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Your facility could be held liable if others misuse your patient records

HIPAA privacy rules require consent for routine use

Under newly published federal standards regulating medical record privacy, you could be held liable if the privacy of patient records is violated by the insurers, accrediting agencies, or others to whom you provide records, according to the American Hospital Association in Chicago. The regulation is expected to cost the health care industry more than \$25 billion.

The regulation was required by the Health Insurance Portability and Accountability Act (HIPAA) of 1996.

“The security regulation will require us to ensure security of information with business partners and to validate [secure computer] linkages to business partners and physician access to medical information,” says **Janice Roach**, executive director of Tri-City Regional Surgery Center in Richland, WA.

In your contracts, include wording that indicates your business associates agree to protect health information, advises McDermott, Will & Emery, a law firm in Washington, DC.¹

“The covered entity could be liable under certain circumstances if it

EXECUTIVE SUMMARY

New federal standards for medical record privacy required by the Health Insurance Portability and Accountability Act could make you liable for privacy violations by insurers, accrediting agencies, and other groups with which you share patient records. The regulation carries civil and federal criminal penalties for violations. Some groups predict that compliance could cost the health care industry \$25 billion.

- The regulations apply to oral, written, and electronic communication.
- You will have to obtain consent for routine use and disclosure of patient information.
- Set up a compliance team to review your policies and procedures and training.
- Set up a system to track people who access medical records.

Some of the regulations bring encouraging news

There is some good news in the final regulations on privacy of medical records, experts report. For example, providers may disclose the entire patient record when making disclosures to other providers for treating the patient.

"There is no requirement that this type of disclosure be limited to only the minimum necessary information," according to McDermott, Will & Emery.¹ "Providers vigorously sought this change."

However, for most disclosures, such as information submitted with bills, providers are required to send only the minimum information needed for the purpose of the disclosure.

Also in the final rules, providers don't have to obtain special consent to use patient information for cost studies and for marketing, and fundraising in limited circumstances. The final rules also eliminated the proposed requirement for employee certification of training and compliance.

"This is a significant change from the proposed rules, which would have required initial certification of employees and recertification every three years," according to McDermott, Will & Emery.

Reference

1. McDermott, Will & Emery. *Health Law Update* Dec. 27, 2000; 17(10). ■

knew that the business associate had violated the requirements of the final rules," the firm warns.

And that's not your only concern. Civil penalties are \$100 per incident, up to \$25,000 per person, per year, per standard. Federal criminal penalties range from \$50,000 and one year in prison for obtaining or disclosing protected health information to \$250,000 and up to 10 years in prison for intending to sell, transfer, or use the information for commercial advantage, personal gain, or malicious harm.

Prepare yourself for sticker shock. The cost of complying with the regulations could dwarf Y2K compliance, experts warn. While the Department

of Health and Human Services (HHS) previously estimated that it would cost \$3.8 billion for the entire health care field to comply with the privacy rules, estimates from the international rating agency, Fitch in New York City, put the cost at more than \$25 billion. According to the report, the cost includes modifying information technology systems or purchasing new ones, hiring and retraining staff, and changing existing processes for maintaining patient privacy.

Health care providers that don't assess properly and budget for HIPAA requirements "will place themselves at risk for possible financial peril," warns Fitch analyst **Rebecca Lageman**. The new regulations will take effect in early 2003. (For information on accessing the regulations, see box, p. 27.) Stronger state laws, such as those covering mental health, HIV infection, and AIDS information, still apply.

You'll need consent for routine use

The two biggest changes for same-day surgery providers are that you will have to obtain consent for routine use and disclosure of patient information, and the privacy requirements apply to paper and even oral communications. However, health care providers who do not electronically transmit any health information are not covered by the rules.

"The privacy regulations will require us to obtain proper authorization from patients and tightly control who can have access to protected patient information," Roach says.

You must receive patient consent before information is released for purposes of treatment, payment, and health care operations.

"This is a major change from the proposed rules and is already being criticized by the health care community," according to McDermott, Will & Emery. "Health care providers and health plans also will need to obtain a second, separate authorization for any other uses or disclosures, including research."

For example, you must obtain specific patient consent before releasing information to financial institutions for loan approvals, employers for

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Information that can be disclosed

The Health Insurance Portability and Accountability Act of 1996 allows information to be disclosed for:

- Oversight of the health care system, including quality assurance activities
- Public health
- Research, generally limited to when a waiver of authorization is independently approved by a privacy board or institutional review board
- Judicial and administrative proceedings
- Limited law enforcement activities
- Emergency circumstances
- For identification of the body of a deceased person or the cause of death
- For facility patient directories
- For activities related to national defense and security

Source: Department of Health and Human Services, Washington, DC.

employment decisions, or life insurers for marketing purposes. "Patients have the right to request restrictions on the uses and disclosures of their information," according to HHS.²

The rules say patients must be able to see and obtain copies of their records and request amendments. In addition, you must have a history of most disclosures accessible to patients. **(For good news in the regulation, see related story, p. 26.)**

Three steps to take now

So what should you do now? Here are some suggestions from people in the field:

- **Set up a compliance team.**

BayCare Health Systems in Green Bay, WI, has set up a compliance team with a subteam assigned to address HIPAA assessment and implementation. "We have the wheels in motion," says **Karen Kohler**, health information manager. The team includes the information systems manager, a representative from a large clinic, a manager from a small clinic, the patient accounts manager, a representative from ambulatory services, and the director of operations.

Assessment is the first step, she says. "We need to determine where we are, look at policies in existence, look at what we need to change, and

assess our need for a formal education program for employees, particularly in the privacy issues." **(For information on changing your policies and procedures, see story, p. 28.)**

- **Establish audit trails.**

Limiting access to records isn't sufficient, Roach says. "We already limit access on a need-to-know basis, but we will have to establish audit trails that can demonstrate our compliance."

Bartlett Regional Hospital in Juneau, AK, tracks every move regarding a patient's medical record, says **Patty Detjen**, RN, staff nurse at the hospital.

"Every time you enter information on the computer, you enter your initials," she says. Members of an information team randomly screen charts of patients who have requested that their names be kept confidential, she explains. "If they think you have no business being in there, if it's a blatant breach of confidentiality, you are fired on the spot. If you have business being there, and you can explain, that's acceptable."

- **Train your staff.**

"There are new, more stringent requirements for demonstrating the training of our staff and ongoing assessment of their understanding and compliance with these regulations," Roach says.

You also are required to designate a privacy officer who is responsible for ensuring the procedures are followed, HHS says.

Bartlett Regional Hospital trains every employee once a year on medical record confidentiality issues. Detjen says, "We get down to

COPIES OF THE REGULATION

To view the regulations, along with releases and regulation summaries from the Department of Health and Human Services, go to Web page: aspe.os.dhhs.gov/admsimp. Copies of the *Federal Register* can be found at www.access.gpo.gov/su_docs/aces/aces140.html. You can view the *Federal Register* at many libraries. To order by mail, the cost is \$8. Specify the date (Dec. 28, 2000, for the privacy regulation), and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Send your request to:

- New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250-7954. Credit card orders can be placed by telephone: (202) 512-1800 or by fax: (202) 512-2250.

the point at which we say, "These are our guidelines; this is how you are expected to behave. If a co-worker is not doing it properly, you can call me, and we will check into it.""

The new HIPAA rules bring same-day surgery programs to new levels of security and confidentiality, Kohler says. "Some of those items for upper-level security will probably come into being," she says, referring to biological screenings, retinal scans, fingerprints, and voice scans. "It took a while for the health care industry, but they are already existing in the industrial world."

Although same-day surgery managers currently have to access paper for some information, the future is likely to be totally electronic, Kohler emphasizes. "But we have to realize that we also then need to work with our security to take it to even a higher level."

References

1. McDermott, Will & Emery. *Health Law Update* Dec. 27, 2000; 17(10).
2. Department of Health and Human Services Press Office. *Protecting the Privacy of Patients' Health Information — Summary of the Final Regulation*. Washington, DC; Dec. 20, 2000. ■

Change your policies and procedures

Under new federal rules regulating medical record privacy, you must provide patients with clear, detailed, written information on privacy rights and how their information will be used.

"We will have to establish policies and procedures for patients to review, amend, and/or correct medical information," says **Janice Roach**, executive director of Tri-City Regional Surgery Center in Richland, WA.

The privacy procedures must address who has access to protected information, how it will be used within the entity, and when the information would or would not be disclosed to others.

Your policies and procedure shouldn't allow everyone in your facility equal access to patient records, same-day surgery experts suggest. In a small environment such as a surgery center, people frequently think that their peers are their

SOURCES

For more information on privacy of medical records, contact:

- **Marilou King**, Esquire, Partner, McDermott, Will & Emery. Telephone: (202) 756-8244. E-mail: mking@mwe.com. You can view a complete analysis of the regulations at the law firm's Web site: www.mwe.com/news/indexhlu.htm.
- **Karen Kohler**, Health Information Manager, BayCare Health Systems, 2733 S. Ridge Road, Green Bay, WI 54304. Telephone: (920) 490-9046, ext. 1249. Fax: (920) 405-8003. E-mail: kkholer@baycare.net.

The regulation will be enforced by the Department of Health and Human Services' Office for Civil Rights, which will provide assistance to providers in meeting the requirements of the regulation, including a toll-free line to help answer questions. Telephone: (866) 627-7748. TTY: (866) 788-4989.

friends and so they trust them. Thus, the overall security tends to be more lax, experts warn.

Look at privacy as a professional issue, they advise. Have security built into your system and follow security guidelines. Only people who absolutely have to have access to records should have access to them, experts say. Set up office policies, and adhere to those policies from the beginning, they advise.

Some same-day surgery programs began to make changes to their privacy policies prior to publication of the final rule. For example, the executive director of the ambulatory surgery center at BayCare Health Systems in Green Bay, WI, re-examined the practice of posting the scheduled procedures for the day with patients' names.

"We're becoming very cognizant of privacy issues and who needs to see that," says **Karen Kohler**, health information manager. "We've basically stopped posting that."

The facility even went as far as to stop paging when the next case was ready, although the page included only the doctor's name and the time of the case, not the patient's name, she says. "We're trying to respect that patient's privacy to the highest degree possible," Kohler says.

When examining your policies and procedures, ensure that patients have a means to inquire or complain about the privacy of their records, which is a requirement under the new rules. ■

HCFA sets April 1 to cover cryoablation

Same-day surgery programs should consider offering cryoablation procedures to treat prostate cancer, as the Health Care Financing Administration (HCFA) will cover the procedure in the outpatient setting beginning April 1. HCFA will cover cryoablation, also known as cryosurgery and cryotherapy, when radiation therapy has failed.

“Those are ideal patients to receive the treatment,” says **Harry S. Clarke**, MD, PhD, associate professor in the Department of Urology at Emory University Medical School in Atlanta. “We don’t have any other treatment to offer them.”

Cryosurgery uses extremely cold temperatures to freeze and destroy cancer cells in the area of the prostate gland. Patients are released in 23 hours or less.

“If the patient has a comorbidity, we have a one-night stay; if not, it’s a one-day stay,” says **Duke Bahn**, MD, chairman of the department of radiology and director of the Prostate Center at Crittenton Hospital in Rochester, MI.

Prostate cancer is the second leading cause of cancer-related death in men.

Radiation therapy is associated with a 50% to 80% failure rate, according to Bahn. “Cryotherapy is an emerging alternative that shows great promise,” he says.

According to a study conducted by Bahn that was presented at the 2000 meeting of the Fairfax, VA-based American Society of Therapeutic Radiology and Oncology, for men undergoing cryosurgery after radiation failed, 95% were biopsy-negative five years later if the cancer was still confined within the prostate and 50% when cancer was locally spread. Some reported minor rectal pain or swelling immediately after the surgery, but those effects disappeared within three months.

An advanced form of cryosurgery developed by Endocare in Irvine, CA, combines cryosurgery with ultrasound and temperature monitoring to improve safety and efficiency in the procedure. Currently, more than 25 facilities in the United States offer the targeted cryosurgery procedure (*Editors note: See patient handout enclosed in this issue. For more information, go to the Web site: www.endocare.com.*)

Candidates for cryoablation therapy should

EXECUTIVE SUMMARY

Beginning April 1, Medicare will cover cryoablation, also known as cryosurgery and cryotherapy, as an outpatient procedure when radiation therapy has failed. Radiation therapy is associated with a 50% to 80% failure rate.

- Cryosurgery uses extremely cold temperatures to freeze and destroy cancer cells in the area of the prostate gland. Patients are released in 23 hours or less.
- An advanced form of cryosurgery developed by Endocare in Irvine, CA, combines cryosurgery with ultrasound and temperature monitoring to improve safety and efficiency in the procedure.

have accurate cancer staging with a transrectal ultrasound and a prostate biopsy prior to the procedure, Bahn says. “Knowledge of the exact location and size of the tumor, and the status of nearby structures, such as neurovascular bundles and seminal vesicles, proves crucial to the success of the treatment.”

The cryosurgical procedure is tailored to each patient based on gland volume, tumor size, and extent of the disease, he says.

To achieve a high level of accuracy in staging, use state-of-the-art ultrasound equipment with color-Doppler capability, Bahn advises. Others disagree.

“Prostate cancer is multifocal, and the entire gland is treated [frozen] just as the entire gland is treated with radiation,” Clarke says. “There is, therefore, no need to use special Doppler ultrasound.”

Patients will need a bone scan and CT scan of the pelvis to rule out the possibility of distant metastases (cancer spread), Bahn says.

A bone scan or CT scan is not necessary if the prostate-specific antigen is less than 10 and the Gleason score is six or less, Clarke says.

Bahn recommends lymph node sampling in selected cases. “If distant metastasis or lymph node involvement is confirmed, the patient is not a candidate for cryosurgery,” he says.

Extensive preoperative medication (androgen ablation therapy) is used to downsize the prostate volume and downstage the disease.

Cryosurgery is performed under general or spinal anesthesia. A team approach is used for targeted cryosurgery with a radiologist and a urologist.

Bahn usually makes five to eight needle

punctures in the perineum and, using ultrasound guidance, advances the needles to preselected locations in the prostate gland. "The needle tracks will be dilated for insertion of the cryoprobes used for the freezing," he says.

The placement of probes is extremely critical, Clarke says. "You are making sure the entire prostate gland is frozen without freezing the rectum and urinary sphincter."

Precise temperature monitoring during the procedure is accomplished with multiple thermocouples placed at strategic locations surrounding the gland. After placing a urethral warming device to protect the urethra, the freezing process begins. "We apply a minimum of two freezes [two freeze-and-thaw cycles] for effective tissue destruction," Bahn says. "The entire prostate, including the tumor, and surrounding tissue will be frozen."

The patient is discharged the next morning with a Foley catheter in place for two to three weeks.

One point to keep in mind is that the procedure is highly operator-dependent, Bahn emphasizes. "It takes about 100 patients for a surgeon to be comfortable with it."

His hospital offers a two-day training course in the procedure and offers "virtual" surgery on a phantom. Afterward, his program proctors physicians for up to five patients before they try the procedure solo.

Impotency is an expected side effect of this procedure, Bahn says. "It is due to the intentional freezing of tissue outside of the prostate gland to kill cancer cells that may have already spread beyond the prostate capsule."

Bahn's study showed only 15% of patients regained potency, defined as a firm erection enough for vaginal penetration, and an additional 23% claimed partial recovery. These numbers are essentially the same when compared to the radiation and radical surgery reports, Bahn says.^{1,2} "To make sure you cure the cancer, [impotency] is the only way."

Other complication rates are relatively low, Bahn says. The major complication recorded is a fistula, which is a connection between rectum and prostatic urethra, which occurred in 0.25% of Bahn's patients. "All except one patient who experienced this complication had failed radiation therapy prior to having cryosurgery," he says.

Another complication reported in patient questionnaires is urinary incontinence, defined as use of pad, in 4.3% of patients who have had no prior

treatments for prostate cancer. It was reported as 11% after radiation therapy¹ and 31% after radical prostatectomy.²

"In our study, most patients used one pad for a few drops a day as a protective measure," Bahn says. In the radiation failure group, the incontinence rate was significant higher than in the virgin group, he reports.

Other minor complications include outflow obstruction in 9%, pelvic pain in 11%, scrotal swelling in 17%, and penile numbness or tingling sensation in 14%. "These usually resolved within three months after the cryosurgery," Bahn reports.

Importantly, 96% of patients stated that they would choose cryosurgery again if it became necessary, he says.

Advantages of cryosurgery include the fact that the procedure can be repeated if the first cryosurgery has failed and radiation therapy has failed, Bahn says. Radical surgery or seed implantation is still an option if the first cryosurgery fails, he reports. Also, cost is less than half of the traditional treatment, he says.

On the downside, there have been no long-term randomized multicenter studies, he says. Also, insurance companies don't always cover this procedure, Bahn says. "They may label this procedure as investigational. However, the American Urological Association [in Baltimore] approved this procedure as one of the treatment options and not an investigational [one]." If patients and providers forcefully appeal, they might receive coverage, he advises.

[Editor's note: For more on Medicare coverage of cryosurgery, go to the HCFA Web site: www.hcfa.gov. Click on "coverage policies" and then "decisions." Under "closed decisions," click on "Cryosurgical Salvage Therapy for Recurrent Prostate Cancer (CAG — 00064)."]

SOURCES

For more information on cryosurgery, contact:

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2. Fowler FJ, Barry MJ, Lu-Yao G. Patient reported complications and follow-up treatment after radical prostatectomy. *Urology* 1993; 42:622-629. ■

Will Bush administration overturn rule change?

Doctor supervision dropped for nurse anesthetists

The decision by the Health Care Financing Administration (HCFA) to eliminate the requirement for physicians to supervise nurse anesthetists is in limbo while the Bush administration spends 60 days reviewing recent decisions by the Clinton administration. However, the president of the American Association of Nurse Anesthetists (AANA) in Park Ridge, IL, expressed optimism that the new administration will support the rule change.

“The interesting thing with our rule, even though it was from a prior administration, is that it had wonderful bipartisan support,” says **Larry G. Hornsby**, CRNA. “We are in line with Republican platform and Bush’s campaign statement to give power back to the state.”

Under the new rule, published in the Jan. 18 *Federal Register*, all decisions relating to the supervision of nurse anesthetists will take place at the state level. (For information on how to order a copy of the *Federal Register*, see resource box, p. 27.) The nurse practice acts, board of nursing

rules and regulations, medical practice acts, and board of medicine rules and regulations in 29 states do not require physician supervision of nurse anesthetists, according to the AANA.

“In those areas, nothing will change,” notes **Candace L. Romig**, director of government affairs for the Association of periOperative Registered Nurses in Denver. Also, any hospital can establish stricter standards than required by state law, HCFA points out. At press time, the new regulations, which affect 21 states, were scheduled to take effect March 19, 2001.

Nurse anesthetists are most prevalent in rural areas, Romig points out.

And HCFA specifically named critical access hospitals as one of the areas included in this rule change, Hornsby notes. “Honestly, those are places anesthesiologists are not, have never been, and are not going to be.”

Hospitals and other facilities, including ambulatory surgery centers, now will have more opportunities to use nurses to administer anesthesia to their patients, Romig points out.

The American Society of Anesthesiologists (ASA) in Park Ridge, IL, has called on President Bush to reverse the rule change, which it says will place every Medicare and Medicaid patient having surgery at increased risk of injury or death. The ASA maintains that the rule change will jeopardize the lives of seniors who undergo surgery by eliminating the requirement for a doctor to supervise if a nurse gives the anesthesia.

Neil Swissman, MD, president of ASA, says the ASA would explore every avenue to have this issue redressed, including legal or legislative action. Rep. Dave Weldon (R-FL) plans to reintroduce legislation that would repeal the final rule, according to his office.

The practice of anesthesiology is not simply administering anesthetic agents, Swissman says. “It requires continuous medical judgment before the surgery to diagnose the patient and determine the best anesthetics to use, during surgery when split-second decisions are made, and even after surgery when recovery of the patient and their pain treatment are critical,” he says. “Nurses are not doctors and should not be expected to make those decisions.”

In the July 2000 issue of *Anesthesiology*, published by the ASA, a University of Pennsylvania study reviewed the care of 235,000 Medicare patients and identified 25 unnecessary deaths per 10,000 cases when an anesthesiologist was not involved in the care.¹ A HCFA press release

EXECUTIVE SUMMARY

The Health Care Financing Administration has published a rule eliminating the requirement that physicians supervise nurse anesthetists. The rule, which at press time was scheduled to take effect March 19, 2001, is in limbo while the Bush administration reviews it.

- State law and hospital policy can supercede the rule change.
- The American Society of Anesthesiologists plans to explore legal or legislative action to have the rule redressed.

referred to this study, but called the results “not relevant to the issue involved in this rule.” The study, HCFA said, did not compare certified registered nurse anesthetist (CRNA) practice with nonanesthesiologist physician supervision. And it said the study “did not provide sound and compelling evidence to support maintaining federal preemption of state law,” the standard that HCFA has set in order for the federal government to step in.

In the final rule, HCFA said it received many comments from surgeons asking about the surgeon’s liability as well as questions about who would be considered in charge of the patient’s care. “This final rule does not require supervision, direction, or oversight of any independently licensed practitioner administering anesthesia by the operating surgeon,” HCFA said. “The surgeon would still be able to involve an anesthesiologist as a consultant or in any other capacity.”

This rule does nothing to restrict that relationship, the agency pointed out. “CRNAs, as well as anesthesiologists, are accountable for their own practices, the care they deliver, patient outcomes, as well as insurance liability coverage,” it said.

HCFA received several comments asserting the physician supervision requirement was responsible for surgeons choosing not to practice in some settings because they don’t want the liability associated with the supervision responsibility. “The rule makes no legal change in the scope of malpractice liability, traditionally a state issue,” HCFA said.

Reference

1. Silber JH, Kennedy SK, Even-Shoshan O. Anesthesiologist direction and patient outcomes *Anesthesiology* 2000; 93: 152. ■

SOURCES

For more information on physician supervision of nurse anesthetists, contact:

- **Larry G. Hornsby**, CRNA, President, American Association of Nurse Anesthetists, 222 S. Prospect Ave., Park Ridge, IL 60068-4001. Telephone: (205) 629-3919. Fax: (847) 692-6968. E-mail: Lhornsby@compuserve.com. Web: www.aana.com.
- **Neil Swissman**, MD, President, American Society of Anesthesiologists, 520 N. Northwest Highway, Park Ridge, IL 60068. Telephone: (847) 825-5586. Fax: (847) 825-1692. Web: asahq.org./hcfa/presidentnew.htm.

Same-Day Surgery Manager



Controlling cost is a state of mind

By **Stephen W. Earnhart, MS**
President & CEO
Earnhart & Associates
Dallas

The fact that you need to control the expenses of your department or ambulatory surgery center is understood. It is a requirement of the job. Anyone can understand the simple reality of “money in/money out,” and keep the difference. It works in every business from the local gas station to the Kinko’s store at the end of the street. Our situation is different because the decisions made on where costs are controlled could lead to a life-and-death situation or compromise patient safety.

There are many ways we can cut costs in this industry. We could stop the laborious task of sterilizing everything, and just put all patients on antibiotics. That would be cheaper, but obviously we can’t do that. We could save on staffing by eliminating the pre-op assessments — create a situation of “see who goes south and who doesn’t.” But that doesn’t fit with our mission statement does it? So, while we can control our cost, we need to recognize the fact that due to the nature of our unique business line, we have to do so judiciously.

Controlling cost is incredibly easy. Identifying what costs to control takes more effort. Reducing expenses that do not compromise quality of care and patient safety — ahhh, now here is where we separate ourselves from the local Kinko’s! We have all read articles about cutting costs here and there, researching the effects of such maneuvers, and gauging implications. Maintaining cost at our facilities should be a state of mind. How many staff members in your facility care, I mean really care, about your expenses? Very few, I can assure you. That is where the true opportunity lies in controlling expense.

If I am responsible for ordering supplies for the

center, then I and only I, truly understand where it can be more efficient, effective, and, therefore, more cost-conscious. As your circulating nurse, only I can tell you where waste exists and where it doesn't. Only someone who works at the front desk can really tell you how to control costs at the front desk. Anesthesia consumes up to \$100 per case in some facilities and less than \$35 in others. Why? State of mind! They are either thinking of controlling the costs or they are not. No one but anesthesia personnel can tell you where you can reduce spending in anesthesia. See where I'm going with this?

So, using these examples, odds are very high that these people couldn't care less what your expenses are. They have a job to do. They do it well and then go home to dinner. End of story. Absolutely nothing is wrong with that! They should not even be criticized for their attitude. They have done their job. While we all get fancy-smancy and say, "Cost control is everyone's job," it really isn't. It is your job to make it their job! It will not happen in a vacuum or without effort. Since you are reading this newsletter and column, chances are high that cost control is part of your responsibility. Therefore, a piece of your job is to get the feedback from these people and make it part of their job.

How do you do it? You have to focus everyone on controlling costs by making it first in their minds. You need to label everything in the facility with its unit cost. If someone sees the cost of something before they take it, you are opening a window in their mind to think "Wow! I didn't know that was that expensive. I better see if there is an alternative." It is the same concept in food stores. If there were no prices on food items and whatever you chose from the shelves was automatically billed to your credit card each month — imagine what your food bill would be!

Price controls spending. How can you control cost without knowing the cost to begin with? Make alternative, less expensive options available to physicians as well as staff, side by side on the shelves. Let them see that product "A" is more expensive than product "B." Isn't that the way we shop at stores?

Stop preaching and whining about controlling cost, and start asking for help. When was the last time you called your receptionist into your office and, one-on-one, writing pad on your lap, pen poised in the air, asked, "How can we control expenses at the front desk?" If you want to turn someone around to your way of thinking, ask

him or her for help. Do you really know the cost of the chemicals your cleaning crew is using, and is there a cheaper one available? Have you ever asked for its advice? Anesthesia staff — you gotta love anesthesia — they can be your best friend or worst enemy in the operating room. They will work with you to achieve your goals if you ask them for help. They are professionals, but also human. We all want to know that our opinions are valuable, sought out, and respected.

Get your staff thinking about controlling costs and giving you ideas on how to achieve your goal. By the way, what is your goal? Is it posted? Is it discussed at staff meetings? Make your efforts to control costs more than just a goal; make it a state of mind in your staff.

[Earnhart & Associates is an ambulatory surgery consulting firm specializing in all aspects of surgery center development and management. Earnhart can be reached at 5905 Tree Shadow Place, Suite 1200, Dallas, TX 75252. E-mail: searnhart@earnhart.com. Web: www.earnhart.com.] ■

Accurate coding: It's all in the details

Length of wound repair, path report are key

You think you've done everything you can to improve billing and claims filing processes: computerized systems, electronic filing, and even tickler files that tell you when to follow-up with

EXECUTIVE SUMMARY

Same-day surgery managers can help coders file claims quickly and accurately by educating surgeons as to the need for details in the operative reports and development of templates that prompt physicians to include those details. The templates should be specific to the same-day surgery program's needs and should address the procedures for which details are commonly missing.

- Reports on arthroscopic procedures should describe all procedures following the insertion of the scope.
- Wound repairs should have length of wound as well as depth.
- Pathology reports should be in the record for coders to include results of biopsies.

managed care companies regarding payment. The one area that is often overlooked is the documentation needed by the coder to accurately code the claim, say experts interviewed by *Same-Day Surgery*.

If the claim isn't coded correctly, the claim is denied or paid at a lower rate than you might be due, says **Cheryl D'Amato**, RHIT, CCS, director of health information management for HSS, a Hamden, CT-based company that specializes in coding and payment for health care facilities.

Accurate coding depends on documentation from the surgeon, and there are many same-day surgery procedures that often are not fully documented, says D'Amato. "Wound repair, arthroscopy, biopsy, and debridement are commonly the most difficult to code because the documentation is incomplete," she says.

Although physicians capture enough detail for their own billing, operative reports are generally not as specific, says **Rita A. Scichilone**, MHSA, RHIA, CCS, CSCP, CHC director of the coding program for the American Health Information Management Association in Chicago. This is why it is good to have a strong working relationship with the physician's office staff, she suggests.

"Whenever possible, compare the reimbursement or claim filed for professional fees with the claim filed for facility fees," she recommends. "This will enable the coder to identify details of the procedure not included in the operative report."

Arthroscopy is a good example of a procedure in which documentation for coders is often scant, says Scichilone. "The surgeon will write that he or she 'did a scope' but doesn't define whether it was diagnostic only or if a procedure followed the approach." If there is another procedure such as a meniscectomy, the use of the scope to approach the area is not reimbursed, but the following procedure is, she adds.

Debridement is another area that requires detailed documentation, says D'Amato. "There are different codes for different levels of debridement. Skin and subcutaneous level is coded differently than debridement that involves bone and muscle."

Surgeons also need to document the use of additional techniques to enable the coder to include them on the claim, points out Scichilone. "If a wire locator is used or if a CT or fluoroscope is used for guidance, the surgeon must write those specific techniques in the operative report," she says. "Otherwise, the coder does not even know about them and can't include

them in a claim without documentation."

There are several ways a same-day surgery manager can improve documentation that will help coders. "Teach your nurses and physicians about coding," says Scichilone. Show examples of claims that are coded with general, nonspecific documentation compared with claims that are coded with detailed documentation, she suggests. The difference in reimbursement will point out the importance of detailed coding.

Educate your coders as well, adds Scichilone. "Sometimes an incorrect pain management code is simply the coder not understanding epidurals or different types of joint injections," she says.

Recognize that your coders need as much detailed information as possible, says D'Amato. "Some facilities also insist that coding will not occur until the full operative report and the pathology report is in the record," suggests D'Amato. The pathology report is especially helpful when the procedure was for biopsy, she explains.

Make sure you have a process set up for coders to send the records back to the physician for more information, says D'Amato. This will enable them to code the claim correctly, she adds.

This process can involve a designated contact person in the physician's office or simply e-mails to the physician's own address, says Scichilone.

Templates also can be set up for operative reports, says D'Amato. "These forms can remind the surgeon to document the patient's comorbidities such as diabetes or hypertension. Forms also can prompt documentation of details such as length of wound repaired or depth of debridement."

Be careful with forms you use. "Boilerplate" reports may overlook some changes made during a case or not report some of the details,

SOURCES

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same-day surgery administrators point out.

"Stay away from canned reports that don't vary from procedure to procedure," Scichilone warns. "If all of your operative reports look exactly the same, managed care companies might suspect falsification." ■

Final Stark II rule expands ASC exemption

The final Stark II regulations maintains and expands the special exception for ambulatory surgery center (ASC) services.

Under the final rule, services that would otherwise constitute designated health services, but that are paid by Medicare as part of a composite payment for a group of services as a separate

benefit, which includes ASC services, will not be considered designated health services for purposes of the Stark law, says **Eric Zimmerman, JD**, associate with McDermott, Will & Emery, a law firm in Washington, DC, that represents the American Association of Ambulatory Surgery Centers. (*Editor's note: To see the new rule, go to the Web: hcf.hhs.gov/regs/physicianreferral/default.htm.)*

"Accordingly, when an IOL [intraocular lense] is included in an ASC bundled payment rate, the IOL will not be considered to be a designated health service," Zimmerman says.

"Moreover, HCFA [the Health Care Financing Administration] established an additional exception for other prosthetics, prosthetic devices, and durable medical equipment implanted in a Medicare-certified ASC by the referring physician or a member of the referring physician's group

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Editorial Questions

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practice, even when the Medicare payment for these items is separate from the ASC payment.”

Previously, the Stark law was somewhat ambiguous in its application to services furnished in ASCs, he says. “While we believe that Congress intended for ASC services to be outside the scope of the physician self-referral proscription, the law [previously] could be read to apply to certain services furnished in ASCs,” including many common implants such as IOLs, he says.

The final rule, which was published Jan. 4, 2001, in the *Federal Register*, is effective Jan. 4, 2002. (For information on how to access the *Federal Register*, see resource box, p. 27.) The Final Rule was published with a 90-day comment period. HCFA will respond to comments no later than April 4, 2001.

[Editor's note: On Jan. 5, American Health Consultants, publisher of Same-Day Surgery, sent a Fax Bulletin on the Stark II regulations to all SDS subscribers for whom we have a fax number. If we don't have your fax number and you would like to receive future Fax Bulletins, please contact our customer service department with your fax number. Telephone: (800) 688-2421. Fax: (800) 284-3291. E-mail: customerservice@ahcpub.com.] ■

Tips on how to manage a successful SDS program

In the current regulatory and reimbursement environment, managing an outpatient surgery program can be overwhelming. For help on costing surgical procedures, containing costs, and surviving reimbursement changes, among other topics, attend the Seventh Annual Same-Day Surgery Conference March 4-6 in Orlando. The conference is sponsored by American Health Consultants, publisher of *Same-Day Surgery*.

Topics will include advice on reprocessing, antibiotic resistance, hazards in the workplace, achievement of excellence, surgical trends and new technologies, accreditation, risk management, medical errors, the nursing shortage, the outpatient prospective payment system, and motivation of employees. The conference includes opportunities to network with your peers at lunches and a reception, as well as a Downtown Disney excursion.

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CE objectives

After reading this issue, the continuing education participant will be able to:

- Identify clinical, managerial, regulatory, or social issues relating to ambulatory surgery care and management. (See “Robotics and virtual imaging: Science fiction or fact,” in the supplement.)
- Describe how those issues affect nursing service delivery or management of a facility. (See “Virtual imaging spurs debate,” in the supplement.)
- Cite practical solutions to problems or integrate information into their daily practices, according to advice from nationally recognized ambulatory surgery experts. (See “Accurate coding: It's all in the details,” p. 33, and “You can build tomorrow's ORs today,” in the supplement.) ■

Frequently Asked Questions about Prostate Cancer Treatment and Targeted Cryosurgery (Excerpt)

Q. How does targeted cryosurgery treat prostate cancer?

Targeted cryosurgery, a procedure developed by Endocare (Nasdaq: ENDO), is the use of cryosurgery (application of extreme cold to destroy tissue) in combination with ultrasound and temperature monitoring to precisely destroy cancer cells in and around the prostate gland. When extreme cold is introduced into the prostate gland, the prostate tissue is destroyed, including cancerous cells. Physicians have found that targeted cryosurgery is most effective for patients with Stage T1 through T3 prostate cancer. Unlike other surgical procedures, targeted cryosurgery can be repeated if prostate cancer recurs.

During targeted cryosurgery, a patient is first treated with epidural anesthesia. A thin catheter that circulates warm fluid is placed in the urethra to protect it from cold temperatures. Next, six to eight slender cryoprobes are inserted through a small incision into the prostate gland. Liquid argon is circulated at the tips of the cryoprobes, freezing the entire prostate gland. This begins the cooling process, during which the cryoprobes freeze tissue symmetrically around the probe tip. Tissue that reaches -40°C is destroyed. After approximately 10 minutes, the physician completes the first freeze cycle and then administers another treatment to help ensure that all cancer cells are killed. The entire procedure lasts about one to two hours.

Q. What happens following the targeted cryosurgery procedure?

Following the targeted cryosurgery procedure, the patient waits in the recovery room until the anesthesia wears off and then, depending on how he feels, can return home immediately or spend the night at the hospital. The patient goes home with a catheter in place to help with urination the week following treatment. In general, patients can resume a normal lifestyle immediately after the procedure, but strenuous activity should be avoided for a few weeks.

Some patients may experience mild soreness for two to three days following targeted cryosurgery; however, this side effect is common among all surgical prostate cancer treatments. To relieve any soreness or swelling, patients can place an ice pack on the abdomen. Long-term side effects of targeted cryosurgery are similar to other therapies and may include impotence, bladder outlet obstruction, pelvic pain, chronic urgency, rectal injury, and incontinence. The rate of incontinence after targeted cryosurgery is lower than with other therapies. Patients should be aware that impotence occurs in 80% to 90% of patients who undergo targeted cryosurgery. This is due to the intentional freezing of tissue outside the prostate gland to kill cancer cells that may have already spread beyond the prostate capsule.

Freezing tissue beyond the prostate capsule is an important decision that helps in curing the cancer and not leaving behind viable prostate tissue that could become malignant. Although this process may damage the nerves that allow a man to get an erection, most urologists advise treating such tissue because if not, cancer cells may still remain.

(For more information, see story, p. 29.)

Q. How effective is targeted cryosurgery in the treatment of prostate cancer?

In the July 2000 issue of the peer-reviewed journal *Urology*, a comparative study of 163 prostate patients treated with two methods of cryosurgery reports that 97% of patients treated with targeted cryosurgery were cancer-free after six months. In another study presented at the 1998 World Endo-Urology Conference, 97% of patients treated with targeted cryosurgery showed no signs of cancer at one year. Five-year combined data for both traditional cryosurgery and targeted cryosurgery show that of 988 patients treated, 82% had negative biopsies.

Q. Who is a candidate for targeted cryosurgery?

The best candidates for cryosurgery are men with Stage T1-T3 disease and high Gleason scores and prostate-specific antigen levels. In these patient populations, cryosurgery has been found to be safe, effective, and medically necessary. Because targeted cryosurgery can be repeated if all the cancer cells aren't destroyed, some patients choose the treatment for this reason. Others turn to targeted cryosurgery for treatment if radiation therapy or brachytherapy has failed.

Q. How many prostate cancer patients have been treated with cryosurgery?

Several thousand men have received cryosurgery to treat prostate cancer. This therapy, first introduced in the 1960s, has seen dramatic improvements during the past five years with the use of temperature monitoring, argon-based cryogen, and ultrasound guidance techniques. The temperature monitoring and ultrasound visualization used in targeted cryosurgery allow the physician to precisely freeze the prostate gland while sparing other critical areas of surrounding tissue. The use of argon-based cryogen provides physicians with better control and accuracy, ensuring that a freezing level of -40° C is achieved and confined to a specific area.

Source: Endocare, Irvine, CA. Web: www.endocare.com.

Robotics and virtual imaging: Science fiction or fact?

Emerging technology offers opportunities and challenges

The robot is ready, the surgeon has completed his virtual tour of the patient's anatomy, and the audiovisual tech has confirmed that the observers in distant conference rooms can see the operating table clearly. As the surgeon sits at the console and grabs the control handles, his mind flashes to the days of playing video games with a joystick.

No, you haven't just read the opening to a new science fiction novel; you've read a description of what is possible today with a variety of technological advances that are available now or in development for near-future use.

"There is great potential for robotics in same-day surgery," says **Kenneth Salisbury**, PhD, professor in the departments of computer science and surgery at Stanford (CA) University and scientific advisor to Mountain View, CA-based Intuitive Surgical, a company that manufactures robotics for surgery.

Enhancing dexterity

Surgeons want to do more complex minimally invasive surgery, but the laparoscopic tools that are now available don't offer the dexterity needed for work with very small vessels, Salisbury says.

Dexterity is enhanced with a robotic tool that has a moveable wrist that can cut and suture inside the body, he says.

The use of robotic tools, also called telesurgery, is advantageous when working with small vessels in areas such as eyes because the risk of normal hand tremors is reduced since the robot is steadier than a human hand, Salisbury adds.

Another advantage of robotics is the ability to reduce the scale of motion.

"While the surgeon may move the control stick 5 mm, we can program the computer to reduce the scale of motion from 5 mm to 1 mm," he explains. This increases the surgeon's ability to operate accurately on a very small scale, he adds.

Moving robotics into OR

Several companies have developed robotic devices for surgical applications, says Salisbury. (See resource box, p. 3.) While there is a capital investment for the robot and the computer that operates it, the most critical cost for many

EXECUTIVE SUMMARY

New technology that is in development and just appearing in the marketplace might present challenges that surgeons and same-day surgery managers haven't dealt with previously.

- Robotics can improve dexterity and turn more complicated procedures into minimally invasive procedures that might become outpatient or 23-hour stay.
- Virtual imaging might replace diagnostic procedures such as colonoscopies for some patients, meaning an increase in therapeutic colonoscopies.
- Operating rooms under construction today must take into account a need for additional physical space and communications or electronics support for technology that might not be available when construction begins.

facilities is the replacement cost for the surgical tools, he says.

“Although the tools can be sterilized and re-used for a certain number of procedures, they do have to be refurbished by the factory periodically,” he explains.

The initial investment for the robotic surgical system produced by Intuitive Surgical is \$1 million, says **Sheila Shaw**, manager of corporate communications for the company.

“This price includes the computer, the surgeon’s console, the robotic equipment, the software, and instruments for initial procedures,” Shaw says.

After the initial investment, different tools can be purchased at prices that are comparable to standard laparoscopic tools, she adds.

Salisbury also sees the advantage of combining telesimulation as a way for a surgeon to practice the procedure before surgery. By using virtual imaging, computer simulation, and robotics, the surgeon can practice on patient-specific anatomy prior to the procedure, he says.

Virtual not always a substitute

Virtual imaging is another technology that has given rise to a number of debates within different specialties.

Virtual imaging is a process of using sophisticated CT scanning equipment to produce images that are stored and subsequently recreated by a computer to produce a visual image of the organ, explains **Lester Rosen**, MD, FACS, professor of clinical surgery and colorectal surgeon at LeHigh Valley Hospital in Allentown, PA.

For example, the radiologist or surgeon subsequently can take a virtual tour of the colon and look for abnormalities, he explains.

The debate among gastroenterologists is whether virtual imaging can replace colonoscopy as a screening tool for colon cancer, says **Michael J. Stamos**, MD, FACS, a surgeon at Harbor-University of California at Los Angeles Medical Center in Torrance and chairman of the professional outreach committee of the American Society of Colorectal Surgeons in Arlington Heights, IL.

There are advantages and disadvantages of virtual endoscopy as a screening tool for colon cancer, Rosen says. **(For more on the**

disadvantages and advantages, see related story, p. 3.)

“Because the virtual colonoscopy is less threatening to many patients, we may see an increase in the number of patients using this procedure to screen for colon cancer,” says Stamos. “This may increase the percentage of conventional colonoscopies that are therapeutic rather than diagnostic.”

Planning for future can be tricky

Emerging technology also provides a challenge for same-day surgery managers who are planning renovations or new buildings, says **Judith H. Bernhardt**, RN, CNOR, director of surgical services for Norton Hospital in Louisville, KY.

The new surgery building that Bernhardt and her staff moved into the week of Thanksgiving 2000 consists of 14 operating rooms that surround a central core and contain the latest surgical, sterilization, video, and even air-conditioning equipment, she says. **(For more about the OR, see related story, p. 4.)**

Although her facility is equipped with the latest, Bernhardt points out that the challenge is trying to build for the future. “When you are

SOURCES

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- **Michael J. Stamos**, MD, FACS, Department of Surgery, Harbor-UCLA Medical Center, 1000 W. Carson St., Box 25, Torrance, CA 90509. E-mail: mstamos@ucla.edu.
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- **Judith H. Bernhardt**, RN, CNOR, Director of Surgical Services, Norton Hospital, 200 E. Chestnut St., Louisville, KY 40202. E-mail: judith.bernhardt@nortonhealthcare.org.

RESOURCES

For information on surgical robotics, contact:

- **Intuitive Surgical**, 1340 W. Middlefield Road, Mountain View, CA 94043. Telephone: (650) 237-7000. Fax: (650) 526-2060. Web: www.intusurg.com. Intuitive manufactures a robotic surgical system that was approved for use in minimally invasive cases by the Food and Drug Administration in 1999.
- **z-kat**, 2903 Simms St., Hollywood, FL 33020. Telephone: (888) 566-8122 or (954) 927-2044. Fax: (954) 927-0446. Web site: www.z-kat.com. A robotic arm that can be used for surgery is in development.
- **Integrated Surgical Systems**, 1850 Research Park Drive, Davis, CA 95616. Telephone: (530) 792-2600. Fax: (530) 792-2690. Web site: www.robodoc.com. The company manufactures robotic systems for orthopedic and neurosurgery.

planning, you have to think outside the box and imagine what might be available in the future," she says.

You also have to be prepared to make changes during your construction phase to accommodate technology that might come onto the market, Bernhardt points out.

"For example, we thought we had the best washer and decontamination system planned, then we learned of another that received better reviews from peers," she says. "Changes were made to accommodate the new system, and we are glad we made the change." ■

Virtual imaging spurs debate

Intervals between colonoscopies uncertain

While the idea of not having to undergo a colonoscopy to screen for colon cancer might be appealing to most patients, there are situations in which virtual imaging does not do an adequate job, says **Michael J. Stamos**, MD, FACS, a surgeon at Harbor-University of

California at Los Angeles Medical Center in Torrance, CA, and chairman of the professional outreach committee of the American Society of Colorectal Surgeons in Arlington Heights, IL.

For example, "studies have shown that virtual imaging does not detect polyps less than 6 mm," he says.¹

Although proponents of virtual imaging point out that polyps less than 6 mm are generally not malignant, the question that arises is how to determine the interval between exams. "Guidelines for colonoscopy set eight to 10 years as the interval between exams," says **Lester Rosen**, MD, FACS, professor of clinical surgery and colorectal surgeon at Lehigh Valley Hospital in Allentown, PA. "But we know we can miss small lesions in virtual endoscopy, so I am not as comfortable waiting 10 years to re-examine the patient," he adds.

At this time, there are no guidelines related to intervals between virtual colonoscopies, he says.

"An actual colonoscopy also allows the surgeon to see a trail of blood in the colon, while virtual colonoscopy does not," says Rosen. "Dry stool and bowel contour thickness changes also can affect how accurately the image can be read."

Virtual imaging requires clean colon

Both virtual and actual colonoscopy require patient preparation, but the colon has to be optimally clean for effective virtual imaging, while the surgeon can remove bits of fluid and dry stool with suction during an actual colonoscopy, explains Rosen.

"The colon also may be distended more during virtual imaging so the radiologist can get the best pictures, and the extra distension can cause greater discomfort to the patient and increase the risk of injury," he adds.

If the virtual image exam shows any abnormalities that need to be looked at more closely, the patient has to undergo the exam prep again, points out Stamos.

"For this reason, and the fact that some things may be missed with the virtual exam, I recommend my high-risk patients undergo the actual colonoscopy only," he says. High risk is defined as patients with a family history

of colon cancer, prior history of polyps themselves, symptoms such as bleeding or change in bowel habits, adds Stamos.

The real value to virtual imaging of the colon might be for patients who have a cancer that blocks the surgeon's view of the colon beyond the cancer, says Stamos. "Virtual imaging of the colon can show me if there are other polyps or potential cancers that I will also need to remove," he says.

This helps the surgeon operate more effectively since he or she knows what is beyond the first cancer, he adds.

The noninvasive nature of virtual imaging is a definite advantage for patients, says Stamos.

"The current technology is still first generation, and improvements are constantly made, so I do see that virtual imaging might turn into an important screening tool," he says. "If the fear of colonoscopy is removed, more patients may undergo a screening, and we'll be able to detect and treat colon cancer more effectively."

Reference

1. Fenlon HM, Nunes DP, Schroy III PC, et al. A comparison of virtual and conventional colonoscopy for the detection of colorectal polyps. *N Engl J Med* 1999; 341:1,496-1,503. ■

You can build tomorrow's ORs today

Changing technology offers unique challenge

Emerging technology promises many new opportunities for same-day surgery staffs, but the challenge is building space to handle technology that we don't even know about today, contends **Judith H. Bernhardt** RN, CNOR, director of surgical services for Norton Hospital in Louisville, KY.

"We used to work with 10-year plans, but now we hope that our plan for next year is on target," she explains.

Bernhardt and her staff moved into a new

facility in November 2000 that has 14 operating rooms that handle inpatient and outpatient surgery.

Six of the rooms are equipped with docking stations for laparoscopic equipment, Bernhardt explains. While these six rooms are the primary location for laparoscopic procedures, the equipment is portable, so any operating room can handle a laparoscopic procedure, she adds.

"We also have computers in all of the rooms that enable the surgeons to view X-rays and lab work reports without having to search for paper reports or films," Bernhardt says. "In the future, the computers will tie into a system that can show the patient's full medical record if needed."

Using equipment for educational purposes

Four of the Norton rooms are equipped with video, audio, and transmission equipment so the procedures can be taped or broadcast live to hospital conference rooms or even distant sites. "We are a teaching facility, so this capability will increase our capability for education," she explains.

In addition to the high-tech equipment, each operating room has its own warmer cabinet that holds blankets and fluids, points out Bernhardt.

"This improves efficiency since a nurse doesn't have to leave the OR to find warm blankets for patients," she explains.

Another nice feature of the new facility is storage areas for each specialty, she says. "Someone looking for ENT equipment has only one place to go and doesn't have to look through other supplies or equipment to find what is needed," she explains.

The new facility was built contiguous to the old OR department, and now that it is open, the old OR area is being renovated into comfortable waiting areas, says Bernhardt.

While it is important to make sure the technical and clinical side of the OR is in top-notch shape, Bernhardt points out that anything that can be done to make the family and patient's experience more comfortable must not be forgotten.

"Make sure signage, waiting areas, parking lots, and food services are accessible and easily found," she suggests. ■