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Some single-use devices can be reprocessed safely, GAO report says

Joint Commission surveyors are asking questions — Are you ready?

Here are two bits of surprising news that could affect your opinion on reprocessing of single-use devices (SUDs): First, the General Accounting Office (GAO) has released a report that says some SUDs can be reprocessed safely.[1] Second, the report surprised same-day surgery managers by disclosing that surveyors with the Joint Commission on Accreditation of Healthcare Organizations will collect information on the practice.

The surveyors will collect data about in-house reprocessing of SUDs on behalf of the Food and Drug Administration (FDA). Beginning in July with the publication of the final FDA regulation, and for six months, Joint Commission surveyors will ask three types of questions:

1. Does the hospital reprocess and reuse devices labeled for single-use, and if so, which devices does it reprocess or reuse?

2. Is the hospital aware of the FDA's requirement for registration and listing of the devices it chooses to reprocess and reuse?

EXECUTIVE SUMMARY

A General Accounting Office report said some single-use devices (SUDs) can be reprocessed safely when appropriate procedures are followed.

- Reprocessing SUDs isn't always safe, the report said. Surveillance doesn't detect all infections and injuries resulting from reprocessed SUDs. Also, safe reprocessing procedures aren't always followed.
- Many types of SUDs can't be effectively cleaned and sterilized.
- Accreditation surveyors will ask providers questions about whether they perform in-house reprocessing. The data won't identify hospitals when they are submitted to the Food and Drug Administration (FDA).
- At press time, the FDA was scheduled to release its final regulation on reuse in July.

3. Does the hospital intend to continue to reprocess and reuse such devices?

Although the Joint Commission won't identify individual hospitals when it supplies this information to the FDA, the practice raises a number of red flags, says **Mark Mayo**, facility director at Valley Ambulatory Surgery Center in St. Charles, IL, and executive director of the Illinois Freestanding Surgery Center Association. Mayo is consulting editor for *Same-Day Surgery*.

"It's fine if they just collect that data," Mayo says. "But now it opens the hospital to a more thorough in-house inspection by the Joint Commission about the efficacy of their reprocessing process."

The Joint Commission is making a good-faith effort to help the FDA, he says. "But I can see surveyors saying, 'Oh, you reprocess? We want to take a look at that,'" Mayo says.

Anthony Tirone, director of federal relations for the Joint Commission in Washington, DC, says reprocessing already is addressed in the current standards, such as infection control, and the survey process won't change based on responses to the surveyor's questions. But he doesn't go as far as to say that the surveyors won't look at reprocessing SUDs.

"If there are indications that the facility is having problems with infection following surgery, we would look at that," Tirone says. "If it leads to the reuse of single-use devices, we would look at that."

A government stamp of approval

For its part, the GAO has examined the data and given reprocessing SUDs a qualified stamp of approval. **(For caveats regarding safety of reprocessing, see story, p. 100.)**

"The results of clinical studies show that selected devices can be reprocessed safely if appropriate procedures are followed and closely monitored, a view shared by many professional organizations and infection control experts," said **Janet Heinrich**, associate director of health financing and public health issues for the GAO, in June 27 testimony summarizing the report before the Senate Committee on Health, Education, Labor, and Pensions.[2] (Both the report and the testimony can be accessed on the GAO's Web site: www.gao.gov.)

The GAO bases this finding on four types of information it gathered:

• Well-developed clinical studies have established the safety of reprocessing some types of devices, the report said. Some evaluations of reprocessing single-use endoscopic instruments published in peer-reviewed scientific journals found that those SUDs could be reused at least several times without increasing patient risk, according to the report.[3, 4]

No health risk with proper care, experts said

• Hospital infection control practitioners, risk management executives, and patient safety experts at the Centers for Disease Control and Prevention (CDC) all said that careful reprocessing of the types of SUDs that can be properly cleaned and sterilized does not pose a health risk.

"The head epidemiologist of CDC's Hospital Infection Program told us that although the CDC does not specifically monitor SUD reuse, he was confident hospital infection surveillance systems would have uncovered infections resulting from SUD reuse if they had occurred," the report said.

• Only a very small percentage of reports to the FDA's Medical Device Reporting program concerned adverse outcomes involving reused SUDs.

• Several of the reports of patient adverse events allegedly related to SUD reprocessing were inaccurate, not relevant to the debate, or difficult to interpret, the report said.

"Everybody seems to say it's safe, except for manufacturers," Mayo says.

About 20% to 30% of American hospitals reuse at least one type of single-use device, according to the GAO report. Health care personnel "distrust"

SOURCES

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the single-use label for three reasons, according to the report:

• The FDA cannot require manufacturers to support the designation of a device as single-use.

• The FDA's approval requirements for SUDs are less extensive than those for reusable devices.

• Health care personnel perceive that manufacturers have an economic incentive to market devices as single-use that could be sold as reusable.

Going beyond the label

"I think the GAO report highlighted the fact that the single-use label doesn't necessarily mean single use. They reported instances of manufacturers saying a device was single use and then providing instructions on how to reprocess," says **Pamela J. Furman**, Esq., executive director of the Association of Medical Device Reprocessors in Washington, DC.

The single-use label may sometimes be for marketing purposes as opposed to being a legitimate safety warning, she claims.

The GAO was unable to verify two claims that officials repeatedly heard, according to the report.

"Health care personnel told us that they believed that some SUDs were identical to reusable devices," the report said. "Similarly FDA officials and health care personnel told us that they recalled that the labels of some devices were changed from reusable to single-use in years past without significant design changes."

Although *Same-Day Surgery* readers might expect that manufacturers and reprocessors would find little to agree on about the report, both sides agree that FDA oversight is needed.

"FDA oversight is an important part of ensuring patient safety," says Furman, who represents the reprocessors.

On the manufacturing side, **Louis Mazzarese**, consultant in regulatory and clinical affairs and co-founder of the Association of Disposable Device Manufacturers (ADDM) in Washington, DC, says, "The report I believe confirms ADDM's position: The FDA's approach to regulating these devices has been inadequate, and further oversight is need to ensure patients exposed to these types of devices don't experience safety or efficacy problems."

At press time, the FDA's final regulation on reuse was scheduled to be published in July, and implementation was scheduled to take place in 2001. Ambulatory surgery centers were exempt in the proposed regulation. **(For more on the proposed regulation, see *SDS*, January 2000, p. 1, and February 2000, p. 23. For legislative action, see story, p. 100.)**

Mazzarese disagrees that a new regulation is necessary. "Existing laws and the existing [FDA] classification system work just fine," he says. "We just need to apply them."

Mazzarese isn't the only one expressing concern about a new FDA regulation. In her testimony, Heinrich said, "The new framework is cumbersome and will be difficult to implement."

The GAO report says the FDA faces barriers such as the additional work of reviewing applications for SUD reprocessing, which will be required under the new regulation.

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Consider caveats of reprocessing safely

Although the General Accounting Office (GAO) has reported that some devices can be reprocessed safety when proper cleaning and sterilization procedures are followed, the report included some caveats.[1]

It is difficult to identify sources of infection in individual patients, and it can be particularly difficult to trace infections back to the use of specific medical devices, said **Janet Heinrich**, associate director of health financing and public health issues for the GAO, in June 27 testimony summarizing the report before the Senate Committee on Health, Education, Labor, and Pensions.[2]

"Current medical device surveillance systems almost certainly do not detect all infections and injuries resulting from the use of reprocessed SUDs, or from the use of medical devices in general, and there is general agreement that many types of SUDs cannot be effectively cleaned and sterilized," Heinrich said. The report gave an example of a reprocessing firm that only reprocesses 15 "families" of devices, and many of these were opened but unused devices.

Furthermore, procedures for safe reprocessing aren't always followed, she added.

The FDA has received reports from device manufacturers of damaged, unclean, or nonsterile reprocessed SUDs taken from hospitals that had been reprocessed by third-party reprocessors.

That agency found at least one of the claims had merit, according to Heinrich's testimony. In March 1999, a manufacturer said six reprocessed GI biopsy forceps at a Florida hospital were not sterile. The devices were labeled for single use and had been reprocessed by a third-party reprocessing company, according to Heinrich.

"Although there is no evidence that these reprocessed devices have harmed patients, this case demonstrates the possibility that some reprocessed SUDs sterilized according to current protocols might not be free of bacterial contamination," she said.

How can same-day surgery centers ensure that SUDs are reprocessed safely? The GAO report spelled it out: ". . . Institutions must be able to clean [the SUD] thoroughly, sterilize it to acceptable standards, and ensure that reprocessing and reuse will not degrade its functioning."

Cleaning is a critical step, the report emphasized: ". . . even measurably sterile devices can harbor biological material from previous uses that may prove a health risk for subsequent patients. Potentially, this biological residue by itself can prove toxic to new patients, and it also can form a crust to shield harmful bacteria from sterilization procedures."

Bills address reuse issue

The legislative arena, on both the national and state level, has been actively involved in the issue of reprocessing single-use devices (SUDs):

- Nationally, the Reprocessed Single Use Medical Device Patient Safety Act of 1999 (HR 3148) was referred to the House Subcommittee on Health and Environment. In addition to premarket 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.
- In Missouri, a bill (HB 1195) would regulate, and some organizations say it would prohibit, the reuse of SUDs. The bill has been referred to the House Public Health Committee.
- A Maryland bill (SB 28) proposed hospitals provide written notice to patients about the hospital policy regarding reuse of SUDs. The bill died after receiving an unfavorable report from the Senate Finance Committee. ■

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2. General Accounting Office. Medical devices: Reprocessing and reuse of devices labeled for single use. Statement of Janet Heinrich, associate director, health financing and public health issues; Health, Education, and Human Services Division; before the Committee on Health, Education, Labor, and Pensions, U.S. Senate. Washington, DC; June 27, 2000. ■

Same-Day Surgery Manager

Hospital CEOs express competitive concerns

By **Stephen W. Earnhart**, MS
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Earnhart & Associates had the distinct honor of addressing the Texas Hospital Association annual meeting recently. Senior level management from several hundred hospitals attended, and I couldn't resist the temptation to poll as many of them as possible. I felt like a reporter for some small-town newspaper, but I was able to obtain feedback on several issues.

Hospital CEOs are concerned about the outflow of outpatient surgery to the competition. They are fearful of competing hospitals establishing programs that will take their surgeons and their cases away from them. Further, they feel the drain of cases from "frustrated" surgeons doing their own facilities or doing cases that have a facility fee attached to it being performed within the walls of the physician's practice.

Most of them acknowledge that they have procrastinated dealing with developing their own centers outside the walls of their hospitals and are looking for ways to reduce that "brain drain" without jeopardizing bond or tax issues.

Many are fearful of doing something for the surgeons that will now have to be done with radiologists, pathologists, and / or every other service line in the hospital.

Reimbursement is another concern for the administrators. Most are confused about the upcoming changes in outpatient reimbursement and the effect on their institutions. Many said that they have heard that their revenue reductions could be anywhere from a decline of 30% to an increase of 5%. (This reporter had to agree with them. It is very confusing! We were not able to offer any comfort to the masses.)

Finding and retaining experienced nurses — especially PACU nurses — was a major concern. (They used the word "PACU." How cool that they knew that term! They must be discussing this problem in meetings to know that acronym.) Since the nursing shortage is real and significant, I asked what they were doing about it in their institutions.

At this point I could tell that most of them were lost, but they did make valiant efforts to recall staff meetings on the subjects. Some of their thoughts on the matter were:

1. **More on-the-job satisfaction.** ("Define please," I asked. The responses were vague.)

2. **Stronger recruitment activity.** ("How?" The responses were vague.)

3. **Better benefits.** ("Such as?" They weren't sure.)

At this point, several glanced at their watches, gently reminding me that they were in a hurry.

Removing the pressure point, I pointed out that our own internal survey revealed as many as 200 new ambulatory surgery centers are opening this year alone. I asked, "Could this be contributing to the nursing shortage?" Most thought that trend was playing a major role in their losing their experienced operating room staff.

Another matter CEOs named as a cause for concern is increasing difficulty dealing with reimbursement in general. One of the areas they expanded upon was a greater "take-it-or-leave-it" attitude among some managed care companies. They cited the fact that it is increasingly difficult to negotiate competitive contracts.

Hospitals boost telecommunications

Telemedicine seemed to be a hot topic at the conference — especially in the area of rural locations "telecommunicating" data back to the main hospital to be "overread" by the medical staff. This seemed significant to hospitals that were expanding their base of business into new areas, especially "underserved" areas or in areas where

it was not feasible to establish a new hospital but the population was growing.

Along those lines, the idea of "specialty hospitals" such as orthopedics seemed hot. We are dealing with several orthopedic hospitals ourselves, and the trend seems to be gathering momentum even in the traditional hospital setting.

Lastly, it does appear that many of the CEOs we spoke with acknowledge that vertically integrating their business line is going to require outsourcing some traditional hospital business. America is a land of opportunity, and many enterprising individuals are coming out of the hospital to launch their own firms that can provide these services faster, cheaper, and often in a more customer-oriented environment.

Many of the services that revolve around the operation room, such as transcription services, billing, ambulatory surgery, anesthesia, etc., are being served via for-profit companies. Hospitals seem to be aware of this growing trend and are "exploring" opportunities to determine how they can work with the changing service lines.

As long as there is plague and famine, hospitals will be around. However, I suspect that in the not-too-distant future they will morph into something significantly and distinctly different from what we know today.

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Extended care adds revenue potential

(This month's issue includes the first part of a two-part series on extended recovery care. In this month's issue, we explore options for how to provide extended care, information on state regulations, an overview of the financial picture, and information from a recent survey. In next month's issue, we'll cover how to select patients and procedures.

Advances in technology as well as clinical areas such as anesthesia have increased the number of procedures that can be safely performed outside the hospital inpatient surgery department, but how can same-day surgery programs take on the more complicated cases within the parameters of outpatient surgery?

The best answer for many centers may be the addition of a unit designed to handle overnight stays. If you are considering this move, be aware of the benefits you will enjoy as well as the obstacles you might face, say experts interviewed by *Same-Day Surgery*.

A major benefit of adding recovery care or short-stay to your same-day surgery program's service mix is the ability to attract a more diverse mix of cases, physicians, and patients, says **Joni Steinman**, managing principal, AUSMS Healthcare Consultants in San Diego.

The ability to keep patients for 23 or more hours gives a surgery program manager a chance to accept more complex cases, but you need to plan carefully to address the financial and regulatory issues, she says.

EXECUTIVE SUMMARY

The ability to keep patients longer for observation and monitoring provides the opportunity to accept more complicated cases. Managers planning recovery care should address the following issues:

- Understand your state's regulations regarding recovery care.
- Plan to accept non-Medicare surgical patients because Medicare does not allow recovery care within its definition of outpatient surgery.
- Educate your payers as to the significant savings they can enjoy by using a same-day surgery program with recovery care.

The first step in setting up a recovery care unit is to decide what you want to accomplish, says Steinman.

"What level of care do you want to provide? What type of setting do you want to offer?" she asks. Once you've figured out what cases you'll handle, how long you want to keep patients, and what ancillary services you'll provide, look at your state regulations from the perspective of what you want to do, she adds.

It is tough to say which states permit recovery care, says Steinman. "Some states permit 24-hour care in licensed surgery centers but don't have any regulations to govern 'overnight' stays, while others do have governing regulations." **(See regulatory challenges, p. 103.)**

Only Illinois has an active demonstration

project that permits designated sites to keep patient up to 72 hours, she adds.

The Recovery Care Survey 2000 conducted by the Federated Ambulatory Surgery Association (FASA) in Alexandria, VA, shows that the state in which a same-day surgery program is located plays a significant role as to whether the program offers recovery care, says **Kathy Bryant**, JD, executive director of FASA.

"Although 34 states have recovery care centers in 1999, 50% are in four states [California, Texas, Indiana, and Colorado]," she says.

Colorado leads the country with 63% of freestanding ambulatory surgery centers offering recovery care centers, says Bryant. The FASA study looks only at freestanding surgery centers with recovery care centers. **(See survey results, p. 106.)**

Some centers are simply one or two beds designated as 23-hour care; others are separately licensed facilities that are adjacent to the outpatient surgery center. There are also special units designated within hospitals as short-stay or surgical recovery care, Steinman says.

Another approach to set up a recovery care center for freestanding centers, is to license the recovery care center as a hospital, says **Jackie Street**, chief executive officer of the Idaho Falls (ID) Recovery Center. Her surgery center is not licensed as a hospital, but the attached recovery care center does have that license.

When you are licensed as a hospital, the building codes are stricter and the staffing requirements are well-defined," explains Street.

"In our state, there are no staffing requirements for an ambulatory surgery center, but as a hospital, our recovery care center must have an RN on duty at all times," she points out. "Our staff also has to have the same level of training to handle patient emergencies, such as codes, as hospital staff."

A major obstacle for Street's application was the threat to the local hospital's Medicare status, because the recovery care center and the hospital are only two miles apart. Because Medicare's definition of outpatient surgery does not allow a recovery care stay, Street's recovery care center cannot accept a Medicare outpatient surgery patient; however, her center can offer other services such as chemotherapy and infusion services to Medicare patients.

This ability to offer some services raised the concern that hospital services were duplicated within a small geographic area and were reducing the cost efficiency of services to Medicare patients, she says.

"We had to make it clear that although we would be eligible to provide service for some Medicare patients, we could not duplicate hospital services such as inpatient care, emergency service, and inpatient surgery," she says.

Once it was clear that the Idaho Falls Recovery Care Center was operating with a hospital license that was very limited in scope of service, the center received Medicare approval.

Even if your state regulations are not amenable to recovery care centers now, be sure to look at them periodically, says Steinman. "There are changes from time to time that may be related to changes in your state's administration."

Monitor regulatory issues through involvement in state associations, informal networks, and national organizations, she suggests. "Stay on top of the proposed changes or opportunities to re-address the issue so you can make changes when possible." ■

SOURCES

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Be persistent against regulatory roadblocks

Even if you are located in a state with fairly clear rules written to govern recovery care centers, there might be gray areas, says **Carol Blanar**, administrator and director of nursing for Sagamore Surgical Center in Lafayette, IN.

In 1996, when Blanar started planning for her center's recovery care service, she was told that her center could keep patients up to 24 hours and it didn't matter when the clock started.

"We decided that we would start the clock

when the patient arrived in the recovery care center, but after we built our five overnight suites, the state then said the clock starts as soon as the patient arrives at the surgery center," says Blanar.

Starting the 24-hour clock at the patient's arrival is impractical because it doesn't allow for delays such as the prior case running long, the surgeon arriving late, or delays in lab results, she explains.

You also run into the problem of patients who checked in at 7 a.m. for surgery having to go home at 7 a.m. the next morning, says Blanar. "Physicians may not be able to see them early enough to discharge them by 7 a.m., she says. "Most patients want something to eat, or they may not be able to get a ride home that early."

After fighting to change the rules for three years by lobbying legislators, meeting with key people within the proper departments and by garnering support from all surgery centers, Blanar says she has won. "We can start the clock as early as the patient's arrival but no later than when they enter the operating room."

Blanar who is president of the Indiana Federation of Ambulatory Surgery Centers, has begun lobbying efforts to support proposed legislation that will allow stays of 48 hours to 72 hours within Indiana recovery care centers.

State may try to protect hospitals

While Blanar ran into trouble with different interpretations of the state statutes, **Trent Kaufman**, executive director of Gem City Bone and Joint, an orthopedic same-day surgery center in Laramie, WY, faced a more serious challenge when he contacted the state department that oversees licenses for health care facilities.

"I was told that they would do everything possible to stop us from setting up a recovery care center because it would threaten the smaller hospitals in the state," says Kaufman.

Gem City Bone and Joint is located in an area that is not just rural, but frontier, he explains. The organization has seven clinics statewide that feed into the primary facility in Laramie, he says.

"While the local hospital claimed we would be stealing their patients, the reality is that 70% of our patients using the recovery care center come from outside Laramie and would have gone outside Wyoming for their hospital stay," he says.

"Our argument was that we could keep Wyoming patients in Wyoming by offering this service," Kaufman explains.

Although it took one year and an opinion from the state attorney general's office for a final ruling, Kaufman was able to set up his recovery care center.

Requirements differ from state to state

"We were required to have a 1½-hour firewall between the two areas; we discharge patients from the surgery center and admit them to the recovery center; and we cannot float staff from one area to the other," says Kaufman.

Hospital-based programs have fewer regulatory challenges, but if you're in a state with certificate of need requirements, you may have to redesignate beds or ask for additional beds to set up a recovery care center, says **Debbie Proctor** RN, department head of the outpatient center and surgical admissions center at Promina DeKalb Medical Center in Decatur, GA.

"When we set up our 23-hour stay unit in 1992, we used existing beds, but we redefined them as short-stay unit beds," explains Proctor.

If the facility had not had bed count available to transfer to the short-stay use, the hospital would have needed to submit a certificate of need application for additional beds, she adds. ■

Mixed financial results for extended recovery care

Financially, recovery care centers might not generate great profits, says **Trent Kaufman**, executive director of Gem City Bone and Joint, in Laramie, WY.

"After rent, staffing, and other overhead costs, it is difficult to break even within our recovery care center," he says. "But when you look at the surgery center side of the business, we are doing well with the cases we can accept now as compared before the recovery care center's opening.

Being able to keep patients longer than 23 hours enables a same-day surgery program to handle more complicated cases such as total knee or joint replacements, mastectomies, and breast reconstruction, says **Mark Mayo**, facility director for Valley Ambulatory Surgery Center in St. Charles, IL, and executive director of the Illinois Freestanding Surgery Center Association. These

cases require longer stays for observation or monitoring and might generate higher levels of reimbursement, adds Mayo, who is consulting editor for *Same-Day Surgery*.

Even with the ability to handle more complicated cases, your recovery care center won't see Medicare surgical patients, he says. Because Medicare rules require patients who will need observation and monitoring for an extended stay to have surgery at a hospital, recovery care centers don't see Medicare surgery patients. This might change, says Mayo.

Mayo and representatives from other same-day surgery associations will meet soon with the Medicare Payment Advisory Committee (MedPAC), a Washington, DC-based advisory group to Congress. The group will present information to the MedPAC staff to use as they develop a report on the efficacy of post-surgical care centers that Congress requested, says Mayo. The report should be completed by the end of 2000, he adds.

If the findings are supportive of surgical recovery care centers, the door may open for same-day surgery programs and associated recovery care centers to accept Medicare patients for a greater number of procedures, says Mayo.

Communicate your plans

In the meantime, let your key third-party payers know that you are planning a recovery care center, says **Joni Steinman**, managing principal for AUSMS Healthcare Consultants in San Diego.

Reactions to recovery care vary from region to region, says Steinman. Let your payers know before you open what you are planning, why you are offering the service, and how it will benefit their members and their plan, she says.

"Focus your initial talks with payers who are receptive to new ideas and provide factual backup that shows how you will provide a higher nurse-to-patient ratio, a lower cost of care, and a more enjoyable experience for the patient," Steinman suggests.

Costs are significantly lower with recovery care centers, says Steinman. In an unpublished study conducted by AUSMS Health Consultants, the cost of a hysterectomy in a same-day surgery center with a recovery care center was $1,810 vs. a hospital cost of $3,130.

Cost of a shoulder manipulation at the surgery center and recovery care center was $2,892 as compared to $5,472 in a hospital setting. Offering payers proof of the savings they can expect can be accomplished by surveying local hospitals and comparing their numbers to your costs, Steinman says.

Also pay attention to when your payers want you to identify the patients as recovery care admissions, suggests **Debbie Proctor**, RN, department head of the outpatient center and surgical admissions center at Promina DeKalb Medical Center in Decatur, GA.

"At first, we let physicians schedule patients for our short-stay unit at the time they scheduled the surgery," says Proctor. Payers, who don't want patients staying overnight unless really necessary, objected to this practice. Now the decision to send the patient to short-stay is made in the post-anesthesia care area, she says.

Educate payers

Educating your payers is important, says **Jackie Street**, chief executive officer at Idaho Falls (ID) Recovery Center. "We had a difficult time at first with our payers because, as a recovery care center licensed as a hospital, we didn't fit the traditional definition of a hospital for the payers," she says.

One of the main problems was the flat fee charged by Street's facility. "Everyone wanted an itemized bill, and Medicare requires it," she says. Because Street's facility accepts Medicare patients for nonsurgical procedures such as

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chemotherapy, IV therapy, and blood transfusions, she switched to an itemized bill to accommodate Medicare.

"I was making progress with my other payers by showing them how an itemized bill would require additional staff and overhead charges to generate the bill that would increase the overall amount, but we are just too small to fight Medicare," she says.

Although many third-party payers follow Medicare's lead in determining what procedures to cover and where they should be performed, a same-day surgery manager should not let the lack of Medicare reimbursement stop an investigation into the viability of a recovery center, says Steinman.

There are many benefits to a recovery care center for same-day surgery programs, and education of third-party payers can result in reimbursement of recovery care, she says. Setting up a recovery care center now can give you a competitive advantage if recovery care centers are approved for Medicare patients, Steinman points out.

Even without Medicare patients, your surgery center can benefit financially from new patients that can be served, says Steinman.

"You can attract a more diverse case load, a different patient population, and new surgeons if you offer the capability of handling more complex cases," she explains. ■

Recovery Care Surgical Mix

Procedure Types	1995	1999
Orthopedic	35.9%	28.8%
Plastic Surgery	25.4%	25.4%
General Surgery	8.9%	14.39%
ENT	8.5%	14.3%
Gynecology	16.6%	10.7%
Urology	1.1%	2%
Dental	0.5%	1.7%
Neurosurgery	0.2%	1.2%
Other	0.2%	0.6%
Podiatry	0.2%	0.4%
Ophthalmology	0.8%	0.3%
Pain Block	0.6%	0.2%
Gastroenterology	1.1%	0.01%
Total	**100%**	**100%**

Source: Federated Ambulatory Surgery Association. Post-Surgical Recovery Care Database. Alexandria, VA; 1999.

Survey by FASA looks at recovery care

Some surprising findings

While most same-day surgery managers might think that their centers need to perform a high number of procedures per year to support a recovery care unit, that is not the case, says **Kathy Bryant**, JD, executive director of the Federated Ambulatory Surgery Association (FASA) in Alexandria, VA.

"One of the most surprising findings of *Recovery Care Survey 2000* was how many small ambulatory surgery centers had recovery care units," says Bryant. "Sixteen percent of the programs that had recovery care performed fewer than 1,000 procedures per year."

Data for benchmarking, advocacy efforts

The 2000 survey gathered data from 119 free-standing surgery centers that offer post-surgical recovery care of up to 72 hours. The questionnaire collected information that included average charges, nurse-to-patient ratios, lengths of stay, typical procedures, and ownership. The survey information will be used in two ways, according to Bryant.

"We will share the information with FASA members and other surgery center managers who can use it as a benchmarking tool," she says. If someone doesn't yet offer recovery care, this survey can be a resource in the decision-making process, she adds.

"We will also use the information in advocacy efforts with groups such as MedPAC [Medicare Payment Advisory Committee in Washington, DC]," Bryant says. **(See story on financial picture, p. 104.)**

The 2000 survey shows that the average charge for recovery care is $566 per day compared to the average charge of $507 in FASA's first recovery care survey in 1996. Orthopedic procedures account for the largest volume of recovery care (28.8%), with plastic surgery representing about 25% of recovery care procedures. **(See box at left.)**

General surgery and ear, nose, and

RESOURCE

One copy of the *Recovery Care Survey 2000* is provided free to each member facility of the Federated Ambulatory Surgery Association (FASA). Other copies can be ordered at a cost of $50 for FASA members and $75 for nonmembers. To order, contact:

- **FASA**, 700 N. Fairfax St., Suite 306, Alexandria, VA 22314. Telephone: (703) 836-8808. Fax: (703) 549-0976. E-mail: FASA@fasa.org.

throat procedures each represented less than 9% of recovery care cases in the 1996 survey, but they grew to more than 14% each in the 2000 survey.

Of the top five volume specialties in the 1996 survey, only gynecology dropped from 16.6% to 10.7% in the 2000 survey.

The specific procedures that most often led to recovery care are abdominoplasty, anterior cruciate ligament reconstruction, face lift, laparoscopic cholecystectomy, and breast reduction. ■

OIG won't seek penalties for outpatient PPS errors

HCFA offers resources to aid implementation

The Office of Inspector General (OIG) has announced that it will not seek civil or criminal penalties for innocent errors, mistakes, or even negligence committed by outpatient providers during the implementation of the outpatient prospective payment system (PPS).

"The government's primary enforcement tool, the civil False Claims Act (FCA), covers only offenses that are committed with actual

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knowledge of the falsity of the claim, reckless disregard of the truth or falsity of the claim, or deliberate ignorance of the truth or falsity of the claim," said **June Gibbs Brown**, inspector general, in a June 23 letter addressed to the American Hospital Association.

The OIG listed some examples of mitigating factors that the agency will consider when deciding whether the impose civil or criminal penalties. Those factors include:

- the clarity of the regulation;
- the complexity and novelty of the billing system;
- guidance from the Health Care Financing Administration (HCFA) and fiscal intermediaries;
- the extent to which the provider has attempted to understand the regulation;
- the quality of training provided for billing personnel;
- whether the provider has an effective compliance program.

The outpatient PPS is scheduled to be implemented for hospital outpatient departments on Aug. 1. The ambulatory surgery center PPS is scheduled to be published in November 2000 and implemented in April 2001.

Other news

If a hospital hasn't had an off-campus same-day surgery program designated as provider-based, but the hospital treats it as provider-based, the hospital might not be required to apply for provider-based status in order to submit claims after Oct. 10, 2000, according to the McDermott, Will, and Emery law firm.

However, if HCFA challenges the provider-based status of the same-day surgery program, the hospital must demonstrate that the program meets the criteria to be designated as provider-based. Otherwise, HCFA can recoup past payments, according to the firm.

HCFA has set up a reference guide for the outpatient PPS on its Web site (www.hcfa.gov/medlearn/refguide.htm). The reference guide includes a booklet of "Frequently Asked Questions and Answers," which also are available in printed form.

(For an excerpt of those questions and answers, see the Medicare Learning Network insert, enclosed in this issue.)

At press time, HCFA was setting up an outpatient PPS listserve and links to local fiscal intermediaries on its Web site. ■

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. (See "Some single-use devices can be reprocessed safely, GAO report says," and "Survey by FASA looks at recovery care.")
- Describe how those issues affect nursing service delivery or management of a facility. (See "Be persistent against regulatory roadblocks.")
- Cite practical solutions to problems or integrate information into their daily practices, according to advice from nationally recognized ambulatory surgery experts. ■

Medicare Learning Network for Outpatient PPS Frequently Asked Questions and Answers (Excerpt)

I. BENEFICIARY SERVICES

Question: Will the Health Care Financing Administration (HCFA) be revising the 2000 Medicare beneficiary handbook or mass mailing a supplemental brochure that describes the revised coinsurance calculations?

Answer: Updated information will be included in the *2001 Medicare Handbook* that will be mailed to all beneficiaries in October 2000. More detailed information is available upon request in a separate booklet that can be mailed free of charge if a beneficiary requests additional information.

II. CLAIMS PROCESSING/ BILLING

Question: Is it appropriate for a hospital to bill for visits and procedures that are furnished by nonphysician practitioners? In many hospitals, nurses furnish outpatient services such as counseling sessions, preoperative evaluations, triage sessions, and urinary catheter placements. Also, some hospital-based physical therapists perform nonexcisional wound debridements, and in other hospitals physical and occupational therapists apply casts and strapping devices.

Answer: If the nonphysician practitioners (e.g., nurse practitioners, therapists, etc.) are employees of the hospitals, then these practitioners cannot bill for visits and procedures. As in the case above, these nonphysician practitioners would not be paid for counseling sessions, pre-op evaluations, triage sessions, or urinary catheter placements. The services/procedures provided would be bundled in the visit. However, if the nonphysician practitioner is an independent practitioner, he/she can bill for separate services (e.g., diabetic education), which would be paid separately.

Question: Should a hospital bill the HCPCS Level II code V2785 (corneal tissue processing) if a corneal transplant procedure is terminated before the corneal transplant is completed, but after the donor cornea has been inserted? Or should the hospital simply report the CPT corneal transplant code with the modifier -74 (discontinued surgery after the administration of anesthesia)?

Answer: The hospital should report the CPT corneal transplant code with a modifier -74.

Question: How should the units of service be reported when there are two modifiers reported next to a CPT code?

Answer: The units of service are independent of the modifier on the claim. It should be reported next to the service code.

Question: Please specify by name which prosthetics would be billed by the hospitals under HCPCS Level II code L8699 (prosthetic implant, not otherwise specified). For example, would this code be used to bill for intracoronary stents, and other items without a specific code that are listed in the Balanced Budget Refinement Act (BBRA) conference report?

Answer: To obtain this information, please review the pass-through and new technology list, which is featured on HCFA's Web page (www.hcfa.gov).

Question: How will fiscal intermediaries (FIs) be able to determine that the ordering physician is involved since the claim reports the attending physician?

Answer: It is not necessary to make a distinction.

Question: On a 12X type of bill, which laboratories are included vs. excluded?

Answer: Pathology and blood banking are the primary laboratories included. Additional information can be found in CR1141.

Question: If a claim is submitted with condition code 20 or 21 with both covered and noncovered charges, will it reject?

Answer: Yes.

Question: Should demand bills be submitted by the provider with the charges indicated in the covered and total charge fields or the noncovered and total charge fields?

Answer: The charges should be indicated in the noncovered and total charge fields.

Question: Will Value Code 17 be filled out by the provider or the FI?

Answer: It will be filled out by the FI.

Question: How long will it take to get ambulatory payment classification (APC) claims paid? Providers are concerned that FIs will be backlogged and delay payments even after claims can be processed.

Answer: Contingency planning has begun and will be in place to help providers through this transition period. More details regarding the contingencies will soon be available on the HCFA Web site.

Question: Should corneal tissue be reported with charges or acquisition costs?

Answer: It should be reported with charges.

Question: How will services be treated when HCFA creates two new codes in place of a CPT code? A specific example is for stereotactic radiosurgery (CPT code 61793). (This issue is discussed on p. 18,469 of the April 7, 2000, *Federal Register*).The rule says that HCFA has created two codes, GO173 and G0174, in place of 61793. The problem is that these codes are not in the CPT manual and thus hospitals will have to go in and manually adjust their systems to add in these new codes. If they code CPT code 61793 on a claim, it appears that it will be rejected (note that code 61793 has a status code of "E" in Addendum B, indicating it has been replaced). It would be nice if the grouper could make this conversion for hospitals (i.e., if a hospital coded 61793, the grouper would automatically convert it to a new code), but I don't think this can be done since there are two new codes and the grouper wouldn't know which one to assign. This seems like a significant burden for hospitals. I think it is important for hospitals to know which other CPT codes this has happened to.

Answer: To our knowledge, this has not happened with any other CPT codes. At this time, this is the only code of its kind.

Question: Why are there no HCPCS Level II "S" codes listed in the Addendum B of the April 7, 2000, *Federal Register*?

Answer: Level II S codes are non-Medicare codes.

Question: Would it be appropriate for a hospital to append a modifier -25 to a CPT medical visit code, in order to be paid for a medical visit that is rendered in one clinic when on the same day in another hospital department, the same patient had an "S" or "T" indicator procedure performed? This appears to be the only way that a hospital would generate payment for both the medical visit and the procedure / surgical service.

Answer: The hospital must use a combination code that consists of both the visit code and the procedure code with a modifier -25.

Question: Do the finger and toe modifiers apply to radiology CPT codes 73160 and 73660? These codes state "finger(s)" and "toe(s)" in their description, thus it appears as though they already classify one or more fingers, one or more toes being X-rayed on a single hand or a single foot. This should be clarified as soon as possible since many hospitals are planning to report each finger and each toe that is X-rayed thus triggering a plain film APC for each finger and each toe on a single hand / foot.

Answer: The toe modifiers would not apply to radiology CPT code 73660. When determining whether modifiers should be used for the toes and / or fingers, please review the following criteria:

1. Was the code used to report another service? If the answer is **YES**, then use the code to describe the service. If the answer is **NO**, then review the code descriptor.
2. Is the code descriptor singular or plural? If it is singular, use the procedure code with the specific modifier. If it is plural and the code descriptor includes more than one X-ray, use the CPT code to appropriately describe the procedure. For example, a patient comes in for a broken middle finger of the left hand. The physician orders an X-ray of the middle finger. The CPT code assigned to this procedure would be 73140-F2. However, if the patient comes in for two broken fingers (middle digit and second digit of the left hand), and the physician orders an X-ray of both digits, then the CPT code assigned would be 73140. This one CPT code would be used for both digits.
3. Determine the anatomic site. If a procedure was done on a specific site but the CPT code descriptor describes a general site, then use a modifier.

Question: Can a hospital use as an official source for the laterality status of a CPT code the bilateral status indicator that is listed in the Medicare Physician Fee Schedule Database at www.hcfa.gov / stats / pufiles.htm#carrpuf.

Answer: Yes.

Question: Does the APC 090 include the pass-through payment for a pacemaker generator? There is no HCPCS Level II code provided for hospitals to report a pacemaker generator, or should the hospitals report the L8699 for a pacemaker generator?

Answer: This information can be obtained by reviewing the pass-through and new technology list that is featured on HCFA's Web page (www.hcfa.gov).

Question: Does an observation room have to have a HCPCS code?

Answer: HCPCS are not required; however, charges are required.

Question: Do you need charges with each surgical CPT code? If it is an ER charge, does the charge go on the line with the surgical HCPCS code?

Answer: When multiple surgical procedures are performed at the same session, it is not necessary to bill a separate charge for each procedure. It is acceptable to bill a single charge under the revenue code that describes where the procedure was performed (e.g. operating room, treatment room, emergency

room, etc.) on the same line as one of the surgical procedure HCPCS codes and bill the other procedures using the appropriate HCPCS code and the same revenue code, but with "0" charges reported in the charge field.

If a surgical procedure is performed in the emergency room, the charge for the procedure must be billed with the emergency room revenue code. If an ER visit occurs on the same day, a charge should be billed for the ER visit and separate charge should be billed for the surgical procedure(s) performed. (Although, as described above, a single charge may be billed for all surgical procedures, if more than one is performed in the ER during the same session.)

We understand that some hospitals currently bill a single ER visit charge, which includes charges for any surgical procedures that are performed in the ER at the time of the ER visit. Under the outpatient prospective payment system (OPPS), HCFA will require that hospitals bill separate charges for ER visits and surgical procedures; however, HCFA will postpone this requirement until Jan. 1, 2001, so that hospitals will have sufficient time to separate charges, if they do not currently do so. To ensure proper payment under the new system, hospitals must bill separate HCPCS codes for the ER visit (using modifier 25) and the surgical procedure(s) even if they do not separate charges between ER visits and surgical procedures during the remainder of calendar year 2000.

Question: If three EKGs are performed, will all three be paid using modifier 76?

Answer: Yes.

Question: Do type "S" procedures that have modifiers get discounted?

Answer: Type S procedures are not subject to multiple procedure discounting (with the exception of aborted procedures). In other words, if a type S procedure is billed with modifier 50, the procedure should receive a 200% payment because it is not a type "T" and is, therefore, not subject to discounting.

Question: In many smaller, rural hospitals, the recovery rooms close at a certain time. The patients remaining in recovery are then moved to an observation area to complete their recovery. Please explain how this should be billed under OPPS.

Answer: Both recovery room and observation costs are packaged into the payment rate for the surgery. There is no separate payment. If a hospital moves patients into observation in the circumstance described, it is not a covered observation service. Observation has to be ordered on a patient-specific basis. Outpatient observation must be for the purpose of determining whether an individual patient will recover sufficiently to be discharged or must be admitted; it is not to be used as a substitute for recovery room services. If that individual determination is made, the charges for observation can be shown on the claim, and those charges will be used in setting the price of the procedure when APC rates are updated. There is still no separate payment for the observation.

Question: Based on what we learned in the reimbursement training session, drugs will be paid at 95% of the average wholesale price (AWP), but the first claims example shows revenue code 250 with no HCPCS code. Should we train the providers to use revenue code 636 and HCPCS codes for drugs, or is this not a claims issue?

Answer: Only drugs and biologicals approved for transitional pass-through payment will be paid at 95% of the AWP. An initial list of these items is included in Addendum K of the April 7, 2000, outpatient PPS final rule, and an updated list was posted to the HCFA Web site on May 12, 2000. Most drugs are packaged into the APC payment rates and are to be billed using revenue code 250.

A HCPCS code is not required for packaged drugs. Certain high-cost drugs that are not packaged (e.g., tissue plasminogen activator / activase or TPA) but are paid as separate APCs as well as drugs approved for transitional pass-through payments that will be paid based on the AWP must be billed with revenue code 636 and the appropriate HCPCS code.

Question: Regarding observation services, if for some reason these services are denied, what impact would this have on reimbursement since such services are packaged?

Answer: The denial would not affect the APC payment because observation services are packaged. However, the decision would impact outlier and transitional corridor payments.

Question: If there is an ER visit and procedures are performed, such as minor surgical procedures, will all services be billed as line items with revenue code 450 or will each service be reported by the appropriate revenue center?

Answer: Report the appropriate revenue center code for each service based on where the service was performed. Surgical procedures can be billed in revenue code 450.

Question: Could you please document in writing which of the Part B inpatient services are and are not subject to OPPS?

Answer: The following services are paid under outpatient PPS when provided to an inpatient who does not qualify for Part A payment:

- diagnostic X-ray tests and other diagnostic tests (excluding clinical diagnostic laboratory tests);
- X-ray, radium, and radioactive isotope therapy, including materials and services of technicians;
- surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations (splints and casts, etc., include dental splints);
- implantable prosthetic devices;
- pneumococcal vaccine and its administration, hepatitis B vaccine and its administration;
- certain preventive screening services (pelvic exams, screening sigmoidoscopies, screening colonoscopies, bone mass measurements, prostate screening.)

NOTE: Payment for some of these services is packaged into the payment rate of other, separately payable, services.

The following services are paid under other payment methods when provided to an inpatient who does not qualify for Part A payment:

- clinical diagnostic laboratory tests, prosthetic devices other than implantable ones and other than dental which replace all or part of an internal body organ (including contiguous tissue), or all or part of the function of a permanently inoperative or malfunctioning internal body organ, including replacement or repairs of such devices;
- leg, arm, back, and neck braces, trusses, and artificial legs, arms, and eyes, including adjustments, repairs, and replacements required because of breakage, wear, loss, or a change in the patient's physical condition;
- outpatient physical therapy, outpatient occupational therapy, and outpatient speech pathology services;
- ambulance services;
- screening Pap smears, screening fecal occult blood tests, and screening mammography.

Question: Can hospitals HCPCS code all drugs and biologicals packaged using revenue code 636, if they choose, or are they limited to the published list?

Answer: Packaged drugs can be billed with revenue code 250. Packaged drugs billed in revenue Code 250 may be HCPCS coded. Drugs that will receive separate APC payments or transitional pass-through payments must be billed with revenue code 636 and HCPCS coded.

Question: Are critical access hospitals (CAHs) exempt from the codes that are deemed inpatient services?

Answer: Yes. CAHs, however, are subject to the observation policy, which states that observation is not a means to perform inpatient surgery on an outpatient basis. The FIs may look to the inpatient list to assist them in local medical review decisions.

Question: What about revenue code 760, post-procedure radiology and ASC? This is routine monitoring time. Revenue code 760 would be used if complications arose beyond the "routine" for that particular procedure time. Revenue code 762 is true observation not "routine" monitoring, so what about 760?

Answer: The revenue codes 760-769 are packaged, whether they represent treatment room charges or observation charges.

Question: With the delay in the effective date to 8/01/00, we assume this means service dates on/after 8/1/00. Is this true?

Answer: Yes, the delay will apply to claims with dates of service 8/1/00 and later.

Question: Will providers be given an extension to file elections for reduced coinsurance to 7/01/00 as a result of the delay?

Answer: Yes, providers will be given an extension to file elections for reduced coinsurance to 7/01/00 as a result of the delay.

Question: Will HCFA be publishing this delay to FIs officially through the CR process?

Answer: Yes, HCFA will be publishing the delay to FIs officially through the CR process. It will be reflected in CRs 1220 and 1229.

III. COVERAGE

Question: Is there a new designated drugs and biologicals list coming out soon?

Answer: HCFA hopes to have this out in June. (Question and answer posted 5/24/00.)

Question: Why weren't coronary stents included under devices?

Answer: Devices that came on the market prior to 1996 were packaged in with the APC. However, devices that came on the market after 1996 that applied for new technology and were approved were issued a c-code. For a list of new technology devices, see HCFA's Web page at www.hcfa.gov.

IV. MEDICAL REVIEW

Question: Does Medical Review need to perform a complex medical review on claims suspended due to the OCE partial hospitalization edits?

Answer: Additional information on medical review will be included in the clarification of PM A-00-23 that will be released shortly. The OCE PHP edits do not absolutely require complex review if a determination to pay can be made without review or with only routine review.

Question: Since observation services are bundled into APC payments, does Medical Review review these services for medical necessity? If the observation room services are not medically necessary, does Medical Review deny the line and send the claim through the OCE again? Observation is a major problem. PRO groups are looking at this in their sixth scope of work.

Answer: When OPPS begins, Medical Review should not focus their review on observation rooms, but should review them for medical necessity if pulled during random review. If the observation services are not reasonable and necessary, they should still be denied. All claims will go through the OCE again after medical review, however, denial of observation room changes does not affect the reimbursement. These denials will affect future APC rates.

Question: While HCFA states this will not affect workload, with claims returning to the OCE after MR review, there is the increased ability to less workload due to claims being errored out by the OCE. A workload adjustment should be considered. Another reason for workload adjustment is the increased PHP claims that will come to MR for review. These are very time-consuming.

Answer: We recognize the shift in workload due to PPS and will be monitoring closely.

V. PAYMENT

Question: Is the average wholesale price for drugs, biologicals, etc., going to be from a frozen point in time or will they be updated?

Answer: They will be updated on an annual basis. January 2001 will be the next time it is updated. When it is updated, HCFA will make the list of average wholesale prices available.

Question: Payment rates on the *Federal Register* go to two decimal places, but the downloadable spreadsheet goes to five or six places. Which one will actually be used?

Answer: Two decimal places will be used.

Question: How are new providers treated for TOPS?

Answer: There are default rates available for the new providers.

Question: Where does the deductible get applied first: the APC services or the non-APC services?

Answer: It is applied to the APC services first.

Question: Is the 776 coinsurance cap wage adjusted?

Answer: It is a flat amount and not wage-adjusted.

Question: HCFA's Web site contains an updated list of transitional pass-through items and new technology services under OPPS. The provider is wanting a more complete definition of the C codes listed so they can determine whether they have those products. Where did these C codes come from? We can't locate them in the HCPCS level II manual.

Answer: We (policy staff and coders in CHPP) assigned the C codes in a very short period in April. Especially for devices, they are too short to be meaningful. We have written long descriptors, and they are going to be on the HCFA Web site shortly. They will include more information about the manufacturer, type of device, and model.

Please forward additional questions to OPPSquestions@hcfa.gov.

Source: Health Care Financing Administration, Baltimore. Web: www.hcfa.gov/medlearn/faqs.htm.