on quality.

change to less expensive products, they often will not cooperate.

“You never tell doctors what to do,” Blake advises. “But give them good data and let them come to the right decision.”

• **Challenge vendors.** “We all have to continue to challenge our vendors,” Blake advises. “They’re an important part of the solution, and better competition among vendors makes it stronger.”

Standardizing supplies also can help improve this process. “Look at the top 10 and 25 items that you’re spending the most money on, and those are the targets for volume and money being spent,” Blake says.

Ask vendors what they can do to improve those costs for the surgery center.

“We can push a vendor, and, in some cases, they might say, ‘I have this other product that’s not a brand name, but I’m hearing it’s just as good. So, let me get you a couple of samples,’” Blake says.

The goal is not to push vendors to reduce the costs to the point that they’re not making a profit, but to goad them into finding a win-win situation in which they show the ASC a product that is cheaper and just as useful, he adds.

• **Grow existing practices.** “An ASC is more efficient at the cases it already is doing,” Blake says. “If we do the same cases over and over again, we get pretty efficient at it, and that’s very important.”

Central Park ENT & Surgery Center is competitive with small bread-and-butter-type cases. Also, the ASC is positioning itself to serve as an inexpensive alternative to costly hospital surgeries and post-op care.

“We’re a small, independent center and can be cost competitive, but we have to be smart about it,” Blake says.

“We’re starting to see more and more patients as deductibles rise,” Blake says. “They recognize that they’re paying for the procedure until they get to the \$6,500 deductible, and the average person is not going to hit that number.”

• **Recruit new physicians.** An ASC should employ physicians who are in different stages of their careers. There should be younger physicians and those with mature practices, Blake advises.

THE GOAL IS NOT TO PUSH VENDORS TO REDUCE THE COSTS TO THE POINT THAT THEY’RE NOT MAKING A PROFIT, BUT TO GOAD THEM INTO FINDING A WIN-WIN SITUATION IN WHICH THEY SHOW THE ASC A PRODUCT THAT IS CHEAPER AND JUST AS USEFUL.

“You’ve got those who are thinking about retirement and starting to slow down, so if you don’t bring in new people, you’ll have people starting to retire at the same time,” he explains.

• **Be price competitive and transparent in pricing.** “If you go to our website, we list our major prices and the things we do,” Blake says. “Price transparency is more and more a part of our business,

and it enables us to draw business to the surgeons in our center.”

For example, one woman called the ASC, saying she needed ear tubes for her son. “She said, ‘I got an ENT and live 45 minutes away. But the doctor wanted me to take my son to the children’s hospital for ear tubes. He’s otherwise healthy, and I have a \$6,000 deductible, and I called the hospital and it was \$5,900 just for the facility fee,’” Blake recalls. “She said, ‘What am I looking at for your center?’ and I said, ‘It’s a \$1,677 cash price for that procedure, including doctor, anesthesia, and facility fee.’”

The woman brought her son to the ASC, found a doctor she liked, and the procedure was performed there.

“I get more phone calls because of the price transparency,” Blake adds. “Some people in the internet age will look around and ask what their options are and look at the cost differences.”

As Americans’ deductibles rise and they become more educated about healthcare, they pay more attention to costs.

• **Stay ahead of the reimbursement curve.** Blake has been pushing payers to accept bundled rates and believes there will be a breakthrough soon. “We think we’ll go to a bundled rate eventually, but we’re not there yet,” he says. “The insurance companies are not quite ready to move to bundled rates, saying their IT systems are not designed to do it yet.”

Once they are ready, the ASC will be able to make the change quickly.

“One of the nice things about being smaller is we can be quicker at changing than bigger systems,” he says. ■

A Few Suggestions for Better Operations

Credentialing tops the list

ASC boards focus on the big picture of a surgery center's staffing, services, and financing. But they also might pay closer attention to some of the operational details that can help or hinder an organization's efficiency.

"I've got a list of the top things that anyone on the board of an ASC should be queued in on," says **Neil Brodsky**, MD, AGAF, medical director at Queens Endoscopy Center in Fresh Meadows, NY. Brodsky speaks about common operational pitfalls at national ASC conferences.

The following is Brodsky's list:

- **Credentialing:** "All physicians on staff are credentialed and privileged for procedures they want to do, including new procedures they want to bring in to the surgery center," Brodsky says.

Physicians also must have delineated privileges, as described in the medical staff bylaws. Medical staff must maintain a list of surgical procedures that are appropriate for the surgery center.

- **Peer review:** "We review cases quarterly," Brodsky says. "We have a committee of physicians, a nursing administrator, and physician volunteers who have an interest in doing a quality review."

The reviews involve looking at whether the appropriate procedures are performed and what new procedures might work for the center.

"If a physician wants to introduce a new procedure, we have to make sure we have appropriate due diligence," he says.

The procedure must be appropriate, and the surgeon must

be trained on performing the procedure.

- **Board composition:** "We have to make sure the composition of the board represents physicians," Brodsky says.

Physicians can rotate on and off the board annually. The board also must assume full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation as well as for oversight and accountability of quality assurance programs.

- **Discrimination issues:** The ASC must create a culture in which discrimination is not permitted. Larger surgery centers might need a human resources manager. Smaller organizations could contract for these services.

"If you don't have human resources as part of your skill set, then send people out for training," Brodsky offers. "The law firm we use for most legal matters also has done presentations for us on human resources, and we use the firm for HR advice."

Handling staff issues, particularly as they might relate to federal laws and regulations, is not a simple task.

"I would urge people to not put this on the back burner because it can come back to bite you in a big way," Brodsky says.

- **Sexual harassment:** Sexual harassment issues have made major headlines in recent months, and for a very good reason: This is an issue that can cause major problems in a workplace.

Inappropriate touching, conversations, and other examples of sexual harassment can result in lawsuits and regulatory complaints. This type of behavior also can negatively affect

staff morale and lead to high turnover.

"If someone makes a complaint against another employee, then deal with it, investigate it," Brodsky stresses.

- **Formal warnings:** When it involves work effort, tardiness, or absenteeism, an ASC should be consistent, fair, and equal with staff, Brodsky says.

"We say, 'three strikes and you're out,' and keep a formal warning on the employee's file," he says.

For instance, Brodsky recalls the case of an employee whose skills were excellent, but who had difficulty arriving to work on time. After three strikes and warnings, the surgery center fired the employee.

- **Infection control:** "We're an endoscopy center, so we make sure we're cleaning scopes appropriately and monitoring for any infection," Brodsky says.

If there are any infections or adverse outcomes related to the surgery, these must be reported to appropriate governmental agencies.

- **Monitoring patients:** "Patients here receive a phone call the day after the procedure, and they're asked about pain, etc.," Brodsky says. "We do random reviews of charts, checking to make sure there was appropriate medication for the procedure and making sure the pathology reports are sent out and received."

- **Following national guidelines:** "If you don't follow national guidelines in terms of appropriate procedures, then the center can be penalized by payers," Brodsky says. "We have to make sure everyone is doing exactly the right thing."

- **Checks and balances:** "I can't

overestimate how important it is to have a quality assurance committee and to make sure you have checks and balances,” Brodsky says. “Usually, a nurse manager runs a

QA committee, keeping minutes.” The committee reviews information, following a checklist concerning case reviews, infection outbreaks, pathology incidents,

patient complaints, transfers to hospitals, and other issues.

“It becomes very rote, and you don’t want to miss anything,” Brodsky says. ■

Four Steps to Making ASCs More Efficient

Surgery centers increasingly are under regulatory scrutiny, and their industry is evolving quickly. One of the more predictable changes is the push for greater efficiency and cost-cutting.

The regulatory focal point and greater emphasis on cost-cutting traditionally have been on hospitals, but now are shifting to the ASC industry, notes **Lori Callahan**, director of Algonquin Road Surgery Center.

ASCs are responsible for high-quality patient care and helping investors realize a return on investment. This means cost-cutting pressures overlapping with improving patient care practice, she adds. Callahan offers the following four strategies for cutting costs without negatively affecting quality care:

1. Negotiate with vendors, using cost data.

“I have this large board in my office, and I put on it the implant cost by vendor,” Callahan explains. “I list everything they’re charging.”

The chart illustrates which vendors charge more and which charge less. Then, Callahan shows vendors the reimbursement differences between like products. If an ASC director cannot negotiate a lower cost based on these data, then the surgeon can try.

“The surgeon can go in and fight to get the price reduced,” Callahan says. “We need a physician advocate

to come in and push those prices down for us.”

Directors can take the same cost spreadsheet to investor meetings to show ASC owners each case and the implant used based on cost and what payers will reimburse.

2. Hire the right staff.

When a surgery center’s staff is a poor fit, it can affect cost and quality.

“Sometimes, if you bring in someone who’s only used to a hospital or large department, they’ll be used to doing one thing at a time,” Callahan says. “ASCs need to find people who can multitask and change.”

The two main qualities a director might seek hiring new employees are finding people who provide the highest-quality care to patients and whose work provides a return to the ASC’s investors, she says.

“If I don’t meet those goals, then I will struggle,” Callahan says.

Other desirable qualities in staff include:

- ability to speak out when they feel something could have been done better;
- personality that enjoys work for more than just a paycheck;
- ability to follow infection control, safety management, and other important areas.

“We have staff competencies and benchmarks for people to meet, and our board gives employees a bonus every year based on measures the ASC has to meet,” Callahan notes.

3. Pay attention to contracts.

A surgery center that passively accepts whatever contracts payers offer might run into financial constraints over time. Instead, ASCs should negotiate contracts, paying attention to the details of what insurers will pay and how these contracts are structured, Callahan says.

“We are finding that insurance companies are willing to step up and work with us more,” she notes.

This willingness to listen and renegotiate has been increasing over the past few years, but there also have been more barriers to reimbursement.

“This year, we’re seeing more insurance companies denying payment if they can’t read the physician’s signature, and we never saw that before,” Callahan adds. “We audit cases to see why we received a denial on this, and then we collect data and educate physicians.”

4. Benchmark for quality and finances.

ASCs should benchmark their patient care quality outcomes and financial/cost outcomes, she says. Comparing their results with competitors and peers will help ASCs identify areas of improvement, and it will provide information that can be used during vendor and payer negotiations. It’s also a good way to look for trends and determine how to stay ahead of those trends, Callahan notes. ■

'No One Likes Me'

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

I try to make it a point to visit with new staff at each of our facilities whenever I can, although I haven't in a while. I am always learning from these interactions. My questions and their answers are, for the most part, predictable, but there are some interesting exceptions.

For example, a new response to my scripted questions has come up several times from different facilities. When asked "Is everyone making you feel included and part of the team," the answer I usually get and am seeking is, "Oh, yes, everyone is so nice and making me feel right at home."

However, the feedback I've received lately from half a dozen new staff in different locations is not something I want to hear. It's along the lines of "I don't feel like I fit in" or "I don't think the staff here likes me."

Maybe this feeling is pervasive. Maybe I hadn't seen or heard about it before. So, I investigated, engaging in conversations with human resources, some trusted staff members, and others to better understand why some people are liked and others are not. I discovered that employees who are liked or popular with their co-workers demonstrate certain traits.

Some are decision-makers who take their job seriously, seem trustworthy, are motivated, don't mind sharing the load, and are perceived as working hard. Conversely, those who are not as popular or well liked are often

viewed as manipulative, gossipers, conniving, rude, quiet, or possess other traits.

Here are some of the other things I have learned about unlikable colleagues:

- **Negative people are difficult to like.** Nothing works right. The administration is stupid. The docs are crybabies. I try to avoid these people because negativity can be toxic to everyone it touches.
- **They smile, but just with their facial muscles and with nothing behind it.**
- **They are always right, and it is someone else who made the mistake.** I personally respect and like those who can say they made a mistake and own up to it.
- **They take the praise but not the blame.**
- **They don't reach out to co-workers except with text messages.** Sometimes, it's important to pick up the phone and call.
- **They don't ask others who have been working there questions.** Nothing flatters someone like asking their opinion. Try this today: Ask a co-worker a question or solicit their opinion on something.
- **They cannot say "Thank you."** These people cannot express a little gratitude for someone who went out of their way to help.

- **They are just plain selfish.**

These people never bring anything to the meetings, food, ideas, encouragement, or anything that contributes.

- **Then there are the hard-to-define areas, such as poor manners.** This could be someone who chews food with his or her mouth open, smacks gum, exhibits noticeable body odor, swears all the time, or burps loudly.
- **They don't pay back borrowed money.** Everyone remembers a debt not paid.
- **They always have their hands on their phone, communicating with someone else instead of the person in front of them.**
- **They are passively aggressive to those around them, thinking no one can see right through them.**

Everyone wants to be liked. Start by thinking about how certain behaviors can affect those around you.

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. ■

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SAME-DAY SURGERY

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CME/CE QUESTIONS

1. How might an ambulatory surgery center (ASC) that bills properly for procedures violate the False Claims Act?

- a. They are falsely accused of violations by a whistleblower.
- b. The government is going after honest ASCs as well as dishonest ones to increase their penalty collection rate.
- c. Surgery centers have corporate structures and relationships that are complex and could possibly violate federal law, which exposes them to False Claims Act liabilities.
- d. None of the above

2. Which of the following is something surgery centers should not do if they want to avoid violations under the False Claims Act, Anti-Kickback Statute, and Stark Law?

- a. Deviate from standard physician compensation
- b. Assume the government is too busy to check every ASC's

- a. business relationships
- c. Engage in improper relationships with anesthesiologists
- d. All of the above

3. Which of the following is an effective way to cut supply costs?

- a. Threaten vendors with cutting off all business if they do not lower prices.
- b. Show physicians what their peers are spending on supplies, encouraging competition and discussions.
- c. Purchase supplies from resale auctions.
- d. None of the above

4. What must a surgery center have in place for physicians?

- a. Bonuses based on case load
- b. Flexibility in credentialing
- c. Credentialing and delineated privileges, as described in the medical staff bylaws
- d. All of the above

CME/CE OBJECTIVES

After reading *Same-Day Surgery*, the participant will be able to:

- identify clinical, managerial, regulatory, or social issues relating to ambulatory surgery care;
- identify how current issues in ambulatory surgery affect clinical and management practices;
- incorporate practical solutions to ambulatory surgery issues and concerns into daily practices.



SDS ACCREDITATION UPDATE

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

Life Safety Compliance Trends, Update, and Look Ahead

The federal Life Safety Code standards for ambulatory surgery centers (ASCs) will continue to evolve over the next few years. They are moving toward patient safety-centric policies and procedures, and it might not be long before the next big changes arrive.

“We’ll be riding a wave for the next three to four years of continuous flux in life safety codes, as they settle on something that is acceptable that industry can handle and that also maintains patient safety,” says **James Peck**, operations manager and life safety healthcare specialist at Riteway Building Services in Winter Park, FL. Peck speaks about life safety compliance at national conferences.

A healthcare facility’s physical plant is important, and ASCs are starting to recognize this, Peck notes.

“In my personal opinion, this may have to do with the insurance industry and risk,” he explains. “Insurers are seeing the need to ensure that the people they underwrite the risk for are adhering to [all] regulations to ensure their risk is as low as possible.”

When the Centers for Medicare & Medicaid Services (CMS) adopted the 2012 codes of the National Fire Protection Association (NFPA), ASCs suddenly needed to rely on experts for life safety inspections, Peck says. The environment of care pertains to everything mechanical within a surgery center, including backup generators, medical gas

systems, vacuum systems, fire alarms, and sprinklers. Each device must be inspected at least annually.

The Accreditation Association for Ambulatory Health Care (AAAHC) updated its standards in the recently released 2018 Accreditation Handbook for Ambulatory Health Care. The update includes the 2012 Life Safety Codes, says **Mary Wei**, MBA, assistant director of accreditation services at AAAHC.

“From my perspective, the most significant change in the 2012 codes isn’t really the codes,” Wei says. “Yes, there are some new requirements, but the most significant change was in how CMS defined [facilities] — what is now new and what was existing.”

Before the 2012 codes, new facilities were dependent on whether the organization was a participating provider with Medicare. If an ASC wanted to enroll with Medicare, then it was considered new at its enrollment, regardless of the age of its building, Wei explains.

“Now, with the adoption of the 2012 safety codes, Medicare took a more thoughtful approach and can go back to whenever the facility’s physical plant was built, regardless of whether the provider is a Medicare participating provider,” Wei explains.

CMS drew a line under the date of July 5, 2016. Any facility with permits approved prior to that date would be considered an existing facility. Any ASC with permits after that date is considered new.

AAAHC’s new handbook contains a physical

“IT’S NOT MEANT TO BE AN ALL-INCLUSIVE LIST OF ABSOLUTELY EVERYTHING, BUT IT IS MEANT TO REPRESENT EVERYTHING THAT WE WOULD POSSIBLY LOOK AT IN A SURVEY.”

environment checklist, including the 2012 changes.

“It’s not meant to be an all-inclusive list of absolutely everything, but it is meant to represent everything that we would possibly look at in a survey,” Wei says.

Surgery center administrators, who are just getting up to speed on the 2012 Life Safety Code changes, should brace themselves for another change, possibly in 2018. NFPA updates its own standards every year or two, and it typically takes CMS several years to adopt these.

“In 2016, CMS adopted NFPA guidelines for 2012, four years after the guidelines were written,” Peck says. “CMS read through everything, made some amendments to it, and then adopted the actual guidelines and put them out to the medical industry. These are the current standards CMS is effectively going to enforce, and CMS is the enforcer of all of these guidelines put forth by the [NFPA].”

The 2015 NFPA 99 guidelines also are out and in front of CMS for consideration.

“CMS is going through them and, more than likely, we suspect they’ll start enforcing those in the spring of 2018,” Peck says. “We’ve looked through them, and there are a ton of changes. They tend to side on the side of safety for the patient.”

Inspectors Must Be Certified/Credentialed

One of the biggest changes on the horizon is a requirement that only certified/credentialed experts be allowed to inspect and certify the functionality of medical equipment, Peck says.

Currently, ASCs can hire an outside contractor to conduct the inspections. Or, they can hire a

vendor’s certified technician for each piece of equipment, or they can hire someone who performs this work on a regular basis. In the future, only those who have received special training and certification/credentialing will be permitted, he says.

“ASC administrators need to ensure the contractor they’re hiring and the technician, who is actually doing the inspections, have certification and credentialing,” Peck notes.

"THESE ASSESSMENTS HAVE TO BE FORMATTED IN A MATRIX SO IT'S CLEARLY EXPLAINED THAT THERE IS SO MUCH RISK INVOLVED IN UTILIZING THAT PIECE OF EQUIPMENT."

Another big change involves risk assessments.

“Risk management is massive in the healthcare environment because everything in healthcare is risk-based,” Peck says. “These assessments have to be formatted in a matrix so it’s clearly explained that there is so much risk involved in utilizing that piece of equipment.”

Because of this growing emphasis on risk assessment, the next changes to the Life Safety Code likely will not allow ASCs to hand someone a life safety compliance checklist and be finished with the inspection.

“You need to understand why it is that you’re doing it, and

that’s where the thrust of the new compliance is going forward,” Peck says.

Measure Equipment

Risks

The next change will add layers of analysis to risk assessment. For example, ASCs will need to discern how much risk is involved in pieces of equipment and whether the risk directly or indirectly affects patient care. Then, they’ll present findings to their governing body.

“Say there is a backup generator, and it has a huge level of risk because the ASC is located in Florida, and we lose power on a regular basis,” Peck says. “So, we assign that a level 1 risk, and because of that risk, we now need to ensure that piece of equipment is inspected on a periodic basis.”

The ASC decides whether the inspection will take place weekly, monthly, quarterly, or annually. Then, this assessment and decision are placed in the organization’s policies and procedures. Risk assessments like this are conducted for each piece of life safety equipment.

Another example involves fire alarm systems, which also carry a high level of risk. It will no longer be acceptable to simply direct some people to meet to discuss how to act in the event of a fire. ASCs must hold fire drills with all staff on a quarterly basis, at a minimum, Peck says. The practice fire drill includes staff walking through the steps, complete with mock patients.

“It’s nice to sit down and discuss it, but we need to see you do it,” he says. “The regulations give you the guidelines, saying this needs to be done and completed, but how you do it is up to you,” Peck says. “We suspect that in the first quarter of 2018, we’ll hear about the acceptance of NFPA 99 2015, and our suspicions have been right thus far.” ■

Emergency Preparedness Standards in a World of Endless Disasters

AAAHC updates standards for 2018

Many ASC directors and staff were concerned about the federal emergency preparedness final rule after the new federal regulations were published in 2016. Then, events in this year put disaster preparation into sharper focus. A series of disasters struck North America: hurricanes, storms, and flooding in Texas and neighboring states; hurricane infrastructure damage and floods in Puerto Rico; incredibly fast fire destruction in California; and the nation's worst gun massacre by a single gunman in Nevada kept emergency preparedness and recovery on everyone's minds.

CMS' new Condition for Coverage for Emergency Preparedness requires ASCs to be proactive in new ways, including coordinating emergency preparations with their communities.

The CMS regulations took effect in November 2016, and organizations had until Nov. 15, 2017, to implement them. The AAAHC's revised standards will be implemented during surveys, as of March 1, 2018.

CMS issued a 74-page "Appendix Z" memorandum on June 2, 2017. The memorandum, sent to state survey agency directors, provided background information and interpretive guidelines for the emergency preparedness final rule.

Appendix Z suggests using these survey procedures:

- Verify the facility has created an emergency preparedness plan by asking to see a copy of the plan.
- Ask facility leadership to identify the hazards (e.g., natural disasters, man-made accidents, facility, geographic, etc.) that were identified in the facility's risk assessment and how the risk assessment was conducted.

- Review the plan to verify it contains all the required elements.
- Verify that the plan is reviewed and updated annually by looking for documentation of the date of the review and updates that were made to the plan based on the review.

"IN THE CASE OF A NATURAL OR MAN-MADE DISASTER, THEY HAVE TO DEMONSTRATE THEY'RE WORKING WITH THE COMMUNITY TO TEST AND TRAIN THEIR PROVIDERS ON THE COMMUNITY EMERGENCY PLAN."

The AAAHC's new handbook includes everything that CMS has released in the revised conditions for coverage, including the core elements, says **Mary Wei**, MBA, assistant director of accreditation services at AAAHC.

"In the case of a natural or man-made disaster, they have to demonstrate they're working with the community to test and train their providers on the community emergency plan," Wei says.

The new conditions for coverage include these five aspects of emergency preparedness, according to AAAHC:

1. emergency plan;
2. policies and procedures;
3. communication plan (internal and external);
4. training and testing;
5. integrated healthcare systems.

When hurricanes hit a region, the surgery centers in that area often sustain damage, says **Tess Poland**, RN, senior vice president of accreditation services at AAAHC.

"I was in conversation with an organization that was impacted by the hurricane," Poland says. "The ASC is a part of that community at large, and so it was meaningful to them that the community's support system was in place."

Although the ASC's own natural disaster damage prevented the organization from helping with disaster recovery, the ASC's staff benefited from disaster planning, she adds. Prior to the hurricane, the ASC had conducted disaster training. When the actual disaster happened, the staff drew on the earlier drills when reacting to the emergency.

"A critical component to any disaster planning is to evaluate that mock drill, put together a corrective action plan that looks at what worked and what didn't, and evaluate your staff in how they react and respond to the drills," Poland says.

CMS Offers Disaster

Drill Choices

Some people commented on CMS' proposed emergency preparedness rule that ASCs should not be required to participate in a yearly community mock disaster drill because ASCs are not designed to accommodate an influx of patients

in an emergency. CMS responded by revising its standards to allow either a community disaster drill or a tabletop exercise annually, or facility-based disaster drill. A tabletop exercise features key personnel discussing simulated scenarios in an informal setting, according to CMS.

The CMS final rule also specifies the following changes for ASCs:

- In a risk assessment, ASCs should consider where they will transfer patients, including entering into an agreement with a local hospital and creating a back-up plan for when the local hospital is affected by the emergency.
- ASCs must document the name and location of any receiving facility for patients and on-duty staff who are relocated during an emergency. ASCs

can close or cancel appointments in the event of an emergency.

- ASCs must establish an effective communication plan that allows for patient information to be released in the event of an evacuation.
- Base the training and testing program on the ASC's emergency plan, risk assessment, policies and procedures, and communication plan.

Surgery centers looking for more information about emergency preparedness can find a robust library of resources through CMS, Wei says.

"There is a site that is a really good source for samples of policies and training and templates, called ASPR TRACIE," she adds.

A technical resource site, this U.S. Department of Health and Human Services healthcare emergency

preparedness information gateway website can be accessed at: <https://asprtracie.hhs.gov/>. This site contains mass violence resources, including information about surge capacity for terrorist bombings. The paper suggests that outpatient surgery centers might not be directly affected by a mass casualty event, but could provide supplies in an emergency situation. These resources might help an ASC create better templates and procedures for emergency planning, Wei notes.

"Rather than using templates built for a hospital that wouldn't be applicable to an ASC, they can use these as a jumping-off point and tailor them to be their own templates," she says. "That's what these resources do: offer suggestions." ■

AAAHC's Updated Standards Include 'Elements of Compliance'

Move is away from broad-based statements

The AAAHC rewrote its standards to include elements of compliance. The 2018 Accreditation Handbook for Ambulatory Health Care contains revised standards that will be implemented in surveys starting March 1, 2018.

"It's in a far different format than in the past," says **Mary Wei**, MBA, assistant director of accreditation services at AAAHC. "We're moving forward a more transparent process for facilities to see which part of the standard they may be challenged to comply with, or which part they did really well on," Wei explains. "So, we think it will be a great change for facilities and will reduce some of the variability between surveys and surveyors."

The change also means organizations can look at surveyor's comments and see what the surveyor really meant, she adds. The new

handbook is available both in paper and PDF. The PDF version features fillable forms. Elements of compliance contain decision points that indicate what surveyors look for to determine compliance. The new standards were written to be more succinct, concise, and to present clear points that each accredited organization should meet.

For example, current standards are broad-based statements that embody many elements of compliance. One standard for 2017 reads: "Patients are treated with respect, consideration, and dignity." Now, in the 2018 guide, there is a list of elements of compliance, under the standard. For that example, these include the following:

- Patients are provided appropriate privacy: at check-in and in evaluation and treatment areas.
- Interpretation services are available.

- To the degree that it is known, patients are provided with information concerning their diagnosis, evaluation, treatment, and prognosis. When it is medically inadvisable to give such information to a patient, the information is provided to a person designated by the patient or to a legally authorized person.

- Patients receive the opportunity to participate in decisions involving their healthcare, except when such participation is contraindicated for medical reasons.

"Yes" responses are counted and applied to a rating chart that includes "fully compliant," "substantially compliant," "partially compliant," "minimally compliant," or "noncompliant."

For more information about the 2018 handbook, please visit: <http://bit.ly/2xaOib>. ■