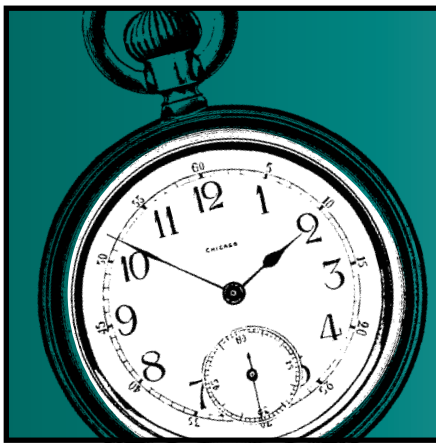
AMERICAN HEALTH CONSULTANTS®



Same-Day Surgery®

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

INSIDE

FEBRUARY 2000

VOL. 24, NO. 2 (pages 13-24)

American Health Consultants® is A Medical Economics Company

Controversy erupts over whether to disinfect or sterilize endoscopes

New estimate: 2.7% of procedures with disinfected scopes cause infections

As if same-day surgery managers didn't have enough to worry about: A newly published article estimates that 2.7% of the approximately 10 million procedures done each year in the United States with nonsterilized endoscopes cause infections.[1]

Actually, the 2.7% figure is "probably quite conservative," according to the author, **David L. Lewis**, PhD, research microbiologist at the Environmental Protection Agency's (EPA) National Exposure Research Laboratory in Athens, GA. Lewis is on assignment to the University of Georgia in Athens to study infection control with dental and medical devices. His views don't represent official views of the EPA.

The Food and Drug Administration and the Centers for Disease Control and Prevention (CDC) recently issued a public health advisory on reprocessing endoscopes. The advisory followed a CDC report that found infections were transmitted by bronchoscopes inadequately reprocessed in automated endoscope reprocessors. **(For more on the**

EXECUTIVE SUMMARY

A research microbiologist at the Environmental Protection Agency has published an article that estimates 2.7% of the approximately 10 million procedures performed annually in the United States with nonsterilized endoscopes cause infections.

- That author recommends facilities use peracetic acid sterilization or sheath technology. If facilities decide to disinfect, he recommends a soak time of 45 minutes.
- Most national groups, as well as the Centers for Disease Control and Prevention, say that meticulous manual cleaning followed by a 20-minute soak in 2% glutaraldehyde is sufficient.

advisory, see *Same-Day Surgery*, January 2000, p. 9. For more on the initial CDC report, see *SDS*, September 1999, p. 104.)

Most national groups, as well as the CDC, recognize high level disinfection as the standard for endoscopes. However, Lewis calls on health care providers to use a peracetic acid sterilization process or sheath technology. Only one manufacturer provides the sheath technology: Vision-Sciences in Natick, MA. **(To contact manufacturer, see source box, p. 15.)** Olympus Optical Co. in Tokyo has patented the technology, but a product is not yet on the market.

Although there always is a cost involved in purchasing new technology, these costs are offset by freedom from federal standards that require ventilation systems, personal protection equipment, and monitoring of glutaraldehyde vapors, Lewis said in his article.

When it comes to the groups that say disinfection with glutaraldehyde is sufficient, Lewis' opinions and words are strong. "Current infection control standards are based on willful ignorance, not sound science," he said in his article. "Upgrading infection control standards for endoscopy, therefore, is not so much about resolving differences in scientific opinions. Instead, it is simply about getting people who oversee the issue to put the welfare of patients above their own professional interests."

And Lewis' stance of bucking the system doesn't stop there. For providers who disinfect, "My advice is that physicians should inform their patients that there is a small, but real, risk of infection from nonsterilized endoscopes, and let patient make the decision on whether they're comfortable with disinfection vs. sterilization."

That advice leaves providers with the difficult decisions of whether to sterilize and whether to inform patients if they don't. And they face another dilemma: Conflicting recommendations on soak times for endoscopes from national groups and manufacturers.

"I've certainly not seen such a level of confusion over what to do in any other area of medical practice, regarding infection control," Lewis says.

Why sterilize? Disinfectants are not effective unless a device is completely clean, Lewis emphasizes. "Plain and simple: Any difficult to clean medical device is going to have blood and other patient material that will escape any type of manual cleaning."

Newly published research indicates that endoscopes retain patient materials, even after following cleaning instructions from manufacturers and medical associations, he said in his article.[2] And manufacturers have known for some time that endoscopes cannot be completely cleaned, he claimed in his article, citing an Olympus Optical Co. patent.[3]

"Therefore, I recommend that these devices be submitted to sterilization process, which is more rigorous than disinfection," he says. Lewis recommends using an automated peracetic acid sterilization system. Currently, only one system is on the market: Steris System 1 Process from Steris Corp. in Mentor, OH. The price is $16,200. **(For contact information, see source box, p. 15.)**

Others disagree with the recommendation for sterilization.

"There are no data independent of corporate influence that documents a validated method for cleaning and sterilizing the instrument," says **Lynne Sehulster**, PhD, M(ASCP), microbiologist at the CDC.

Reports have been published in popular press and medical periodicals that are geared toward medical professionals, but aren't peer-reviewed scientific literature, Sehulster says. "Some of these articles call for sterilization of instruments. The thing is, there are no data to support that these instruments can be sterilized."

The worldwide standard for cleaning endoscopes is high-level disinfection, she says.

Is a 10-minute soak acceptable?

Citing research, Lewis claims that most health care providers soak endoscopes in glutaraldehyde for only 10 minutes.[4,5] This short soak time is particularly common in outpatient surgery, where facilities are often in a time crunch, he

COMING IN FUTURE MONTHS

- Colon surgery: Is it better with a scope?
- Ensuring the patient makes an informed decision
- Problems with Viagra and getting patients to admit use
- Use this pathway to reduce LOS and supply costs
- New competency assessment tool proves effective

says. **(For information on a new product that provides high level disinfection in 12 minutes, see resource box, at right.)**

According to Lewis' article, it takes 34.8 minutes for heat and germicides to penetrate slightly viscous bodily fluid when 2% glutaraldehyde is used.

"If a health care facility makes a decision to use high level disinfection rather than sterilization procedure, then I strongly recommend they follow manufacturers guidelines for those high level disinfectants," Lewis says. "It seems like it's not even worth saying, but the fact is, look at the label on 2% glutaraldehyde. It says, 'Soak for 45 minutes to achieve highest level of disinfection,' yet few medical facilities are following those guidelines."

While it's true that some facilities perform a 10-minute soak, these same facilities tend to have outstanding quality assurance on their cleaning and reprocessing, Sehulster says. "They keep adequate documentation of all parameters that need to be measured: concentration of glutaraldehyde, the procedures used for cleaning. Their documentation is really without peer. With all this documentation, plus staff are dedicated to cleaning and reprocessing, the ones I know that do 10 minutes are almost a model that other clinics should aspire to."

However, the only way a facility can adequately disinfect in 10 minutes is "if you clean endoscopes within an inch of their lives," Sehulster emphasizes.

Research indicates that staff who paid the greatest attention to proper cleaning had fewer reports of contaminated instruments after cleaning and reprocessing compared to facilities that had lapses in this process, she says.[6]

"From my review of literature, I haven't found one which found a problem with a thoroughly cleaned and disinfected scope," Sehulster says. "There was always some break in protocol."

Meticulous manual cleaning followed by high level disinfection with 20-minute exposure to 2% glutaraldehyde is supported by the Association of periOperative Registered Nurses in Denver; the American Society for Gastrointestinal Endoscopy in Manchester, MA; the American Gastroenterological Association in Bethesda, MD; the American College of Gastroenterology in Arlington, VA; and the Association for Professionals in Infection Control and Epidemiology in Washington, DC; as well as the Society for Gastroenterology Nurses and Associates (SGNA) in Chicago, according to SGNA's "Guideline for the Use of High Level Disinfectants and Sterilants for Reprocessing of Flexible Gastrointestinal Endoscopes." **(For information on how to order a copy of the SGNA guideline, see resource box, above. For information on proper use of flash**

SOURCES & RESOURCES

For more information on disinfection and sterilization of endoscopes, contact:

- **David L. Lewis**, PhD, Research Microbiologist, National Exposure Research Laboratory, Environmental Protection Agency, Athens, GA. E-mail: lewisdavel@aol.com. Web site: members.aol.com/lewisdavel.
- **Lynne Sehulster**, PhD, M(ASCP), Microbiologist, Centers for Disease Control and Prevention, NCID Hospital Infection Program, Mail Stop C16, Atlanta, GA 30333. Telephone: (404) 639-2314. Fax: (404) 639-3241. E-mail: los0@cdc.gov.

For more information on the Steris System 1 Process, contact:

- **Steris Corp.**, Customer Service, 9260 Progress Parkway, Mentor, OH 44060-1834. Telephone: (800) 548-4873 or (440) 354-2600. Fax: (440) 639-4450. Web site: www.steris.com.

For more information on sheath technology, contact:

- **Vision-Sciences**, 9 Strathmore Road, Natick, MA 01760. Telephone: (800) 874-9975 or (508) 650-9971. Fax: (508) 650-9976. E-mail: info @visionsciences.com.

"Guideline for the Use of High Level Disinfectants and Sterilants for Reprocessing of Flexible Gastrointestinal Endoscopes" is available for $5 for members of the Society of Gastroenterology Nurses and Associates and $10 for nonmembers. Shipping and handling is $4.95. Contact:

- **Society of Gastroenterology Nurses and Associates**, Department of Membership Services, 401 N. Michigan Ave., Chicago, IL 60611-4267. Telephone: (800) 245-SGNA or in Illinois (312) 321-5165. E-mail: SGNA@sba.com. Web site: www.SGNA.org.

Advanced Sterilization Products, part of Johnson & Johnson, has launched a new product, Cidex OPA, a glutaraldehyde-free product that provides high level disinfection in 12 minutes. For more information, contact:

- **Advanced Sterilization Products**, 33 Technology Drive, Irvine, CA 92618. Telephone: (877) 672-6699. Fax: (949) 453-6353.

sterilization, see *SDS*, September 1999, p. 101. For information on problems with cleaning bronchoscopes, see *SDS*, September 1999, p. 104.)

The 20-minute recommendation is different from the 45-minute exposure recommended on the glutaraldehyde label because the current label assumes a "worst-case scenario" when there's been no cleaning of the endoscope before chemical exposure, according to Sehulster.

A study at the University of North Carolina compared a 45-minute soak time with thoroughly cleaned items undergoing a 20-minute soak time. "Through this independent observation, they determined the most critical part of the operation was the cleaning," Sehulster says. "If you thoroughly clean the instrument or surface, in essence you are reducing the organic contamination on the surface. That in turn sets up a better opportunity for the chemical germicide to do its job."

Managers often are reluctant to soak instruments for 45 minutes because the chemicals are strong and might reduce the use time of the instruments, she says. Thorough cleaning with 20-minute exposure to high level disinfectant is the middle ground, Sehulster says. "For all practical purposes, and according to world wide standards, it is considered appropriate for making the instrument ready for the next patient."

References

1. Lewis DL. A sterilization standard for endoscopes and other difficult to clean medical devices. *Practical Gastroenterology* 1999; 23:28-56.
2. Alfa MJ, Degagne P, and Olson N. Worst-case soiling levels for patient-used flexible endoscopes before and after cleaning. *Am J Infect Control* 1999; 27:392-401.
3. Olympus Optical Co., Ltd. Tokyo, Japan. 1995. U.S. Patents 5,408,991; 5,419,311; 5,431,150; 5,458,132; 5,458,133.
4. Gorse G J, Messner RL. Infection control practices in gastrointestinal endoscopy in the United States: A national survey. *Infect Control Hosp Epidemiol* 1991; 12:289-296.
5. Foss D, Monagan D. *A National Survey of Physicians' and Nurses' Attitudes Toward Endoscope Cleaning and the Potential for Cross-infection.* Chicago: Society of Gastroenterology Nurses and Associates; 1992.
6. Deva AK, Vickery K, Zou J, et al. Detection of persistent vegetative bacteria and amplified viral nucleic acid from in-use testing of gastrointestinal endoscopes. *J Hosp Infect* 1998; 39:149-157. ■

Managing Generation X in same-day surgery

They are surprising, frustrating, and our future

WANTED: Perioperative nurse for same-day surgery program. Must be willing to say no to working overtime or assuming additional responsibilities. Must express frustration with coworkers who are less technologically knowledgeable and should be prepared to question all policies, protocols, and requests from manager. Loyalty to employer and long-term commitment not required.

Recognize some members of your staff in that advertisement? Then you might be managing Generation Xers, a group of people born between 1964 and 1980, many of whom fit the above description, according to same-day surgery managers. **(See related story, p. 17. For information on what younger employees want as benefits, see salary survey report, enclosed in this issue.)**

For all of the negative descriptions of Generation X, the group brings a fresh look at the workplace and a creativity that will benefit all staff members, says **Jo Manion,** MA, RN, CNAA, FAAN. Manion is senior consultant at Manion and Associates, an Oviedo, FL-based firm that specializes in helping health care organizations handle issues such as organizational structure, leadership, and change in the workplace. The key to tapping into the positives of these young people is to understand the generation, she adds.

EXECUTIVE SUMMARY

While most same-day surgery managers are members of the baby boom generation, increasingly more staff are members of Generation X, the group born between 1964 and 1980. In addition to being members of the smallest entry-level work force since the 1930s, this group of people grew up with different values, philosophies, and perspectives than the baby boomers. The keys to developing Xers into good staff members with the potential to take on leadership positions include:

- Get to know the characteristics of Generation Xers so you will understand their motivations.
- Recognize their desire to solve problems and make decisions.
- Be their resource for job-related questions as well as overall career planning.
- Respect their personal time.

Generation X: Who are they?

As baby boomers age, same-day surgery managers find themselves supervising and trying to motivate a group of people that seem to have completely different approach to life, work, and management.

This group born between 1964 and 1980 were first called "Generation X" in a 1991 novel, *Generation X: Tales for an Accelerated Culture*, by Douglas Coupland. Although Coupland's book is fiction, the characteristics of the generation he describes are different in many ways from baby boomers, says **Jo Manion,** MA, RN, CNAA, FAAN, senior consultant at Manion and Associates in Oviedo, FL.

"A big misconception about this age group is that they have it easy because their parents have given them everything," says Manion.

The reality is that 43% of Generation Xers are being paid minimum wage, she says. "Even those who are earning more, such as surgery program nurses, are spending as much as 40% of their income on their mortgages, compared to the 14% of income spent on mortgages by their parents."

The good news for Generation X is that it is easier for them to find jobs. Between 1946 and 1964, birth rates peaked at 25.3 births per 1,000 population, creating the age grouping known as baby boomers. This period was followed by a 16-year period during which the birth rate fell to 14.6 births per 1,000 population, creating a total of 44 million X-ers compared to 77 million boomers. This has created the smallest pool of entry-level workers since the 1930s.[1]

Because there are more jobs than people, Generation Xers can be choosy about where they work, says Manion. "One of the biggest complaints managers express to me about managing Generation Xers is their lack of loyalty," says Manion.

This lack of loyalty grew out of the Xers seeing members of their parents generation undergo the trauma of downsizing, re-engineering, and company closings, she explains. "An Xer is not going to look at any job as a lifelong commitment because he or she knows that the employer cannot make a long-term commitment to them."

What you can do is offer Xers a work environment that recognizes their technological knowledge, their independence, and their need for recognition, says Manion. And don't expect problems, she adds. "Managers must be careful not to create a self-fulfilling prophecy that Generation X staff members will be a problem to manage."

Manion suggests that managers learn as much as they can about this group. She suggests a book: *Beyond Generation X: A Practical Guide for Managers* by Claire Raines (Crisp Publications, Menlo Park, CA), as a source of information about how Xers think and what they expect from a job and a manager.

"Once a manager understands the generation's characteristics and why they act the way they do, the manager can create a work environment that is not only positive for Generation Xers, but for baby boomers as well," she says.

Reference

1. Loysk B. Generation X: What they think and what they plan to do. *The Futurist* 1997; 31:39-44. ■

Many members of this generation were latchkey children who had to become self-sufficient early in their lives, she explains. "Children who had to come home from school to an empty house, do their homework, and even start dinner have grown into adults who are accustomed to making their own decisions and finding better ways to accomplish a task," she says.

Because the group also witnessed their parents working 40 to 60 hour workweeks, only to be given a gold watch or a severance notice due to downsizing, Generation Xers are less likely to look at a job as a long-term commitment, says Manion. Managers who want to keep Xers within their program need to know the characteristics of the group and their expectations from a job, she adds. Key expectations of Generation Xers include:

❒ **Compensation for worth.** Generation Xers place value on their time, so asking an Xer to work overtime or spend time outside their normal job responsibilities on a special project means paying them for that time, says Manion. "Xers watched their parents spend much more time at work than at home with their families so they place a high priority on personal time and family time," she says. "They are not unwilling to take on extra responsibilities, they just expect to be paid appropriately."

You must respect Xers' personal time, advises **Diane Mamounis-Simmons**, RN, MSN, CNOR, CNAA, administrator for nursing in surgical services at Northshore Long Island Jewish Medical Center in Long Island, NY. "We create rosters of who is available for overtime, and my supervisors try to give staff members as much advance notice as possible."

❒ **Involvement in decision making**. Xers are accustomed to making decisions and solving

SOURCES

For more information about managing Generation Xers, contact:

- **Laura Weinhagen**, RN, Clinical Director, El Camino Surgery Center, 2480 Grant Road, Mountain View, CA 99040. Telephone: (650) 961-1200. Fax: (650) 960-7041. E-mail: lweinhagen@ecsc.com.
- **Diane Mamounis-Simmons**, RN, CNAA, MSN, CNOR, Administrator for Nursing Services, Northshore Long Island Jewish Health System, Long Island Jewish Medical Center, Lakeville Road, New Hyde Park, NY 11040. Telephone: (718) 470-7404. Fax: (718) 962-6945. E-mail: Mamounis-Simmons@lij.edu.
- **Jo Manion**, RN, MA, CNAA, FAAN, Senior Consultant, Manion and Associates, 5725 Oak Lake Trail, Oviedo, FL 32765. Telephone: (407) 366-6506. Fax: (407) 366-6521. E-mail: jomanion@sprintmail.com.

problems. They are also likely to question managers about procedures and protocols, says Manion.

"I find that Xers are surprisingly self-motivated and willing to tackle problems," says **Laura Weinhagen**, RN, clinical director of El Camino Surgery Center in Mountain View, CA. A manager has to set goals and be available as a resource, but Xers don't want to be micro-managed, she adds.

"I find that Xers can be overwhelmed if the problem is too large, so I break it down into smaller problems to solve as we work our way to the larger problem," adds Mamounis-Simmons.

❒ **Professional development.** Although Generation Xers might not take a position with a same-day surgery program with the intention of staying 10 years, they are serious about developing their skills and their careers, says Manion. "These staff members understand that jobs can be eliminated with little notice, so they want to position themselves to find the next job. If a manager does a good job offering continuing education opportunities, responsibilities that enhance the job, and recognition that the Xer is an important part of the team, the staff member is less likely to leave."

One way to give Xers a chance to gain recognition and expand their job skills is involvement in special committees or task forces. Mamounis-Simmons says, "Not only does involvement on teams give the Xer a chance to demonstrate expertise but it also gives them a chance to gain recognition."

Remember, too, that Xers are extremely comfortable with technology, adds Manion. "Xers are very sophisticated in their knowledge." They can be a valuable resource as technology experts within the surgery program, she says.

❒ **Personal attention.** Another characteristic of Generation X is the need for personal attention. Mentoring is an important way for managers to help Xers develop and grow as key staff members, says Manion.

"Whenever I spend time with an Xer, he or she blossoms," says Mamounis-Simmons. The time can be spent talking about career plans, specific projects within the surgery program, or recognition of the job the Xer is doing.

"One of my two key supervisors is an Xer, and she brings a lot of enthusiasm and creativity to my management team," says Weinhagen. "I believe that Xers can be terrific in leadership positions because they do look for better ways to do things." ■

Same-Day Surgery Manager

ASC management: 9 lessons I've learned

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

There was a time when management of a surgical department was a full-time job. There were always problems with maintaining inventory, making sure staff picked everything on the preference cards for each case, and ensuring the physician lounge was stocked with food. Staffing was typically a challenge, and dealing with budgets and capital equipment requests could drive you nuts.

Although most of us didn't realize it at the time, life was pretty good and uncomplicated. Today, I work with many people involved in the day-to-day management of busy surgical departments and surgery centers, and I nod knowingly. Most of these people could have done my job in

the past before their first coffee break! Surgical management is complex, sophisticated, challenging, and just downright backbreaking. And that is on a good day.

If you can master the basics, the rest will fall into place. Here are many of the basics:

1. **Delegation is key to success.** "No man [or woman] is an island." If you cannot delegate and relinquish some control, you will fail. The product is just too large to handle alone.

2. **Only hire people smarter than you.** I do this ALL the time. It is remarkably easy! You should learn something from the people you hire, or you are wasting a valuable opportunity. Hiring someone with your skills and knowledge base is counterproductive. You want to learn from each person you hire. When you interview people, ask yourself if they can bring new knowledge to your department.

3. **There are only three important line items on your budget.** They are net revenue, personnel cost, and supply cost. Do not be concerned with profits. If you can appropriately manage these three, the profits will be there. Delegate the other line items to someone you don't like.

4. **You will be judged not on facts, but on perceptions.** Perceptions are reality; accept that or move on. If your physicians think your turnaround time is 40 minutes, it is! Convince them it is 10 minutes by showering them with charts and graphs and endorsements by other "friendly-to-the-cause" physicians. Immediately distract your surgeon with something he or she wants if you see the room turnover is going bad. This might be a good time to discuss his capital equipment request.

5. **Keep your staff happy.** Nothing is more destructive to management than poor morale and staff turnover. Don't lose sight of No. 3 (above), but be creative in keeping good staff. Always cull out and get rid of the passive-aggressive staff. They are not worth keeping or trying to convert. They are happy by disrupting others. Ax them!

6. **Walk around.** Always wear scrubs when you can so you can walk through the department. You need to be seen (see item 4) by the staff, patients, and surgeons. Consider wearing a name badge that says "the buck stops here." Don't, however, wear it if it doesn't. Point your finger a lot; it looks impressive unless you point it at a person. (You lose points for that.)

7. **Always take the phone call from your boss.** This is one of those areas we don't always agree on. Assuming your boss is not a "What-are-you-doing-this-minute" person, it is always good to have your supervisor think you are in control, yet available.

8. **A good idea is always the surgeon's idea.** If you want to get something done, make the surgeon, or your supervisor, believe it was his or her idea. Very basic management tool.

9. **Be happy in your position, or make a lot of money.** Why do these two rarely go together? The good news is that with all the new same-day surgery centers going up each year, there are more and more opportunities for strong managers. This growth helps raise the pay. If you are not happy in your job but are making lots of money, well, that is a personal decision.

(Earnhart and 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.) ■

Safe harbors extended to four types of ASCs

A newly published regulation will allow safe harbor exceptions to federal fraud and abuse laws for four types of ambulatory surgery centers (ASCs): surgeon-owned ASCs, single-specialty ASCs, multispecialty ASCs, and hospital-physician ASCs.

"This is good news," says **Michael Blau**, Esq., partner in charge of the Boston health law department for McDermott, Will, and Emery. "At least we have relative specificity for various categories of ASCs."

For example, the government has said that a hospital-physician ASC can quality for safe harbor protection. "In the original [proposed] safe harbor, we were unsure whether any hospital-physician ASC could fall under a safe harbor," he says.

EXECUTIVE SUMMARY

The federal government has published additional safe harbor exceptions to federal fraud and abuse laws that cover four types of ambulatory surgery centers (ASCs): surgeon-owned ASCs, single-specialty ASCs, multispecialty ASCs, and hospital-physician ASCs. This safe harbor protection is allowed for ASCs in which only some of the physicians are surgeons.

- For single-specialty ASCs, all physicians simply have to practice the same specialty.
- Physicians must disclose to patients if they have an investment interest in an ASC.
- At least one-third of each physician investor's medical practice income during the previous 12 months has to be derived from the surgeons' performance of ambulatory surgery procedures, but not necessarily in the ASC where there is an investment interest.
- If your center's financial arrangement isn't covered by one of the safe harbors, it isn't necessarily illegal, just subject to scrutiny.

Others aren't so upbeat. The Federated Ambulatory Surgery Association (FASA) in Alexandria, VA, released a statement saying, "Although FASA believes finalizing the safe harbor is an important step forward, we recognize that the safe harbor is limited and in some ways more restrictive than warranted. FASA will continue to work to improve the interpretation of this law."

The proposed additions to the safe harbors, which covered only ASCs that were entirely owned by surgeons, were published Sept. 21, 1993. The interim final rule on the safe harbors additions was published in the *Federal Register* Nov. 19, 1999. *(The interim final rule can be obtained from www.dhhs.gov/progorg/oig/ new.html or from the* Federal Register *in most public libraries.)* Comment was received on the interim final rule until Jan. 18, 2000, and the interim final rule is subject to change.

Some of the most important changes between the proposed and final safe harbor additions are:

• It's now clear that safe harbor protection is allowed for physician-hospital ASCs, multispecialty ASCs, and single specialty ASCs in which only some of the physicians are surgeons.

• For single-specialty ASCs, not all physicians must be surgeons. They simply have to all practice the same specialty. "That's a significant improvement from the proposed safe harbors," Blau says.

• There's now a disclosure requirement for physicians who have an investment interest in an ASC and refer patients to their facility. Patients must be fully informed of the investor's interest.

The disclosure must be documented, Blau emphasizes. "From a physician standpoint, it's another piece of paper in the registration process that patients are going to have to sign. Make sure it says they read it and understood what they read."

This requirement is an opportunity for surgeons, says **Stephen W. Earnhart**, MS, president and CEO of Earnhart & Associates, a Dallas-based ambulatory surgery consulting firm specializing in all aspects of surgery center development and management.

"I would put a picture of the surgery center on my office wall and probably laminate my ownership share and tack that up there beside it," Earnhart says. "I would tell every one of my patients that, 'I am an owner of the Earnhart Surgery Center, and I hand-picked every staff member there, approved all the equipment purchases, and oversee all the supplies we use. Therefore, I am proud to book your surgical procedure at this great facility.'"

Earnhart's firm encourages its physician partners to let their patients know that the surgery is going to be done in a facility where the surgeon has an opportunity to influence the quality of care and patient safety. "This is golden opportunity for the physician to market not only the surgery center, but themselves," he says.

New one-third requirement

For all four types of surgery centers, there is a new requirement that at least one-third of each physician investor's medical practice income during the previous 12 months has to be derived from the surgeons' performance of ambulatory surgery procedures, but not necessarily in the ASC where he or she has an investment interest.

The reason is that the Health Care Financing Administration (HCFA) and the Office of Inspector General (OIG) view the ASC safe harbor as a workplace exception, Blau says. "If the physician or surgeon is referring him- or herself, and the surgeon is going to perform the surgery on his or her own patient, the surgeon is really using the ASC as an extension of the practice — really his or her own workplace," he says.

The one-third requirement won't disqualify very many, Blau says. "On the other hand, it will draw a line and allow one to distinguish passive

investors who aren't surgeons, who might otherwise be people interested in an investment interest simply to get a financial return and who are in a position to refer to surgeons. That's what OIG is trying to carve out."

There is another "one-third" test that applies only to multispecialty ASCs under the new safe harbor. For those facilities, at least one-third of the *procedures* performed by each physician investor during the previous 12 months needs to have been provided in an ASC where the physician has an investment interest. The reason for this requirement is that in multispecialty ASCs, the OIG was concerned that an investment interest might create incentives for surgeons or physicians to cross-refer among each other, rather than using the ASC as a workplace exception.

"All it does it cut out those who would be more passive investors, in a position to refer, in contrast to surgeons using the ASC on regular basis," Blau says.

Touchy area for hospitals

For hospitals that are interested in becoming partners with doctors in ASCs, safe harbors are helpful, Blau says. "There were serious questions about whether this was permissible."

There is one touchy area for hospitals. The OIG made it clear: If a hospital is going to be a partner in an ASC, and the ASC wants safe harbor protection, the hospital has to disqualify itself from being able to refer to the ASC, Blau says.

The hospital can address this concern by entering into a written stipulation under which the hospital contractually agrees that it won't refer or attempt to influence referrals to the ASC, he says. Examples of violations include patient overflow that is sent to a joint venture ASC or a situation in which a hospital-based physician or members of a hospital-affiliated group practice refer to the ASC. Such referral decisions are imputed to the hospital. "It would be as if the hospital made those referrals," Blau says.

The impact of these safe harbors additions should be a "call for action" for hospitals to start taking care of their surgeons as well as they have been taking care of the patients, Earnhart says. "Like it or not, the patients will stay with the physician — not the hospital — when forced to chose between the two."

Many hospitals find it difficult to compete with physician-owned ASCs, Earnhart says. "Hospitals and surgeons need to start working together on ambulatory surgery programs, or the industry will become so fragmented and unprofitable, with surgery centers on every corner, that everyone loses."

A safe harbor isn't required

Even if your situation doesn't fall within one of the safe harbor additions, you haven't necessarily violated any fraud and abuse laws, Blau emphasizes. "Safe harbors are limited definitions of financial transactions that OIG has specifically said has such a small or no potential for fraud and abuse that they'll immunize from prosecution or sanction or penalty."

However, just because you don't meet the narrow definitions doesn't mean your conduct is illegal. "It just means it's outside the safe harbor and subject to scrutiny," Blau says. "Many financial transactions don't meet every standard and parameter of safe harbor, but are completely legally defensible arrangements."

In fact, an ASC might fall under another safe harbor, such as the small entity or underserved area safe harbors.

So what's the bottom line, according to Blau? "Is the arrangement intended to induce referrals, inappropriately, particularly from physicians who are in a position to refer and not perform surgery on their own patients, or is it a legitimate workplace where physician can provide quality care at a cost-effective price for patients as an extension of their practice?" ■

SOURCES

For more information on the safe harbor, contact:

- **Michael Blau**, Esq., McDermott, Will, and Emery, 28 State St., Boston, MA 02109-1775. Telephone: (617) 535-4010. Fax: (617) 535-3800. E-mail: mblau@mwe.com.
- **Stephen W. Earnhart**, MS, President and CEO, Earnhart & Associates, 5905 Tree Shadow Place, Suite 1200, Dallas, TX 75252. E-mail: searnhart@earnhart.com. Web: www.earnhart.com.
- **Vicki L. Robinson**, Office of Counsel to the Inspector General, Washington, DC. Telephone: (202) 619-0335.
- **Joel Schaer**, Office of Counsel to the Inspector General, Washington, DC. Telephone: (202) 619-1306.

Learn how to select an architect

(This is the second part of a two-part series on renovation and building in same-day surgery. In last month's issue, we offered direction on how to decide whether to build, and we discussed the role that case mix plays.)

An architect with experience in building or renovating space to create a day surgery center is a valuable partner in your project, says **Steve Dickerson**, AIA, principle architect at Eckert Wordell in Kalamazoo, MI.

Not only should the person you hire understand the codes and regulations that apply to surgery centers, but he or she should understand how a surgery center operates in terms of patient flow, workspace needs, and business office requirements, says Dickerson.

Because renovation will be going on at the same time the center is functioning, it requires careful coordination between the architect, the general contractor, and the specialty trades. It also requires special fire and safety watches, maintenance of positive air pressure and flow, efforts to avoid contamination of surgical areas, noise abatement during construction, and safety protection for staff and visitors.

If your state is highly regulated and the state architectural staff are not always easy to work with, it also may help to have an architect who has a positive track record working on other licensed projects reviewed by the same state agency that you will have to face.

There are several ways to find an architect. "One way is to get names of architects used by other day surgery center managers," recommends Dickerson. Another way is to contact the American Institute of Architects (AIA), he says. The organization can refer people to architects by specialty and by geographic region. **(For information on how to contact the AIA, see resource box, below left.)**

Be sure to look at other centers he or she has designed and talk with surgery center personnel who worked with the architect. Also, talk about method of payment before you sign an agreement, says Dickerson. "Be wary of anyone who charges fees based on a percentage of construction costs. This method encourages the architect to design a more expensive project." Negotiating a lump sum fee at the beginning of the project is the best method for most people, he adds.

The AIA also produces a booklet that offers advice on finding, negotiating and working with your architect — *You and Your Architect*. Dickerson recommends this free publication as a good way to make sure you ask the right questions at the beginning of your relationship. ■

RESOURCE

To obtain a copy of *You and Your Architect* or to find names of architects who specialize in health care or surgery centers in your area, contact:

- **The American Institute of Architects**, 1735 New York Ave. N.W., Washington, DC 20006. Telephone: (800) 365-2724 or (202) 626-7300. Web site: www.aiaaccess.com.

Construction costs can vary widely

Costs for renovation or new construction projects differ based on your program's needs and your geographic location, says **Steve Dickerson**, AIA, principal architect at Eckert Wordell in Kalamazoo, MI.

Although prices vary between geographic areas, a good rule of thumb is $165 per square foot of new space vs. $100 per square foot for renovated space, he says. The difference between the two costs is primarily the need to build the shell of the building that already exists for renovation projects.

Another new construction cost is the cost of the land, if you don't already own it, and the cost of site preparation. "Site preparation costs vary widely from area to area," says **Michael L. Gordon,** AIA, of Gordon and Associates Architects in Mount Dora, FL. The South's rocky and clay-filled soil may cost $15 to $25 per square foot to make the site buildable, but the Northeast's soil may only require $5 per square foot, he explains.

While renovation costs are generally lower, they can skyrocket if major structural work is needed to add two-hour-rate firewalls, wider hallways, separate mechanical systems, or a covered area for patient discharge in inclement weather.

The surgery center should be on the grade level of the building so patients can get into the center without using an elevator, says Dickerson. "You also can't be in a wood frame building," he says. "It is too combustible to hold a surgery center." ■

Risk categorization scheme draft published

The Food and Drug Administration (FDA) has published draft guidance on its risk categorization scheme for reprocessing and reuse of single-use devices. The document directs health care providers on how to determine the risk posed by single-use devices that are reprocessed and/or reused. **(For information on the FDA's proposed revisions to its policy on reprocessing of single-use devices, see *Same-Day Surgery*, January 2000, p. 1.)**

The risk categorization scheme (RCS) labels the risk category as low, moderate, or high, and follows these steps:

• Look at the inherent risk as reflected in the device's generic classification. One factor is whether the device is classified as Class I, II, or III under the medical device provisions of the Food, Drug, and Cosmetic Act. **(See work sheet enclosed in this issue.)**

• Determine the risk of infection posed by reprocessing and reusing the device. **(See Flowchart 1, enclosed in this issue.)** Label the risk of infection as critical, semicritical, or noncritical depending on the invasiveness of the device in a method described by E.H. Spaulding in his 1972 article.[1]

• Determine the risk of inadequate performance of a reprocessed and/or reused device. **(See Flowchart 2 enclosed in this issue.)**

If the grade for either risk of infection or risk of inadequate performance is 2, the devices is categorized as high risk. If the score for risk of infection is less than 2 and the score for risk of inadequate performance is less than 2, the scores for all three parameters are totaled. If the total score is 3 or 4, the device is categorized as moderate risk. If the total is less than 3, the device is categorized as low risk.

For clarification, the FDA offers this example:

An anesthesia breathing circuit device consists of flexible or rigid tubing that is used to convey

Same-Day Surgery® (ISSN 0190-5066) is published monthly by American Health Consultants®, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Periodical postage paid at Atlanta, GA 30304. POSTMASTER: Send address changes to **Same-Day Surgery**®, P.O. Box 740059, Atlanta, GA 30374.

Subscriber Information

Customer Service: (800) 688-2421 or fax (800) 284-3291, (customerservice@ahcpub.com). Hours of operation: 8:30 a.m.-6 p.m. Monday-Thursday; 8:30 a.m.-4:30 p.m. Friday.

Subscription rates: U.S.A., one year (12 issues), $499. Approximately 20 nursing contact hours, $549; Outside U.S.A., add $30 per year, total prepaid in U.S. funds. One to nine additional copies, $399 per year; 10 to 20 additional copies, $299 per year. Call for more details. Missing issues will be fulfilled by customer service free of charge when contacted within 1 month of the missing issue date. **Back issues**, when available, are $83 each. (GST registration number R128870672.)

This continuing education offering is sponsored by American Health Consultants, which is accredited as a provider of continuing education in nursing by the American Nurses Credentialing Center's Commission on Accreditation. Provider approved by the California Board of Registered Nursing. Provider Number CEP 10864.

Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. Clinical, legal, tax, and other comments are offered for general guidance only; professional counsel should be sought for specific situations.

Group Publisher: **Brenda Mooney**, (404) 262-5403, (brenda.mooney@medec.com).
Executive Editor: **Valerie Loner**, (404) 262-5475, (valerie.loner@medec.com).
Managing Editor: **Joy Daughtery Dickinson**, (912) 377-8044, (joy.dickinson@medec.com).
Production Editor: **Ann Duncan**.

Editorial Questions

Questions or comments? Call **Joy Daughtery Dickinson** at (912) 377-8044.

RESOURCE

For copies of *Guidance for Industry and Reviewers: Reprocessing and Reuse of Single-Use Devices Risk Categorization Scheme (Draft)*, go to the FDA's Center for Devices and Radiological Health (CDRH) Web page: www.fda.gov/CDRH/reuse, or contact CDRH Facts on Demand at (800) 899-0381 or (301) 827-0111. Specify number 1156 when prompted for the document shelf number.

gases to the patient. It is indirect-patient contacting and is usually constructed of polyvinyl chloride (PVC). It might be labeled for single use or reuse, but the wall thickness of the single use device is usually thinner than the reusable device. The device is often reprocessed by hot water infection. This device is a class I device according to the FDA medical devices classification process.

Flowchart 1: All of the answers to the questions in Flowchart I are no. Therefore, the numerical value associated with infection risk for this device is 0.

Flowchart 2: The breathing circuit does not contain materials, coatings, or components that might be damaged or altered by a single use in such a way that the performance of the device might be affected. Therefore, the numerical value associated with that criteria is 0. The other factors included in Flowchart 2 do not need to be considered in this case.

The total score for the anesthesia breathing circuit is 0. Therefore, this device may be considered low risk.

Reference

1. Spaulding EH. Chemical disinfection and antisepsis in the hospital. *J Hosp Res* 1972; 9:5-31. ■

COMMENTS

Comments may be submitted until March 8. Submit comments to:

- Docket No. 99N-4491, Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852.

CE objectives

After reading this issue of *Same Day Surgery*, the continuing education participant will be able to:

- Identify clinical, managerial, regulatory, or social issues relating to ambulatory surgery care and management.
- Describe how those issues affect nursing service delivery or management of a facility. **(See "Controversy erupts over whether to disinfect or sterilize endoscopes" and "Managing Generation X in same-day surgery.")**
- Cite practical solutions to problems or integrate information into their daily practices, according to advice from nationally recognized ambulatory surgery experts. **(See "ASC management: 9 lessons I've learned" and "Risk categorization scheme draft published.")** ■

AMERICAN HEALTH CONSULTANTS® A Medical Economics Company

Do you know what benefits are valued in your program?

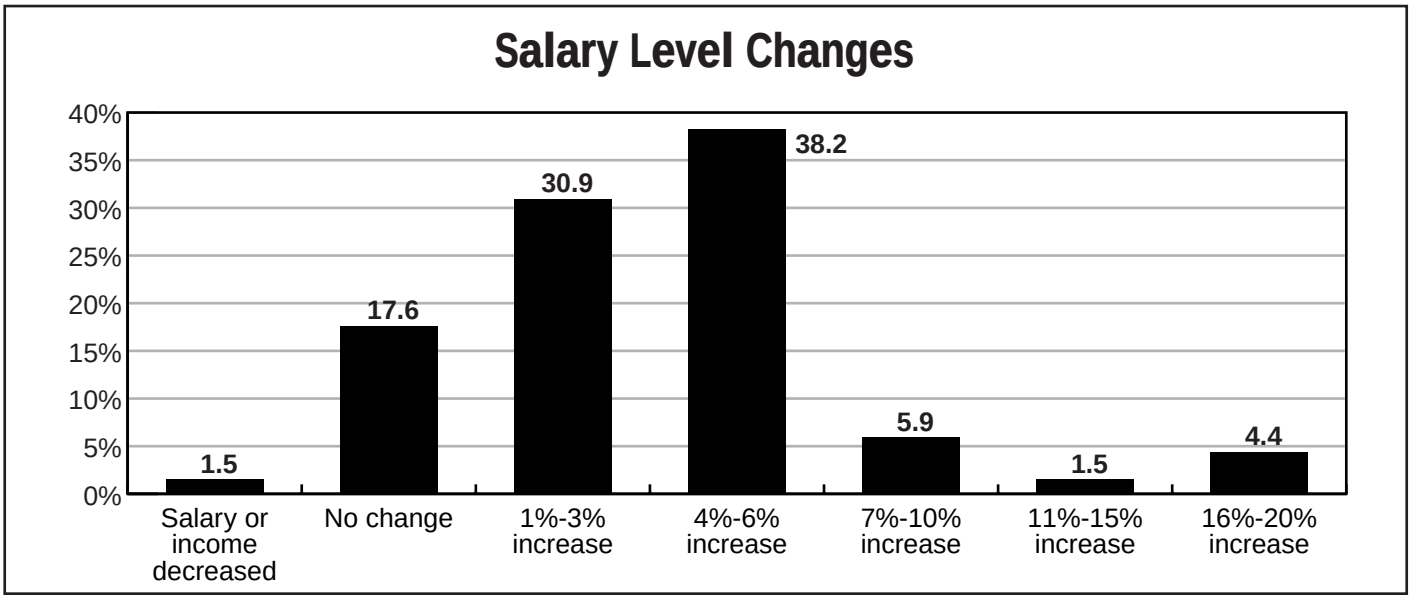
Do you think that you're making your staff happy offering them bonuses and life insurance as part of their benefits package? You'd be better off offering them some freedom to choose their work schedule and tuition reimbursement, according to the most recent *Same-Day Surgery Salary Survey Results.*

The salary survey was mailed in December 1999 to 1,333 subscribers. There were 70 responses, for a response rate of 5.25%. Respondents ranked the following benefits as important or extremely important:

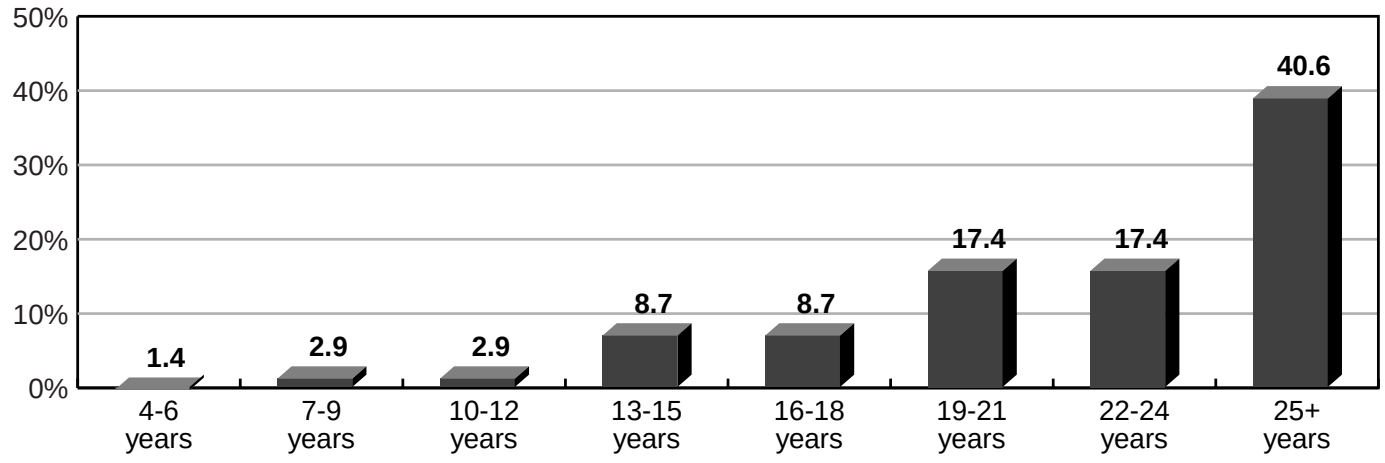
- 401K or other savings plan (90.9%)
- medical coverage (88.4%)
- dental coverage (69.1%)
- pension plan (66.7%)
- some freedom to choose work schedule (59.7%)
- tuition reimbursement (58.2%)
- annual or semi-annual bonus (54.5%)
- life insurance (50.7%)

The high ranking of freedom to choose a work schedule indicates that lifestyle and family is more important than possessions to much of today's work force, says **Cheryl Dendy**, RN, director of St. John Surgery Center in St. Clair Shores, MI. These values are particularly true among the younger work force, she emphasizes.

"People aren't real motivated by income in that age group today," she says. Many younger staff have seen their parents work hard and have decided that for themselves, less income is acceptable,



Number of Years Worked in Health Care



she says. **(For information on managing Generation X, see story, p. 16.)**

However, most *SDS* salary survey respondents (72%) fell into the 41 to 55 age range. Most (35.3%) work 41 to 45 hours a week or 46 to 50 hours a week (33.8%). Forty percent have worked 25 or more years in health care. **(See chart, above.)**

Many same-day surgery administrators and high level managers are tired, Dendy says. In fact, "they're worn out. Health care is a hard field to be part of." For those managers, some freedom to choose work schedule offers a welcome break.

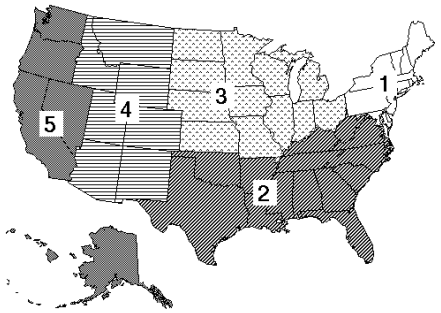
Tuition reimbursement also scored high as a benefit among respondents to the *SDS* salary survey. This ranking reflects the changing technology and increasing expectation for new kinds of competencies, such as patient education, says **Marjorie Beyers**, RN, PhD, FAAN, executive director of the American Organization of Nurse Executives in Chicago. "Nurses need to keep their education up to date. Tuition would make a lot of sense in that perspective."

Directors and administrators also are returning to school. Many, such as Dendy, are studying business. "As administrator, looking at the financial components of the facility is what I need ability to have better understanding of," she says.

A clinical and business degree make a good partnership, Dendy adds. "It helps you to be more diversified," she says.

In terms of salaries, although many readers report a shortage of nurses and nurse managers in the OR, salary increases aren't necessarily reflecting that shortage. The highest percentage of *SDS* readers (38.2%) report a salary increase of 4% to 6%. **(See chart, p. 1.)**

Respondents by Region

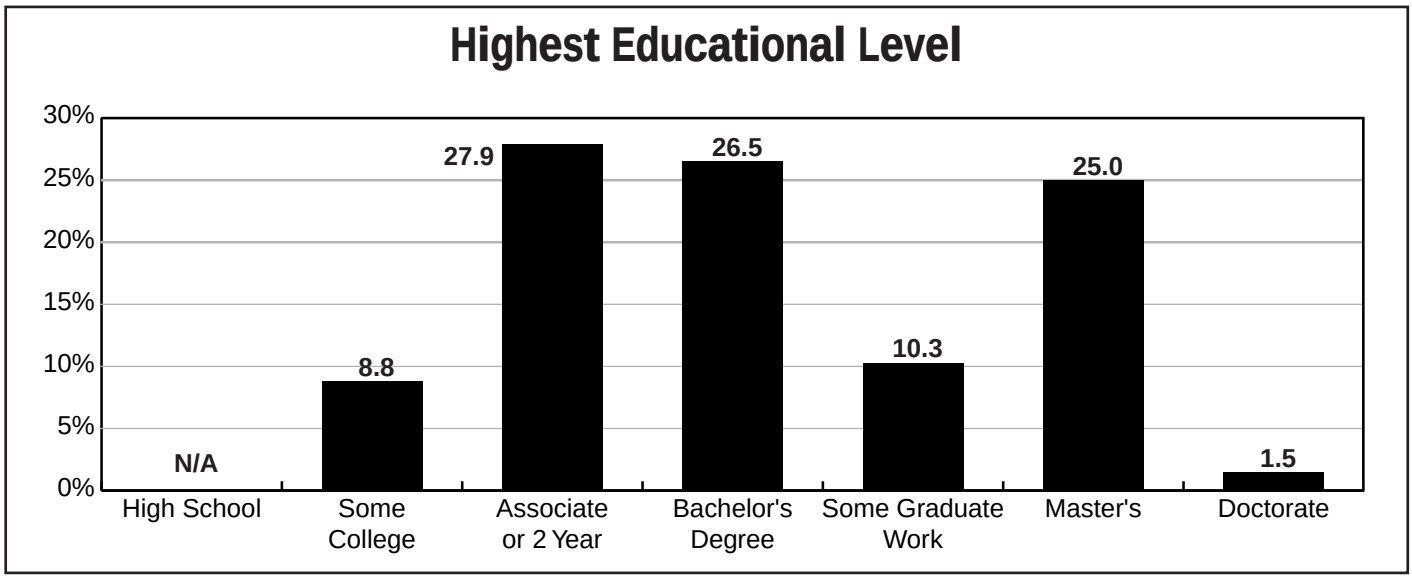


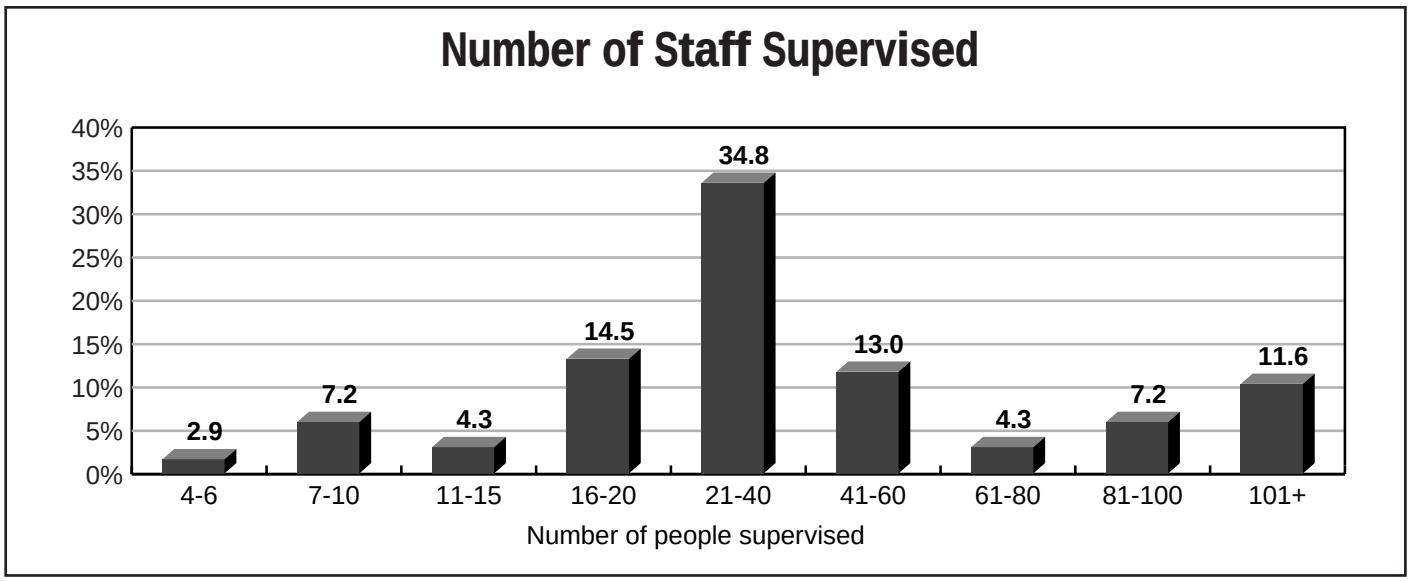
Region 1	**27.3%**
Region 2	**19.7%**
Region 3	**30.3%**
Region 4	**6.1%**
Region 5	**16.7%**

SOURCES

For more information on same-day surgery salaries, contact:

- **Marjorie Beyers**, RN, PhD, FAAN, Executive Director, American Organization of Nurse Executives, One North Franklin St., 32th Floor, Chicago, IL 60606. Telephone: (312) 422-2801. Fax: (312) 422-4503. Web: www.aone.org.
- **Cheryl Dendy**, RN, Director, St. John Surgery Center, 21000 12 Mile Road, St. Clair Shores, MI 48081. Telephone: (810) 447-5015. Fax: (810) 447-5011. E-mail: cheryl.dendy@stjohn.org.
- **Pat Niederlitz**, CHRM, Program Manager, Opportunity AORN Employment and Consultation Services, Association of periOperative Registered Nurses, 2170 S. Parker Road, Denver, CO 80231. Telephone: (303) 755-6304. Fax: (303) 750-3462. E-mail: ptn@aorn. org. Web: www.aorn.org.





"The salaries aren't jumping leaps and bounds, even though there's a shortage," explains **Pat Niederlitz**, CHRM, program manager of the Opportunity AORN Employment and Consultation Services, part of the Association of periOperative Registered Nurses (AORN) in Denver. "It's nothing like what you might have expected."

Luckily, most respondents to the *SDS* salary survey (58.5%) have seen the number of employees in their facility or department increase.

"The reason, in most cases, is that nurses who want to depart a hospital setting find the ambulatory setting more conducive to their lifestyle: with weekends off and no call," Niederlitz says.

OR managers can find lateral and horizontal opportunities because they often are expert clinicians, well organized, and function well under stress, Beyers says.

Dendy has found the opportunity to consult on the side, as do many same-day surgery managers. "I built three facilities, and I'm in the planning process for a fourth," she says.

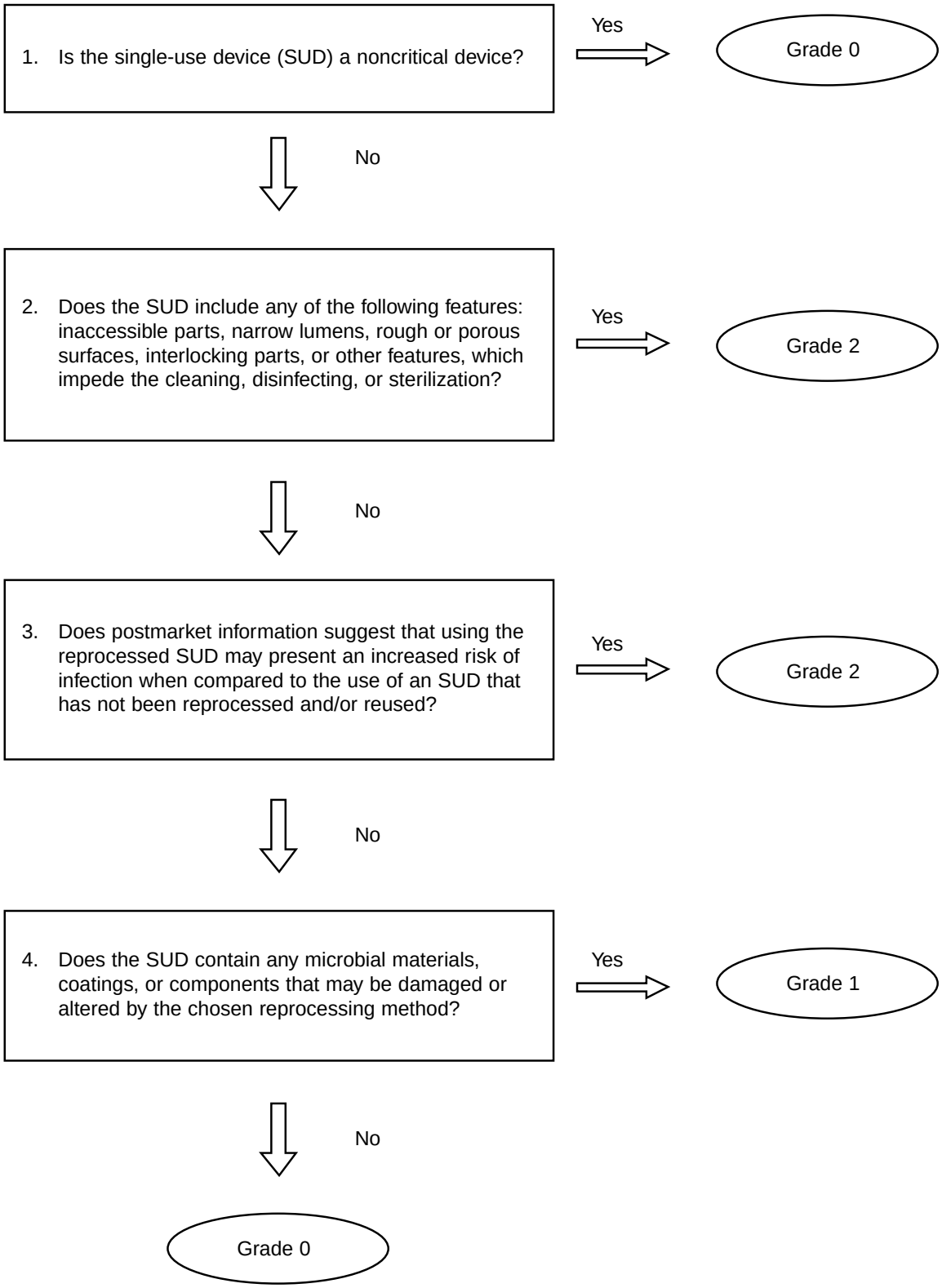
With the loosening of certificate of need requirements across the country, many new facilities are being organized, she says. "The need for consulting is going to be fairly significant over the next five to six years as we see more of a shift into the outpatient setting," she says.

SDS managers have the opportunity to consult in several areas, including designing, staffing, budgeting, and developing cost per case. Also, for the managers with strong experience in information systems, there are opportunities to work with companies that are developing systems for outpatient surgery, Dendy says. "If you love outpatient surgery, it's an exciting and challenging time. There's a lot of opportunity there." ■

Salary Levels by Title

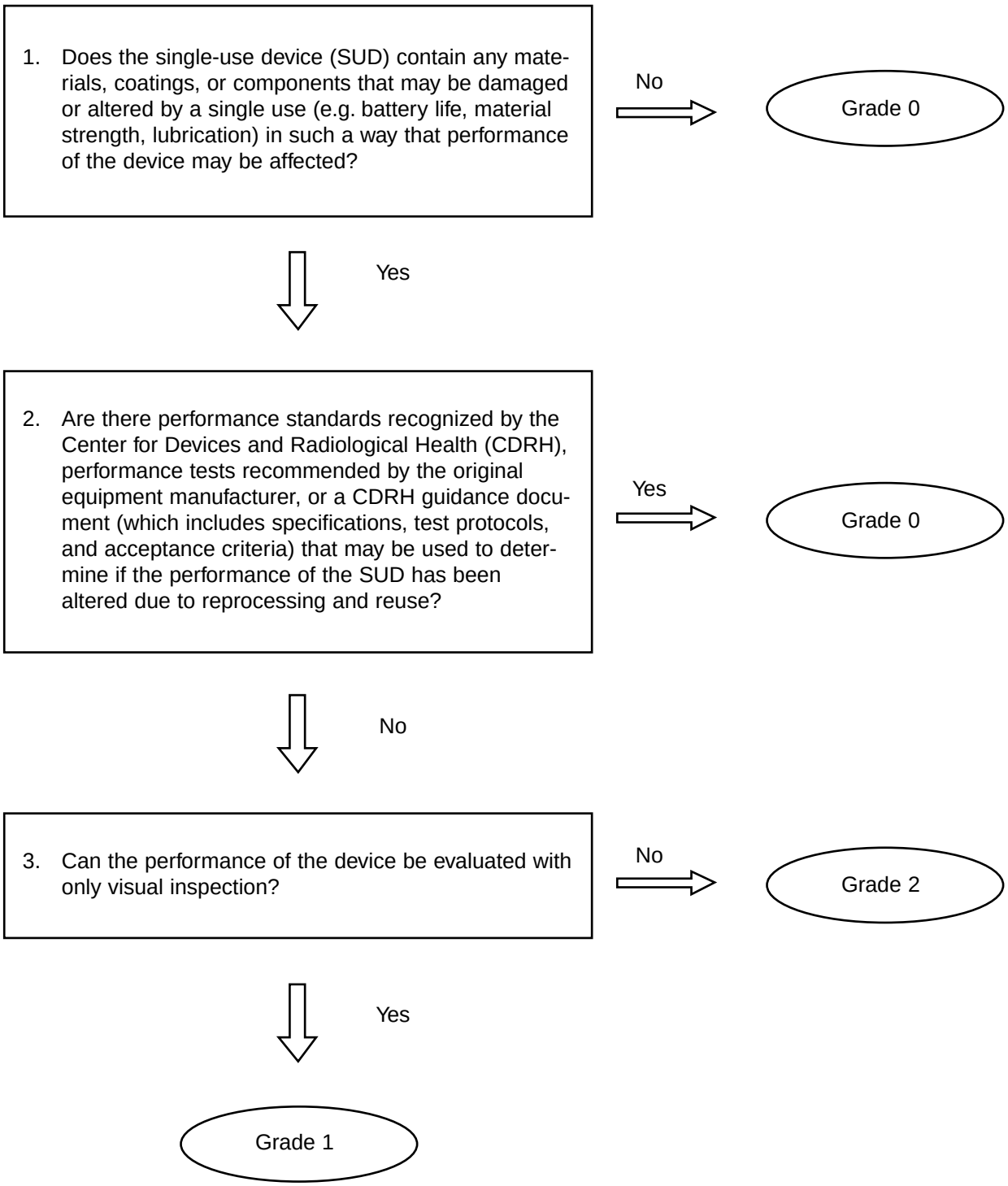
Annual Gross Income	Director/CEO	Administrator	Nurse Manager	Ambulatory Surgery Mgr.
less than $20,000	2.5%	0%	0%	8.3%
$20,000 to $24,999	0%	0%	0%	0%
$25,000 to $29,999	0%	5.6%	0%	0%
$30,000 to $34,999	0%	0%	0%	0%
$35,000 to $39,999	2.5%	0%	0%	0%
$40,000 to $44,999	5%	0%	20%	16.7%
$45,000 to $49,999	10%	0%	0%	16.7%
$50,000 to $54,999	12.5%	5.6%	20%	8.3%
$55,000 to $59,999	15%	0%	10%	16.7%
$60,000 to $64,999	5%	11.1%	0%	8.3%
$65,000 to $69,999	7.5%	0%	10%	8.3%
$70,000 to $74,999	7.5%	22.2%	0%	0%
$75,000 to $79,999	2.5%	5.6%	10%	8.3%
$80,000 to $84,999	10%	0%	10%	0%
$85,000 to $89,999	2.5%	5.6%	0%	0%
$90,000 to $94,999	5%	0%	0%	0%
$95,000 to $99,999	2.5%	0%	0%	0%
$100,000 to $104,999	0%	11.1%	0%	0%
$105,000 to $109,999	10%	5.6%	10%	0%
$110,000 to $114,999	0%	0%	0%	0%
$115,000 to $119,999	0%	0%	0%	8.3%
$120,000 to $124,999	0%	11.1%	0%	0%
$125,000 to $129,999	0%	0%	0%	0%
$130,000 to $134,999	0%	11.1%	0%	0%
$135,000 to $139,999	0%	0%	0%	0%
$140,000 to $144,999	0%	0%	0%	0%
$145,000 to $149,999	0%	0%	0%	0%
$150,000 to $154,999	0%	0%	0%	0%
$155,000 to $159,999	0%	0%	10%	0%
$160,000 or more	0%	5.6%	0%	0%

Evaluating the Risk of Infection — Flowchart 1



Source: Center for Devices and Radiological Health, Baltimore.

Evaluating the Risk of Performance Change — Flowchart 2



Source: Center for Devices and Radiological Health, Baltimore.

Risk Categorization Work Sheet

Inherent Risk

(According to 21 Code of Federal Regulations Part 860)

Class I = 0
Class II = 1
Class III = 2 _____

Risk of Infection

(See p. 1)

Grade 0 = 0
Grade 1 = 1
Grade 2 = 2 _____

Risk of Inadequate Performance

(See p. 2)

Grade 0 = 0
Grade 1 = 1
Grade 2 = 2 _____

If the single-use device resulted in a score of 2 for questions 2 or 3 listed above, the single-use device is categorized as high risk. Otherwise, the score should be totaled.

Total _____

Low Risk: 0-2
Moderate Risk: 3-4

Source: Center for Devices and Radiological Health, Baltimore.