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Ambulatory Surgery Centers

Some proposed Medicare rules worry ASCs

If certain proposed rules regarding Medicare conditions for coverage (CFC) take effect, ambulatory surgery centers (ASCs) will face more complex—and some say unfair—regulatory criteria.

The Centers for Medicare and Medicaid Services (CMS) plans to release final rules later this year, to take effect in January 2009. Until then, ASCs should focus preparations on changes that policy experts consider most likely to be implemented.

According to Susan Hollander, vice president of operations at National Surgical Care, Dallas, a company that operates surgery centers, most of the revisions are needed and long overdue. Since the rules were issued in 1982, CMS has become the largest health care payer in the US, and the number of ASCs in the program has grown to 4,600.

"They have not kept up with the times," she said of the regulators.

In a presentation at the May conference of the newly merged ASC Association (ASCA) in San Antonio, Texas, she warned that stricter wording and undefined terms in some of the changes might have unpleasant consequences for ASCs.

CMS requires ASCs to meet Medicare standards to qualify for reimbursement. It certifies compliance with onsite inspections by one of 4 accrediting organizations: The Joint Commission; American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF); Accreditation Association for Ambulatory Health Care (AAAHC); and the American Osteopathic Association (AOA).

According to CMS, the proposed revisions reflect changes in ASC organization, procedures, and quality assessment since 1982. The revisions were proposed in 2007, and the public comment period ended that October. Before issuing a final rule, CMS will make modifications based on comments it received, including those from the ASCA.

CMS is proposing to revise 3 existing conditions and to create 3 new conditions as follows:

Revised conditions

- Governing body and management
- Evaluation of quality, renamed Quality Assessment and Performance Improvement (QAPI)
- Laboratory and radiologic services.

New conditions

- Patient rights
- Infection control
- Patient admission, assessment, and discharge.

Defining "ambulatory"

For purposes of coverage, the current ASC definition is a surgical facility whose patients do not require hospitalization. CMS proposes to tighten that definition to mean a patient may not be kept and monitored past 11:59 pm on the day of surgery, which the new rule considers an "overnight stay." Hollander said the term is particularly problematic in states that permit and pay for overnight stays. It also fails to define such terms as "active monitoring" and "qualified personnel." Patients who might be kept for

observation would then be forced to go home early, or the stay would likely be transferred to a hospital.

She suggested changing the language to "expected normal recovery" within 1 day and not disqualifying a procedure if the patient needs to stay longer.

The implication for ASCs, she noted, is that "doctors could do more surgery in hospitals, in case [patients] need to stay past midnight." Or surgery centers would stop participating in Medicare because otherwise if any patient stayed past midnight, the center would be in violation of the CFCs.

The new rule poses an opposite problem in defining disaster plans. In a new section, ASCs "must maintain a written disaster preparedness plan that provides for the emergency care of patients in the event of fire, natural disaster, functional failure of equipment, or other unexpected events or circumstances that are likely to threaten the health and safety of its patients." ASCs must coordinate their plans with government agencies and conduct drills.

Because surgery centers vary widely in size and location, Hollander said she was worried that the scope of the wording will result in hardship for some. "There are not snowstorms in Florida," she noted. She said she would like to see ASCs given more leeway in developing plans specific to their circumstances. Here and elsewhere, CMS calculates the cost of meeting conditions based on average personnel and salary assumptions, and these are not realistic for all. CMS estimates the cost of developing a disaster plan to be only $184.

There is little argument that the new quality assessment rule (estimated cost: $2,400) is necessary, according to Hollander: "They are really interested in changing and improving patient care." The current brief rule would be replaced by a detailed requirement that includes data collection, analysis, and design of plans for improvement of outcomes and reduction of errors.

Imaging rule goes too far

One area where ASCs should be vigilant in responding to implications of the proposed rules is in radiologic services.

"This is going to change a lot if the regs go through," Hollander warned. In essence, the surgery center would be treated more like a hospital with a full-service imaging department.

Most ASCs use X-rays or other imaging devices in the course of a procedure—to check implants, for example. They rarely use them for diagnosis or therapy.

However, the new rule would require that a surgery center using portable X-ray equipment be certified as a supplier of portable X-ray services.

That means licensing of the supplier, equipment, and staff; supervision by a qualified physician, meaning one qualified to diagnose from X-rays; and safety and administrative requirements more applicable to imaging centers.

Parts of the new rules are inconsistent as well. In the area of equipment safety, most ASCs now check lead aprons every year, but the new rule would relax that to every 2 years. At the same time, while most ASCs check radiation badges quarterly, the new rule would increase that to monthly.

Hospitals actually have more flexibility in determining the qualifications of radiology technicians, Hollander noted.

Rights and wrongs

Like quality and safety, there is no argument that patients' rights should be acknowledged and respected by caregivers. It is the details of the proposed rule that could cause hardship for an ASC and even, as Hollander demonstrated, result in less patient care.

The patient rights rule is a new condition of coverage. It requires "verbal and written notice" to patients of their rights prior to treatment, in a language the patient understands.

While ASCs already post information about patients' rights, the new rule requires oral explanation in the patient's language, which in some cases will mean calling in an interpreter or using a medical phone-translation service.

According to CMS, the average ASC needs to hire an interpreter 3% of the time.

Hollander said that estimate "assumes the language line is always efficient." The rule would be especially hard on smaller ASCs, which do not have lawyers on staff to explain advance directives and other complex elements of patients' rights.

Another provision calls for documentation, investigation, and reporting of all patient "grievances." Hollander said she feared that clause could be interpreted to cover every patient complaint. Not all complaints are based on discrimination, neglect, or abuse, the usual subjects of grievances. Patients sometimes complain because of unrealistic expectations or inadequate communication, and those complaints can be resolved without resort to the legal process.

Ownership disclosure

The section that Hollander considered most unfair to ASCs, however, addresses disclosure of ownership. It reads, "[The ASC must] disclose, if applicable, physician financial interests or ownership in the ASC facility in accordance with part 420 of this subchapter. Disclosure information must be in writing and furnished to the patient prior to the first visit to the ASC." Surgeons are correctly required to disclose ownership to Medicare beneficiaries, she said. But the new proposed rule means the patient must receive the written financial information before arriving at the facility for the first time.

"They cannot walk in and receive it," Hollander said. "We feel this is going to be a major impediment to patient scheduling." It does not matter if an ASC employee mentions the financial interests when the patient calls to make the appointment, she noted. The ASC must mail a letter with the information, and if it does not arrive in time, the patient may not be allowed to keep the appointment.

"We don't see anything good coming out of this," Hollander concluded.

Potentially equally ridiculous, she said, is the implication of the revised rule for admission, assessment, and discharge. As for the requirement to assess carefully a patient's suitability for surgery, "I think we've all tightened up these procedures since the early days," Hollander said.

The requirements for postoperative procedures are more stringent yet not as clear. Because ASCs now perform more complex surgery than in the past, CMS would require a physician's sign-off on every discharge, followed by assurance of "a safe transition to home."

"Does the ASCs responsibility include the car trip?" Hollander wondered. She noted that ASCA has asked for clarification and recommends that the current requirement to "discharge when stable" be reinstated.

A final rule is expected to be announced by November, with implementation in January 2009. Until then, ASCs will have to keep an eye on the fine print and prepare for its implications. ❖

—Paula DeJohn

Paula DeJohn is a freelance writer in Denver.

In memoriam:
Susan Hollander

On May 26, 2008, shortly after giving the presentation mentioned in this story, Susan Hollander passed away suddenly from a stroke. Hollander had worked for the ASC industry since 1989. She served 9 years on the FASA Board of Directors and had been an AAAHC surveyor since 1996.

"Susan was a wonderful person with the highest of integrity," said Sami Abbasi, chairman and CEO of National Surgical Care, where Hollander was vice president of operations.

"She was an integral part of our NSC team and a strong contributor to our successes. We are very saddened by her passing and will miss her dearly."

References

Ambulatory Surgery Center Association. Medicare Conditions of Coverage: Comparison of Existing Regulations to Proposed Regulations. August 31, 2007.

Department of Health and Human Services. Centers for Medicare and Medicaid Services. Medicare and Medicaid Programs; Ambulatory Surgical Centers, Conditions for Coverage; Proposed Rule. 42 CFR Part 416. *Federal Register.* 72:50470-50487. Aug 31, 2007.
Available at www.ascassociation.org. Look under ASC Legal and Regulatory Center.