Ambulatory surgery center (ASC) staff, like their hospital colleagues, are battling health care-acquired infections (HAIs), but there’s a twist: Most of the newest regulations shaping ASC infection control programs are coming from state legislators, not federal officials.

So far, 9 states have passed laws requiring ASCs to report infections related to the procedures they perform on prescribed forms. That means currently 9 and potentially 50 different sets of rules will determine how ASCs combat and report infections. Meanwhile, the federal government, which in 2008 first ordered ASCs to establish and document infection-control programs along with other quality measures, is debating how it wants ASCs to submit reports on quality and infection data.

The nation’s ASCs have no way of knowing when they will be freed from this regulatory limbo, says Dawn McLane, MSA, RN, CASC, CNOR.

McLane is regional vice president of operations at Health Inventures, LLC, in Broomfield, Colorado.

Establishing a program

The reporting uncertainty does not affect the responsibility of ASCs to develop infection control programs. These were mandated in the Centers for Medicare and Medicaid Services (CMS) Conditions for Coverage section 416.51, which created a new standard for an infection control program. The rule states: “The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases.” It specifies use of nationally accepted guidelines, which experts have been interpreting to mean those issued by such organizations as AORN and the Association for Professionals in Infection Control and Epidemiology (APIC). It requires documentation of the program and its enforcement. It mandates appointment of a “designated and qualified professional who has training in infection control,” although the type of training deemed adequate is a matter of dispute.

Incident provokes crackdown

Both the timing and tone of the new rule are widely viewed as consequences of incidents that turned a critical public spotlight on the ASC industry. In 2007 and 2008, 8 patients were infected with hepatitis C after being treated at the Las Vegas Endoscopy Center, and Nevada health officials determined that up to 50,000 people were at risk for the disease because of poor safety practices at that endoscopy center.

Writing in The Journal of the American Medical Association (JAMA), Melissa K. Schaefer, MD and a panel of researchers noted, “The chain of events resulting from the hepatitis C virus outbreak investigation and patient notification in Nevada highlighted the lack of focused attention to infection control in ASCs.”

McLane agrees: “It certainly made the news,” she says, “and the Conditions for Cov-
The JAMA report reviewed results of a pilot program of onsite inspections in a sampling of ASCs in 3 states. Based on discrepancies in infection control practices, the authors concluded, “attention to infection control in ASCs might be lacking.”

The most common lapses identified in the pilot survey were in hand hygiene, injection safety, sterilization, environmental cleaning, and cleaning of blood glucose monitoring equipment. CMS has since updated its survey reporting documents to include these areas.

The ASC Association responded to the JAMA report with a statement saying, in part, “Since the process lapses were identified, the ASC industry has engaged in a proactive educational effort with ASCs across the country to promote adherence to the new standards.” The association also noted that its own quality monitoring program involving about 650 ASCs has found that “80% of ASCs report fewer than 1.5 postsurgical wound infections per 1,000 patients encountered.”

Delegate, but document

At many ASCs, setting up infection control programs will be a matter of formalizing policies already in place, such as frequent hand washing, protective apparel, and strict rules for single-use medications and devices. To win surveyor and CMS approval, however, the programs will have to be detailed and rigorous.

“Theres a lot of confusion about what’s required,” McLane notes. “ASCs need to know they need to have a formalized program. In the past [for infection surveillance], surgery centers would print out a list of procedures and send it to the physician’s office and ask about adverse events, including infections.”

Now, each program must have certain components, as outlined in section 416.51.
McLane, who is a surveyor for the Accreditation Association for Ambulatory Health Care (AAAHC), says an ASC must prove it can:

- identify and investigate the source of an infection
- provide effective “isolation” or “separation”
- provide surveillance
- maintain written records
- provide education to members of the ASC team.

It is up to the board, or “governing body,” to establish the program. It may delegate authority to a designated person, but it must document in writing that it has approved the policies and procedures in the program and monitors compliance by the staff and surgeons.

**Critical components**

Those 2 components—management accountability and documentation—are critical under the new rule, McLane notes, even if an ASC has a clean track record and is diligent in following accepted practices. She recalls observing a recent survey at an ASC that had trained its staff and physicians in infection prevention. But the surveyor still wrote the center up because it was unable to document that the physicians had had their infection control training.

“Many centers couldn’t document that,” she adds. “It isn’t that it didn’t happen. It just means you didn’t document that.”

**What constitutes training?**

Staff training ranges from posters in clinical areas to online courses to seminars offered by consultants and professional associations. The training session McLane conducts at state ASC association meetings is an example.

The CMS rule specifies that the infection control coordinator must have “training” without further explanation. While in hospitals it is common to have a full-time, certified infection prevention professional on staff, ASCs do not have that luxury.

“We’re not infection control specialists, yet we’re expected to know everything,” was the reaction of Donna Quinn, MBA, RN, CPAN, CAPA, when she began developing a program at Orthopaedic Surgery Center in Concord, New Hampshire, where she is director.

“A one-day course doesn’t fully train you. It’s superficial,” she says. She and the center’s new infection control coordinator, Mary Young, RN, rely in part on training courses offered through the state health department using federal stimulus money. New Hampshire also is one of the 9 states that will begin requiring infection reports later this year.

The ASC Association, in its publication *Focus*, provides a 10-question quiz to help infection control coordinators test the depth of their knowledge. (Sample question: Is flash sterilization acceptable for implantable devices? Answer: No. They should be wrapped, sterilized, and monitored with a biological indicator.)

**When infection occurs**

Because the government has yet to establish an infection reporting methodology for ASCs, states like New Hampshire are taking the lead in tracking ASC-related infections. Beth Daly, chief of the Infectious Disease Surveillance Section at the New Hampshire Department of Health and Human Services, has been trying to help the state’s 26 licensed ASCs prepare for the July 1, 2011, deadline for infection reporting.

The state legislature passed the law, she says, to bring ASC reporting into line with
that of hospitals, which already must report infections under state law.

Daly predicts that, based on the experience of hospital surgical departments, an ASC will have to commit an additional 8 hours per month to meeting reporting requirements.

The state does not provide any benchmarks for infection rates, nor does the law include sanctions.

“The law we have is all about surveillance,” Daly says. However, ASCs will have an incentive to keep infections down because the health department plans to publish facility reports on its website for patients to consider before selecting a surgery center.

New Hampshire ASCs will use a format provided by the National Healthcare Safety Network (NHSN), a division of the Centers for Disease Control and Prevention (CDC), which can be imported into the NHSN’s database whenever that requirement takes effect.

They will compile data on a 46-field Excel template that includes procedure codes, volumes, and infection rates.

**Lighthearted reminders**

At the Orthopedic Surgery Center, staff members attended a training session on NHSN reporting and are in the process of developing an infection control program based on the new rules.

Young says the initial focus was on hand hygiene. “We did a survey of hand washing, and we measured the percentage of hand washing, and are making some changes to improve it,” she says. Changes include placing hand sanitizers closer to the patient care areas instead of on walls. That has made it easier for physicians to comply as they move from room to room.

She is trying to raise awareness of infection control protocols with posters and “lighthearted reminders” during meetings. “We’re making it an attitude rather than a [subject of] discipline,” she explains.

The program also addresses prophylactic antibiotic use before surgery by recording the time of administration for every patient. That will be one of the measures New Hampshire surgery centers will have to report to the health department beginning in July. For 2 years before the state issued its reporting templates, Quinn used an Excel spreadsheet to track infection control measures as well as outcomes.

In February, Quinn was appointed to the state’s Technical Advisory Work Group, where she represents the ASC industry. The group will work to develop infection control policies, and to educate the public as well as health care providers. “Help, more than discipline, is the state’s approach,” she says.

Besides New Hampshire, the following states have laws or regulations mandating infection reporting by ASCs: Massachusetts, New Jersey, Missouri, Arkansas, Texas, Colorado, Nevada, and Oregon.

**Funding going away?**

Both Daly and McLane say they expect more states to establish similar reporting requirements. Progress may be slower in the future, however, because of the way recent infection control efforts were funded. According to the *JAMA* report, CMS is conducting a national version of the 3-state study following a recommendation by the Government Accountability Office (GAO), funded through the American Recovery and Reinvestment Act, known as the stimulus, but that grant ended in fiscal year 2010.

Stimulus money also is behind programs like New Hampshire’s, and it will stop at the end of 2011, Quinn notes. She fears ASCs will be left to shoulder the financial burden.
“It’s difficult to meet those mandates with our current staff,” she says, “and we can’t afford to hire more.”

Young, meanwhile, is going to try. Her long-term goal, she says, is to bring the infection rate down to 0%. “I’m pretty excited to be part of the whole thing,” she says, “because I think it’s a really important segment of ambulatory surgery, that we don’t have infections.”

—Paula DeJohn

References
