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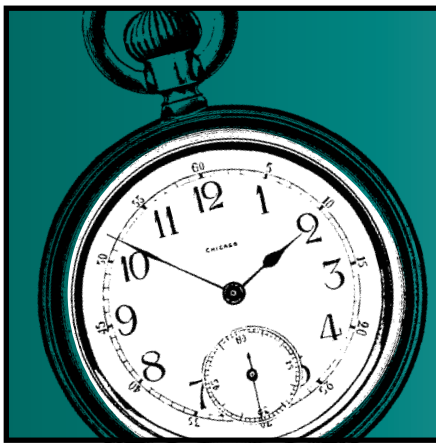

Same-Day Surgery®

Covering Hospitals, Surgery Centers, and Offices for More than 20 Years

INSIDE

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Get ready to be treated like a device manufacturer, if FDA has its way

Feds propose revisions to policy on reprocessing single-use items

Are you ready to be treated like a device manufacturer by the Food and Drug Administration (FDA)? Based on the FDA's proposed revisions to its policy on reprocessing of single-use devices, that's exactly how you might be treated.

"The FDA has made it quite clear in a number of presentations, that reprocessing is an activity they regulate," says **Douglas B. Nelson**, MD. Nelson is chairman of the Technology Committee and Task Force on Single-Use Accessories for the American Society for Gastrointestinal Endoscopy in Manchester, MA, and assistant professor of medicine at

HCFA to phase in APCs for surgery centers and give hospitals supplemental payments

In a tremendous victory for same-day surgery programs, Congress on Nov. 19 ordered the Health Care Financing Administration (HCFA) to phase in ambulatory patient classifications (APCs) over three years for ambulatory surgery centers (ASCs). Congress ordered that these new reimbursement rates, the foundation for an outpatient prospective payment system (PPS), be blended with current rates at a 1/3:2/3 ratio the first year, 2/3:1/3 ratio the second year, and full implementation the third year.

"The obvious advantage of this provision is that it requires HCFA to slowly phase in changes, so that ASCs don't experience abrupt and erratic reimbursement changes," says an advisory memorandum from Michael Romansky, JD, partner in the health law practice at McDermott, Will, and Emery in Washington, DC.

Congress' choice of words — If [HCFA] implements a revised prospective payment system . . . — indicates that Congress disapproves of the payment rule and prefers that HCFA not proceed, he said. "HCFA may

(Continued on page 10)

EXECUTIVE SUMMARY

On Nov. 1, the Food and Drug Administration (FDA) published proposed revisions to its policy on reprocessing single-use devices. The revisions would apply to surgery centers and hospitals that reprocess such devices.

- The FDA proposes a system that labels devices as low, moderate, or high risk.
- The FDA is considering pre-market application or pre-market notification requirements for moderate and high-risk devices that hold reprocessors to the same responsibilities as manufacturers.
- On Oct. 26, the Reprocessed Single Use Medical Device Patient Safety Act of 1999 was introduced in Congress and referred to the House Commerce Committee. The bill would require pre-market safety controls; informed consent of patients prior to using reprocessed class II, class III, and critical class I medical devices; and reports of any injuries or infections that occur as a result of using a reprocessed medical device.

the University of Minnesota in Minneapolis. "Whether in an ASC, or hospital, or third-party reprocessor, they consider that the same activity."

And you might be impacted by the final regulation even if you use a third-party processor, warns **Sherron Kurtz**, RN, MSA, CNOR, CNAA, director of perioperative services at Henry Medical Center in Stockbridge, GA. Kurtz was a presenter at the May 1999 conference on reprocessing sponsored by the FDA and the Arlington, VA-based Association for the Advancement of Medical Instrumentation. **(For more information on the conference, as well as tips to help you evaluate reprocessors, see *Same-Day Surgery*, July 1999, pp. 77, 79.)**

Third-party reprocessors might incur additional costs to comply with the final regulation, she says. "If it gets a lot more expensive for reprocessors, they will pass costs along to us. My thought is: Is this going to make it cost-prohibitive?"

The FDA published their proposed policy revisions Nov. 1 in the *Federal Register*. **(See list of devices, p. 3. For information on how to access a copy of the proposed revised policy and how to submit comments, see box, at right.)**

Here are FDA's biggest proposed changes:

• The FDA suggests using a three-tiered device categorization system (low risk, moderate risk, and high risk) that would consider factors such as the complexity of the reprocessing procedures, the risk of infection from reusing the device, any risk of performance failure, and the scientific information available on reprocessing the device.

• The FDA is considering pre-market application or pre-market notification requirements for moderate and high-risk devices that hold reprocessors to the same responsibilities as manufacturers.

And the enforcement doesn't end there. On Oct. 26, the Reprocessed Single Use Medical Device Patient Safety Act of 1999 (HR 3148) was introduced in Congress and referred to the House Commerce Committee. In addition to pre-market safety controls, the legislation would require informed consent of patients prior to using reprocessed class II, class III, and critical class I medical devices. Also, the bill would require providers to report any injuries or infections that occur as a result of using a reprocessed medical device.

Which same-day surgery devices will be labeled as low risk, and which will be labeled moderate or high risk?

"That seems to be an open question at the moment," says **Pamela J. Furman**, Esq., executive director of the Association of Medical Device Reprocessors in Washington, DC.

The FDA won't necessarily make a list, she emphasizes. Instead, the agency apparently intends to develop a decision flowchart that reprocessors, including facilities, can follow to determine a device's risk category.

Most devices will be labeled moderate risk, Nelson says. "It's clear in material from the FDA

Here's how to obtain proposal, submit comments

Copies of the proposed revised policy can be obtained on-line from the Center for Devices and Radiological Health (CDRH) home page at www.fda.gov/cdrh/reuse/singleuse.pdf. Or call CDRH Facts-on-Demand at (800) 899-0381 or (301) 827-0111. Specify document shelf number 2525 when prompted.

Written comments and suggestions regarding the proposed revisions to the policy should be submitted to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5603 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Comments and suggestions should be identified with the docket number (99N-4491). ■

that moderate risk is their default classification."

That classification could mean much more work for SDS managers that reprocess single-use devices, because the FDA is considering pre-market notification and approval requirements for moderate-risk and high-risk devices. These requirements would be implemented after six months for high-risk devices and after two years for moderate-risk devices.

What's the cost of risking lives?

In other developments, in October the FDA rejected a petition filed by group of device manufacturers to ban reprocessing. The FDA said it was "unable to find clear evidence of adverse patient outcomes." This is the second time in recent years that the FDA has taken this position, Nelson says.

However, not everyone agrees. In introducing the Reprocessed Single Use Medical Device Patient Safety Act of 1999 to Congress, Rep. Anna G. Eschoo (D-CA) said, "Delicate devices, such as balloon catheters and biopsy forceps, are being reused on patients and causing infection and injuries." In fact, a biopsy patient was contaminated with hepatitis B from reused biopsy forceps, she said, quoting an article in Sept. 20, 1999, *US News and World Report*.

"I understand the fiscal constraints hospitals are under," Eschoo said. "Managed health care has cut their payments so drastically that they feel pressured to cut costs wherever possible. However, we can't continue putting patients at

SOURCES

For further information on the proposed revisions to the policy, contact:

- **Pamela J. Furman**, Esq., Executive Director, Association of Medical Device Reprocessors, 1400 16th St. N.W., Suite 400, Washington, DC 20036. Telephone. (202) 518-6796. Fax: (202) 234-0399.
- **Sherron Kurtz**, RN, MSA, CNOR, CNAA, Director of Perioperative Services, Henry Medical Center, 1133 Eagle's Landing Parkway, Stockbridge, GA 30281. Telephone: (770) 389-2356. Fax: (770) 389-2158. E-mail: skurtz@hmc-ga.org.
- **Larry D. Spears**, Center for Devices and Radiological Health (HFZ-340), Food and Drug Administration, 2094 Gaither Road, Rockville, MD 20850. Telephone: (301) 594-4646.

Frequently Reprocessed Single-Use Devices — Draft

The Food and Drug Administration is soliciting comments on its proposed list of Frequently Reprocessed Single-Use Devices. **(For information on how to send comments, see box, p. 2.)** The devices, Code of Federal Regulations (CFR) regulation number, and classification are:

- ❒ Surgical Saw Blades: 21 CFR 878.4820, Class I Exempt
- ❒ Saw Blades: 21 CFR 878.4800, Class I Exempt
- ❒ Surgical Cutting Accessories: 21 CFR 878.4800, Class I Exempt
- ❒ Surgical Drills: 21 CFR 878.4820, Class I Exempt
- ❒ Surgical Mesh: 21 CFR 878.3300, Class II
- ❒ Drill Bits: 21 CFR 878.4540, Class I Exempt
- ❒ Laparoscopy Scissors: 21 CFR 876.1500, Class I Exempt
- ❒ Endoscopic Carpal Tunnel Blades: 21 CFR 888.4540, Class I Exempt
- ❒ Orthodontic (metal) Braces: 21 CFR 872.4510, Class I Exempt
- ❒ Orthodontic (plastic) Braces: 21 CFR 872.5470, Class II
- ❒ Electrophysiology Catheters: 21 CFR 870.1220, Class II
- ❒ Electrosurgical Electrodes and Pencils: 21 CFR 878.4400, Class II
- ❒ Cardiac Catheters and Guidewires: Class II and III, 510(k) and PMA; unclassified
- ❒ Respiratory Therapy and Anesthesia Breathing Circuits: 21 CFR 868.5240, Class I Exempt
- ❒ Biopsy Needles: 21 CFR 878.4800, Class I Exempt; 21 CFR 876.1075, Class II
- ❒ Endotracheal Tubes: 21 CFR 868.5730, Class II
- ❒ Syringes: 21 CFR 880.5860, Class II
- ❒ Sutures: Class II and III, 510(k) and PMA, unclassified
- ❒ Staplers: 21 CFR 878.4800, Class I Exempt
- ❒ Balloon Angioplasty (PTCA) Catheters: Class II, PMA
- ❒ Biopsy Forceps: 21 CFR 876.1075, Class I Exempt, 21 CFR 874.4680, Class II
- ❒ Trocars: 21 CFR 874.4420, Class I Exempt, 21 CFR 870.1390, Class II

Source: Food and Drug Administration, Rockville, MD.

risk in order to save a few dollars."

In the meantime, the FDA is moving ahead by obtaining input on its proposed revisions. Furman and other sources urge same-day surgery managers to offer comments soon. The timetable for implementation is uncertain, but the FDA appears to be pursuing revisions in an aggressive manner, Furman says.

Kurtz hopes final guidelines will be decided quickly. "As a manager who's doing it, I'd like for us to put it to bed and reach a consensus," she says. "It seems that there's a place we can meet, a place in the middle of the road, where we can all find a place to live together."

(For more on reprocessing single-use devices, see SDS*, March 1998, p. 33, for information on the ethical dilemmas; September 1997, p. 118, for advice from the Association of periOperative Registered Nurses; and June 1997, p. 69, for information on liability, safety, and ethical issues.)* ■

Ensure success, follow tips to measure your costs

Managed care contracts and shrinking budgets have forced same-day surgery program managers to be more aware of costs, say experts interviewed by *Same-Day Surgery*.

"Surgery program managers who have a method to gather cost information can produce performance and trend analyses, cost management reports, physician profiles, and documentation for managed care contract negotiations," says **R. Craig Lind**, managing director of Lind/Fitzsimons, a San Francisco-based management consulting firm.

If you don't already have a method of gathering cost information, start simple, says Lind. "Focus on three easily identifiable areas at the beginning," he says. **(See story on collecting costs, p. 6.)** "Keeping your efforts limited to staff, supplies, and a general category titled 'all other costs' will enable you to focus on information that is easy to obtain and affect." There are a number of resources to help you collect this information, he says. **(See box on cost information software vendors, p. 5.)**

The primary goal of gathering information should be to get your costs identified to the CPT or the case level, suggests Lind. By looking at your costs on a CPT level, you can see trends more clearly and identify potential problems, he adds.

Looking at costs on a procedure-specific basis enabled the staff at Landmark Medical Center's same-day surgery program to save more than $100,000 annually by streamlining orthopedic equipment and supplies, says **Sandra Bucci**, MSN, director of patient care services at the Woonsocket, RI, facility. Bucci's staff used reports that show all the costs on a per-procedure, per-physician basis. Costs for orthopedic procedures varied widely because physicians were requesting a wide range of equipment from several vendors.

Using the cost information, Bucci worked with physicians and materials management staff to identify which equipment was effective and acceptable to the physicians. They developed a streamlined list of equipment and supplies that would be kept on hand for orthopedic cases.

Use info to predict revenue

Bucci also uses her cost-management system to evaluate potential costs as she recruits physicians to her surgery program. "We gather costs on elective procedures that physicians want to perform so we will know how our costs compare to our potential reimbursement," she says. This information helps when she is discussing which types of procedures can be handled, especially when the procedure is new to the surgery program.

Adding one or two new procedures wasn't the issue for **Randy Tabor**, project manager at Central Georgia Medical Center in Macon, GA. The hospital is planning a freestanding ambulatory surgery center that will move most of the outpatient surgery procedures out of the hospital's surgery department. As part of the planning process for the center and for the certificate of need application, the staff looked at existing

EXECUTIVE SUMMARY

The only way a SDS program manager can effectively manage is to know the cost of running the program. There are a number of information systems and even some low-tech methods to collect cost information that can be used in the following ways:

- cost reduction;
- managed care contracting;
- physician recruitment;
- planning of new services.

Info System Vendors Offer Cost-Accounting Capabilities

The following is an abbreviated list of companies offering products that help day-surgery managers monitor costs within the surgery program:

1. **Health Information Systems,** Temple SurgiCenter Systems, 2 North Plains Industrial Road, Wallingford, CT 06492. Telephone: (800) 562-7069, ext. 503 or (203) 949-6290, ext. 503. Fax: (203) 949-6299. Web site: www.healthis.com. Health Information Systems offers AdvantX, a Windows-based product that offers integrated systems to handle registration, case costing, medical records, billing, accounts receivable, inventory, quality assurance, and preference cards. Prices vary according to facility and system needs, but a typical five-workstation system ranges from $23,000 to $26,000.
2. **Camberly Systems**, 175 Highland Ave., Fourth Floor, Needham, MA 02194-3034. Telephone: (800) 886-4325 or (781) 444-1424. Fax: (781) 444-2805. Web site: www.camberley.com. Camberly Systems offers SurgeOn, a Windows-based product that includes case costing, materials management, scheduling, registration, billing, accounts receivable, and staff accreditation. The basic system costs approximately $25,000.
3. **McKessonHBOC**, 210 Old Farm Road, Amherst, MA 01002. Telephone: (413) 259-2428. Fax: (413) 259-2600. E-mail: trish.crescitelli@hboc.com. McKessonHBOC produces Pathways Decision Support, a software package that provides financial and clinical management tools. Cost accounting, budget analysis, contract modeling, resource utilization, and risk assessment are included in the software package. Prices vary according to each facility's needs.
4. **Surgicenter Information Systems**, 71 Bradley Ave., Suite 11, Madison, CT 06443. Telephone: (800) 219-7642, ext. 1 or (925) 299-4800. Fax: (203) 318-0095. E-mail: jfreund1@sissystems.com. Web site: www.sissystems.com. Procedural Costing Analysis of surgical cases is integrated within the SurgiCenter Information Systems' surgery management system and is also offered as a stand-alone product. Labor, supplies, equipment depreciation, and overhead costs are taken into account to produce reports that break down costs by procedure.

information to determine potential costs and reimbursement level for procedures offered in the planned surgery center.

"We pulled the information based on ICD-9 and CPT codes to produce a list of outpatient surgical procedures," he explains. "Then we went to the financial services reports for these procedures to see what direct and indirect costs are allocated to each of them." Tabor took his analysis one step further to look at reimbursement for each procedure so he could generate an estimated cost and revenue projection for the planned surgery center.

In addition to using cost information to help plan a freestanding center, the staff at Central Georgia Medical Center also uses the information to negotiate managed care contracts, he says.

Info strengthens contract negotiations

Using specific, documented cost information is very helpful in contract negotiations, says **Craig Veach**, vice president of Health Information Systems, a Wallingford, CT, company that offers cost accounting and other management information systems for ambulatory surgery centers.

"Several of our clients report successful negotiations to change reimbursement levels because they were able to show a managed care company exact cost breakdowns for individual procedures," adds Veach.

Landmark Medical Center is one of the lowest cost hospitals in Rhode Island, and that status attracts managed care companies, says Bucci. But the state also has historically received the lowest reimbursement levels within the Medicare payment system, she adds.

Because of the low reimbursement levels, the staff at Landmark are taking proactive steps to evaluate potential reimbursement for different procedures. "We look at where the procedure is performed and whether or not reimbursement is affected," she says.

"For example, if a surgical case can be scheduled in either an operating room or a procedure room, what will the reimbursement level for each location be?" explains Bucci. If there is no difference in patient care but the reimbursement level is higher in a procedure room, the case is moved, she adds.

While collecting costs can be tedious and does require staff time to collect the data and produce reports, it is an essential part of monitoring the financial health of your day-surgery program, says Lind.

SOURCES

For more information about knowing your costs, contact:

- **R. Craig Lind**, Managing Director, Lind/Fitzsimons, 44 Montgomery St., Suite 500, San Francisco, CA 94104. Telephone: (415) 955-0550. Fax: (415) 673-4042. E-mail: craiglind@aol.com.
- **Sandra Bucci**, MSN, CNA, Director of Patient Care Services, Landmark Medical Center, 115 Cass Ave., Woonsocket, RI 02895. Telephone: (401) 769-4100. Fax: (401) 767-3189.
- **Randy Tabor**, Project Manager, Medical Center of Central Georgia, 777 Hemlock St., Macon, GA 31201. Telephone: (912) 633-1864. Fax: (912) 633-1702.

"Monitoring costs can't be a one-time project, it needs to be ongoing," he says. "A good cost management program is like a gas gauge in a car. It gives you a chance to take action before you run into trouble." ■

Collect cost information in three categories

Setting up a process to collect and analyze cost information may seem like a daunting task, but it can be done if you keep it simple at the start, says **R. Craig Lind**, managing director of Lind/Fitzsimons, a San Francisco-based management consulting firm.

The three areas suggested by Lind are staff costs, supply costs, and all other costs. Collecting this information and allocating the costs to certain procedures can be handled several ways, he says:

• **Staff costs.** "Collect the salary costs of the staff members who are involved in surgical procedures such as all operating room nurses or surgical techs," says Lind. Allocate their salary cost to individual procedures according to length of time in the operating room to obtain a basic idea of salary cost for each procedure, he suggests.

Do not include administrative staff such as patient admissions personnel or scheduling clerks in this category because their time is not really based on a procedure. Those staff spend the same amount of time admitting a patient or scheduling a time for surgery regardless of the complexity or simplicity of the procedure, he explains. The staff costs for personnel not directly involved in surgery should be included in the "all other costs" category.

• **Supplies.** "Most surgery programs have an inventory control program that can produce reports on the costs of supplies actually used in specific procedures," says Lind. If your same-day surgery program doesn't have this capability, you can use physician preference cards to produce a predicted inventory list. "Work with materials management to assign costs to your predicted inventory to compile a cost profile for supplies for specific procedures."

• **All other costs.** Costs within this category are mostly fixed costs that don't fluctuate according to numbers and types of surgical procedures, he says. Rent, depreciation, equipment costs, administrative staff salaries, utilities, and insurance are the most typical costs included in this category.

There are two ways to allocate these costs to arrive at a per procedure or CPT level cost. Because these costs are mostly fixed, you can allocate the cost equally to all procedures, regardless of the type of surgery, he says. The second way to allocate the cost would be based on the length of time of procedure. This would mean that a cataract procedure would include a smaller amount of "all other costs" than a lengthy orthopedic procedure, he explains. Either way of allocating costs to procedures will give you a good idea of your costs. ■

Build or renovate: How do you decide?

(In this first part of a two-part series on adding space to your SDS program, we offer advice on how to decide whether to build and discuss the role that case mix plays. In next month's issue, we'll tell you how to select an architect and construction costs to consider.)

You are adding new physicians to your medical staff. Your facility's new managed care contracts mean new day-surgery patients. Physicians are threatening to leave your facility because it is too hard to get operating room time.

Whatever the reason for your expansion, making the decision to add operating rooms by

EXECUTIVE SUMMARY

Expanding a day-surgery program's physical space, whether through renovation or new construction, is a major undertaking. With a little planning ahead and thinking about the needs of patients, physicians, and staff, you can end up with a facility that works for everyone. Before beginning your construction project, keep these points in mind:

- Hire an architect to survey the space you plan to renovate to find potentially costly items of which you may not be aware.
- Look at the design of the space from an accreditation perspective.
- Figure out what procedures or services you will offer in future years and make sure your space will accommodate them.

renovating existing space or by building from the ground up is not a simple decision to make. There are a number of factors to consider, says **Michael L. Gordon**, AIA, of Gordon and Associates Architects in Mount Dora, FL. The ability to meet federal building codes as well as local building codes is a key consideration when you are renovating existing space, he says. Meeting these codes may require expensive construction to renovate a building, he adds.

Renovation costs are hard to predict without a thorough study of the building, says **Steve Dickerson**, AIA, principal architect at Eckert Wordell in Kalamazoo, MI. For this reason, Dickerson recommends hiring an architect who is experienced in surgery center design to conduct a survey of the space you want to renovate.

"An architect can see if the hallways are wide enough to handle stretchers and wheelchairs or if the building's support columns are placed in such a way that they will impede traffic through the area," he explains.

Ceiling heights are important, too, he says. "Ceilings must be at least 9 feet tall, with a minimum of 2 feet of space above the ceiling to hold the mechanical and air filtration systems."

Several years ago, **Kay Kern**, RN, BSN, MSBA, administrator at the Michigan Surgical Center in East Lansing, oversaw a renovation project in a medical office building. "A set of fire stairs that ran through the center of the building was directly next to the area where the sterile hall of the operating suites would be located," she says. "It took several creative design ideas and an additional hallway within the surgical suite to come up with a design that enabled people to use the fire stairs without compromising our sterile area."

In 1998, her current employer gave her a chance to build a surgery center from the ground up. "We didn't even consider renovation because there was no space to renovate," Kern says. "The multispecialty group of physicians building this center already owned the land adjacent to the medical office building, so there was no issue of finding and purchasing land."

There are several advantages to consider with a new building, says Gordon. "You can make sure that all local and federal building codes for surgery centers are met with no problem." Aesthetically, a new building can easily be designed to meet the outpatient surgery patient's expectations for a quiet, confidential, and noninstitutional atmosphere, he adds.

The addition of a day-surgery center within a hospital is easy from the code requirements, but can be tricky when trying to present the environment you want, says Dickerson.

"People want to go to outpatient centers to avoid the institutional feel of a hospital." If they have to walk through hospital hallways to get to the center, you haven't created a good atmosphere, he explains. "If the center can be located in a part of the building that provides a separate entrance for the outpatient center, it will be more successful."

New buildings give you the opportunity to plan for future growth, says Dickerson. Adding a day-surgery center within an existing medical office building or a hospital means fitting into existing space, sometime eliminating the luxury

SOURCES

For more information about renovating or building ambulatory surgery space, contact:

- **Michael L. Gordon**, AIA, Gordon & Associates Architects, 730 East Fifth Ave., Mount Dora, FL 32757. Telephone: (352) 383-6505. Fax: (352) 383-6130. E-mail: Gordonarchitects@earthlink.net.
- **Steve Dickerson**, AIA, Principal Architect, Eckert Wordell, 161 E. Michigan St., Suite 200, Kalamazoo, MI 49007. Telephone: (616) 388-7313. Fax: (616) 388-7330.
- **Kay Kern**, RN, BSN, MSBA, Administrator, Michigan Surgical Center, 2075 Coolidge Road, East Lansing, MI 48823. Telephone: (517) 319-9000. Fax: (517) 319-0049. E-mail: klkern@aol.com.

of "empty space" for future growth, he explains.

Planning for future growth was one benefit the staff at Michigan Surgical Center enjoyed, says Kern. "Not only did we include two procedure rooms for future use, but we have storage space we don't even use yet," she says.

However, some states, including Illinois, don't allow empty space for future expansion.

A new building may be the dream of every day-surgery program manager and surgery center architect, but the reality is that renovation is a common solution, says Dickerson. "Fifty percent of my clients renovate and 50% build." Many times an urban facility is renovating, and rural facilities are building simply because the land is available. As long as your pre-planning process is effective, both approaches can work, he adds.
(See story on thinking ahead, below.)

Choosing an architect that has experience with surgery centers will also help you ensure a design that is functional and aesthetically pleasing, says Gordon. Make sure you involve people who work within the areas in the initial design phases. Gordon points out that major changes in the center's design should be made in the planning stages, not the construction phase, "It is much easier to erase pencil than it is to break up concrete." ■

Use current, future case mix to plan your center

The key to successful design of a same-day surgery space that won't require updates and additions in the near future is good planning and a crystal ball, say the experts interviewed by *Same-Day Surgery*.

"Know your case mix, and know what equipment and procedures you may be adding in the future," advises **Steve Dickerson**, AIA, principal architect at Eckert Wordell in Kalamazoo, MI.

"If you're planning space for an ophthalmologist, but you don't expect him or her to keep the room fully scheduled, consider what other specialties might use the center. Know what type of equipment or space they will need that is different from the ophthalmologist," he says.

Kay Kern, RN, BSN, MSBA, administrator at Michigan Surgical Center in East Lansing, made a number of changes in the way the administrative and medical records areas were designed to ensure confidentiality of patient records. "We knew we wanted to become accredited, so I had to make sure we could me the accreditation requirements for protection of those records."

Even with careful planning, Kern has one change she says she should have made during the design phase. "We handle most of our preadmits by telephone, but we occasionally have some last-minute patients scheduled or some patients we can't reach by telephone before the day of surgery," she says. "I now wish we had built two private spaces for these preadmission interviews. We have a small consulting room that we use when it's open, but many times we have to conduct the interview in a less-than-private area." ■

Same-Day Surgery Manager

Why hospitals try joint venture ASCs with doctors

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

"Why would the hospital want to joint venture their outpatient surgery business with their physicians?" I hear this question at least once or twice a week. I am accustomed to the question and therefore sensitized to it. But I hear it so often, I thought many *Same-Day Surgery* readers could also be confused.

Typically, when a hospital organization's leaders decide that they are interested in doing a surgery center, especially with physician groups, the hardest sell is often the board of the hospital. Most hospital board members understand the core business of their hospital and help guide and direct it through the changing regulatory course and obstacles. It is not an easy task for the board or the administration of the hospital to explain and justify the many issues they deal with on a monthly basis.

Try to explain to the board that you are going to share one of your more lucrative business lines, outpatient surgery, with a group of your

surgeons. Not only are you going to share the revenue, but you are going to duplicate most of the environment of the hospital's operating room to accomplish that goal! This is a hard pill to swallow for anyone charged with fiscal responsibility or cost containment.

I'm going to share some of our secret tactics we use when called in to explain to hospital boards the reasoning behind the "craziness" of joint ventures. First, few hospitals proactively spin off their outpatient surgery in a new business line. Many will build new departments and add upscale waiting areas with easy access and brightly colored pictures, but that is not going to achieve the result most are looking for — cost control. When you use the same standards, personnel, operating rooms, etc., you are duplicating or reshuffling existing business and not reducing cost. Usually, you are only increasing your cost to pay for the renovated space. Few hospitals see the opportunities involved in developing a freestanding surgery center with their physicians. Let's look at those opportunities:

• **It's better to have a piece of it than lose it all.** There is extremely aggressive activity with physicians developing their own surgery centers in the market place. They are looking for efficiencies that hospitals typically cannot offer them. Many hospitals are aware of this activity and decide to join the physicians rather than fight them. This allows the hospital to retain a significant portion of the revenue of this joint venture.

• **The biggest line item expense in surgery is supply cost and personnel.** It is difficult to achieve reduced supply cost unless the surgeon feels he or she is part of the team. Often when the surgical staff are tied to the bottom line of the operations, they are more cognizant of the cost of materials. This typically allows for standardization — active physician participation in controlling supply costs.

• **A properly developed surgery center is designed for efficiency in staffing.** Every time you put up a wall, you need someone working behind it. That costs money. More physical plant construction helps alleviate that ongoing expense. Incentives to staff to keep their numbers down by sharing the workload further reduces staffing levels.

• **The "learn the business" philology is a major attraction for hospitals.** Hospital leaders understand the efficiencies that most surgery centers have. They want to use their own joint ventured surgery center as a beta site for their inpatient surgery. They want to apply the cost-control measures from the surgery center to the hospital setting. The physician partners are usually more than eager to help in that process.

• **Hospitals need to have a lower-cost provider.** With the upcoming ambulatory patient classifications (APCs) and their reimbursement hit, hospitals need a lower cost provider of surgical services to handle their outpatient surgery. Without significant cost control, hospitals will continue to lose money on outpatient surgery procedures being performed in the hospital operating rooms.

• **Joint venturing with surgeons removes the threat of them doing something on their own.** The ability to joint venture together often results in noncompeting agreements between the hospital and the new venture partner. These agreements allow both parties to sleep better at night because they're not waiting for the other shoe to drop to see who else is going to be a threat to the surgical volume of the organization.

Thus, there are some of the reasons hospitals want — maybe "want" is not the right word, perhaps "agree" is better — a separate surgery center. Regulatory issues always cloud the issue, but being receptive to the changing marketplace in outpatient surgery is just good business.

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Health advisory targets reprocessing endoscopes

As a follow-up to a report from the Centers for Disease Control and Prevention (CDC) that found transmission of infections by bronchoscopes inadequately reprocessed by automated endoscope reprocessors (AERs), the Food and Drug Administration (FDA) and the CDC have issued a public health advisory on reprocessing of endoscopes. **(For more information on the initial CDC report, see *Same-Day Surgery*, September 1999, p. 104.)**

Some health care providers are using AERs to reprocess endoscopes that should not be processed in AERs, the advisory reports. "This practice may have resulted in damaged endoscopes and also raises questions about whether such processing results in an endoscope that is properly

HCFA to phase in APCs

Continued from page 1

choose to forgo implementation of the payment update rather than wrestle with a complicated and time-consuming phase-in mechanism."

And there's more good news, according to McDermott, Will, and Emery's publication, *Health Law Update* (1999; 16:1-2). Hospital-based same-day surgery programs will receive supplemental payments, in addition to APC payments, during the first three years of an outpatient PPS, if the PPS payments are less than the payments that would have been made prior to PPS (i.e., calendar year 1996). These three years of supplemental payments for hospitals are being referred to as the "transitional corridor."

Cancer hospitals will be held harmless under the outpatient PPS indefinitely, which means the reimbursement for cancer hospitals under the PPS will not be less than they received prior to the Balanced Budget Act, which would be calendar year 1996. Rural hospitals with fewer than 100 beds will be held harmless through calendar year 2003.

Congress has ordered the Medicare Payment Advisory Commission (MedPAC), which advises Congress on Medicare payment issues, to study the appropriateness of an outpatient PPS for Medicare-dependent hospitals, sole community hospitals, rural referral centers, rural health clinics, and other types of rural hospitals. "This study reflects Congress' concern with the ability of these entities to remain viable under an outpatient PPS and signals possible future Congressional action in this area," according to *Health Law Update*.

Congress has ordered HCFA to make additional payments for new drugs, devices, and biologicals — those not paid for on an outpatient basis before 1997. Congress also has limited beneficiary copayment liability for outpatient procedures to the amount of the inpatient deductible that year ($776 in fiscal year 2000). Medicare will offer supplemental payments to hospitals to compensate for the difference between the copayment and this limit.

Many of the changes made to reimbursement for hospital outpatient services are budget-neutral, "which means one hospital's gain may be another's loss," the article stated.

If HCFA does proceed with the phased-in period for surgery center reimbursement, implementation will be delayed beyond the previous estimate of July 2000, Romansky predicted. "Assuming HCFA maintains the link between the [ambulatory surgery center] and hospital outpatient payment systems, it may be 2001 before HCFA can possibly implement these regulations."

In other news, the Medicare bill also requires MedPAC to study the cost-effectiveness and efficacy of extending Medicare reimbursement to post-surgical recovery care centers. ■

prepared for patient contact," the report states.

The advisory recommends that health care facilities do the following:

• **Ensure all staff who handle soiled endoscopes comply with the manufacturer's instructions for cleaning the device.** Staff should flush all endoscopes immediately following the procedure, meticulously remove any debris or residuals collected in or on the endoscope, perform leak tests, and visually inspect the endoscope to ensure that it is in proper working order, in accordance with the endoscope manufacturer's recommendations, the advisory says. "These steps are critical regardless of whether your facility manually reprocesses endoscopes or uses an AER."

• **Check with your devices' manufacturers to determine whether your endoscopes can be reprocessed in an AER.** Also, check with the manufacturer to determine whether your endoscopes require that specific steps be taken before being reprocessed in an AER. Not all endoscopes can be reliably reprocessed in an AER, the advisory points out. "For example, the elevator-wire-channel of most duodenoscopes cannot be accessed by the AER and requires manual reprocessing. If not specifically indicated in the AER labeling, it is advisable to ask the AER manufacturer if the endoscope you are using has been tested with their system."

• **Compare the reprocessing instructions provided by the endoscope and AER manufacturers and resolve any conflicting recommendations.** "We encourage you to work with the AER manufacturers' technical staff to clarify conflicting

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information," the advisory says.

• In the absence of specific technical instructions on automated reprocessing for each model of endoscope used in your facility, be sure to follow the endoscope manufacturer's manual reprocessing instructions, as well as the recommendations of the manufacturer of the chemical germicides used at your facility.

• Regardless of whether you manually reprocess your endoscope or use an AER, consider incorporating a final drying step in your reprocessing protocol.

• Check to be sure that your facility's instructions for preparing endoscopes for patient contact are appropriate and your staff are adhering to these instructions.

• Provide comprehensive and intensive training for all staff assigned to reprocessing endoscopes to ensure that they understand the importance of proper reprocessing of all endoscopes used in your facility.

• Implement a comprehensive quality control program. ■

Fraud alert addresses outpatient surgery billing

The Health Care Financing Administration (HCFA) has issued a fraud alert (No. 99-09) stating acute care hospitals are billing outpatient surgery services as one-day inpatient stays.

According to the fraud alert, claims are being submitted using the inpatient type of bill (TOB) 11X with the "from date" equaling the "through date." Hospitals are using a patient status code of 01 (discharged from home or self-care / routine discharge). Ambulatory surgery claims should be billed using TOB 83X or 13X, according to HCFA.

"By billing Medicare for these services as inpatient, the hospital can increase their reimbursement by 83%, since payment is based on the diagnosis related group (DRG), rather than the applicable ambulatory surgical center (ASC)

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All of the Food and Drug Administration's (FDA's) medical device postmarket safety notifications can be found on the Web at www.fda.gov/cdrh/safety.html. Postmarket safety notifications can also be obtained through e-mail on the day they are released by subscribing to the FDA list server. To subscribe, send a message to fdalists@archie. fda.gov. In the body of the text, type subscribe dev-alert.

fee schedule (83X TOB) or the cost of charge percentage (13X TOB)," the fraud alert says. "In addition, the beneficiary would be responsible for the current inpatient deductible, as opposed to the outpatient deductible and/or coinsurance amount." ■

Special offer for alternative nursing newsletter

American Health Consultants, publisher of *Same-Day Surgery* and *Alternative Medicine Alert*, is pleased to announce the publication of a monthly newsletter for nurses on alternative medicine and holistic nursing.

Beginning January 2000, each issue will contain review articles of specific alternative therapies and modalities; abstract and commentary from current medical and nursing journal articles; and columns on controversies in holistic nursing, applying therapies to clinical nursing practice, and legal and ethical issues surrounding holistic nursing and alternative medicine. Subscribers will be eligible to receive approximately 12 contact hours of nursing continuing education credits at no extra charge.

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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, "Build or renovate: How do you decide?")**
- Describe how those issues affect nursing service delivery or management of a facility.
- Cite practical solutions to problems or integrate information into their daily practices, according to advice from nationally recognized ambulatory surgery experts. **(See, "Ensure success, follow tips to measure your costs.")** ■