



## How to Negotiate the Red Tape

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Regulatory skill can literally make or break an ASC. Make sure you're prepared.

*Judith Lee, Contributing Editor*

In the brave new world of ambulatory surgery centers, bricks and mortar, equipment, and staff are important—but they must defer to a higher order. From the moment you conceive of building a center, you should be planning to negotiate several critical regulatory hurdles that truly can make or break an ASC.

“You must take regulatory issues very, very seriously,” says Mark Schutz, MD, who has opened ambulatory centers in several states. “You can’t even open your doors without meeting state and local regulations. You can get the center and up and running, but you can’t charge a facility fee unless you have Medicare certification.”

Experts say that satisfying regulatory agencies must be considered not only at every step of ASC construction, but also prior to construction. Even your choice of location can become a problem if you haven’t fully considered your regulatory challenges. Surgeons have actually built surgicenters and then been forced to “eat” the costs because they could not obtain permission from their state to operate the center. Says Dr. Schutz, “You’re not just designing a surgery center. You’re designing a surgery center that will fit in that space and meet all regulations.”

### Get Help

Unless you are a dyed-in-the-wool policy wonk, you won’t have the time or know-how to negotiate the bureaucratic maze. Your first step should be hiring a knowledgeable person to look after regulatory matters, virtually full-time.

“Hiring an experienced consultant to guide you is the most economical way to proceed, because we are not ‘reinventing the wheel’ with each center,” notes Tammy Ham of Ambulatory Surgery Assistance, in Kansas City. “If you choose to do this yourself, you must hire a nurse manager or administrator who has done this before. In regulatory issues, there is no substitute for experience.”

The more specific the experience, the better, experts say. You should hire a consultant or administrator who has opened a center in your state.

“It pays to know the politics of the state. Some states have more layers of regulation, even prior to the state inspection. In one state, we had to complete fire inspections from the city, county and state,” says Suzanne Broadwater, Director of Operations for Ambulatory Surgery Centers of America, Norwell, Mass. Your project will also go a lot easier, experts say, if you choose an architect who has built ASCs in your state. “The regulations for ASCs differ widely from state to state,” says Regina Boore, ASC Project Coordinator for LaserVision Centers Inc., in Poway, Calif.

### Who Accredits ASCs?

Three organizations accredit ambulatory surgery centers: AAAHC, JCAHO, and AAAASF. These groups survey ASCs to publicly certify a high level of patient care. Also, along with offering a more timely, scheduled Medicare survey, they say accreditation will assist

ASCs with:

- Finding new ways to improve patient care and services;
- Increasing efficiency and reducing costs;
- Developing better risk management programs;
- Lowering liability insurance premiums;
- Motivating staff;
- Strengthening public relations and marketing efforts;
- Recruiting and retaining qualified professional staff members;
- Developing alliances with other provider groups such as hospitals and managed care organizations

**Following is a brief description of each, with contact information.**

**AAAHC, or Accreditation Association for Ambulatory Healthcare.** Incorporated in 1979 as a non-profit organization, its history spans more than 25 years of independent and cooperative efforts by many national organizations, all dedicated to high-quality ambulatory health care. The AAAHC is a leader in ambulatory health care accreditation and serves as an advocate for the provision and documentation of high-quality health services in ambulatory health care organizations. This is accomplished through the development of standards and through its survey and accreditation programs.

*Contact:* Accreditation Association for Ambulatory Health Care, Inc.,  
3201 Old Glenview Road, Suite 300, Wilmette, Illinois 60091-2992  
*Phone:* (847) 853-6060

*Website:* [www.aaahc.org](http://www.aaahc.org)

**JCAHO, or Joint Commission on Accreditation of Healthcare Organizations.** The Joint Commission evaluates and accredits nearly 18,000 health care organizations and programs in the United States. This independent, not-for-profit organization has, since 1951, developed state-of-the-art, professionally based standards and evaluated the compliance of health care organizations against these benchmarks. JCAHO's mission is to continuously improve the safety and quality of care provided to the public through the provision of healthcare accreditation and related services that support performance improvement in health care organizations.

*Contact:* Joint Commission on Accreditation of Healthcare Organizations, One Renaissance Boulevard, Oakbrook Terrace, Illinois 60181

*General Phone:* (630) 792-5000

*Customer Service Phone:* (630) 792-5800

*Website:* [www.jcaho.org](http://www.jcaho.org)

**AAAASF, or Association for the Accreditation of Ambulatory Surgery Facilities.** Founded in 1980 as an accreditation program for outpatient plastic surgery centers, the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF) was established in 1992 to accredit other single-specialty and multi-specialty surgery facilities, owned and/or operated by American Board of Medical Specialties Surgeons (ABMS). These surgeons must be Board Certified in approved Surgical Specialties. The rigid requirements remain the same for each specialty and include all standards, including tiered accreditation, Board Certification within the specialty being practiced, hospital privileges, including transfer privileges for the same procedures being performed within the ambulatory surgery unit and adherence to the appropriate laws and regulations governing ambulatory and office-based surgery units.

*Contact:* Association for the Accreditation of Ambulatory Surgery

## Start with the state

Once you have your experts on board, it's time to contact the state. The first question

Facilities, 1202 Allanson Road, Mundelein, IL 60060  
Phone: 888-545-522  
Website: [www.aaaasf.org](http://www.aaaasf.org)

is: Does your state require a Certificate Of Need? About 22 states have dropped their CON requirements for ASCs, which were introduced two decades ago when states were trying to get federal funding for hospital construction. This was long before managed care, when regulation was used to hold costs down by limiting construction and increasing the use of existing facilities. The federal government lifted its CON requirements about 15 years ago. States which still require them for ASCs include Alabama, Alaska, Connecticut, Delaware, Washington DC, Georgia, Hawaii, Illinois, Iowa, Kentucky, Maine, Maryland, Massachusetts, Michigan, Mississippi, Missouri, Montana, Nevada, New Hampshire, New York, North Carolina, Rhode Island, South Carolina, Tennessee, Vermont, Virginia, Washington, and West Virginia.

"If you don't have to apply for a CON, this is a big plus. When applying for a CON, you are likely to go up against the local hospitals. Find out if the hospitals will fight you; if they don't challenge you, it won't cost as much," says Dr. Schutz.

Even so, a CON application still will be expensive. Ms. Boore estimates that it adds as much as \$150,000 in legal fees and six to 18 months to an ASC project. Because of this, some larger companies that build ASCs elect to build only in states without CON.

If you're locked into a CON state, experts say there are two ways around it: waivers and acquisition. Some states will waive the CON if the ASC is single-specialty, with a limit of \$1 million spent on bricks and mortar, and \$1 million spent on equipment, Ms. Ham says. Of course, if you acquire an existing center, you also acquire its CON, says Ms. Boore.

Even if you are not in a CON state, you must be licensed by the state and comply with state construction regulations. Experts advise getting in touch with the state as soon as you decide to build an ASC.

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"Connect with the state department of health and ask for the ambulatory surgery department. It pays to develop a good rapport with this department. Notify them you are planning to build a center, and request the rules and regulations for surgery centers," instructs Ms. Broadwater.

Experts say that for state licensure, you may be required to submit some or all of the following:

- ASC policies and procedures;
- Description of operations;
- Scope of services;
- Safety and infection control;
- QA or Performance Improvement Plan;
- Business Plan;
- Financial Plan;
- Emergency Plan;
- Fire Plan;
- Disaster Plan.

At the same time, you should be working with the architect on the construction plan. Before you begin construction, consider submitting the plans to the state, Ms. Boore suggests: "Some states will pre-approve construction plans. This will help you avoid problems and cost down the line."

She adds that if state guidelines aren't clear on some issues, don't guess—check with the state. If the state doesn't have guidelines, you and your architect should refer to the American Institute of Architects Guidelines for Design and Construction of Hospitals and Healthcare Facilities.

Although the state is your primary worry, do not forget that you also must comply with local ordinances. Make sure you comply with zoning laws, and local building and fire codes. Do not ask for exceptions, because not all agencies may approve these. “The real construction screw-ups occur when the doctor wants to jury-rig everything with waivers. This can be a big problem down the line, when you're ready to open the doors,” warns Dr. Schutz. “Don't take short-cuts to save money. Do what the local codes tell you to do.”

### The “M” word

As you proceed with design and construction, begin thinking about Medicare certification. It's never too early. This is because completing the Medicare survey can take much longer than you anticipate. Medicare surveys usually are handled by state inspectors, and they are often delayed by heavy inspection caseloads.

“Ask the state regulators when they would prefer you to apply for your Medicare survey. It might be three to six months before your planned completion, or it might be six weeks,” suggests Ms. Ham.

She says communication with the state can be critical to timely completion of the Medicare survey. Some states would like to see your Policies and Procedures prior to the survey, while other states want the documentation at the time of the survey. In general, it's in your best interest to get to know those who can have a big impact on how soon you can seek reimbursement for services.

“I have found that most state employees are accommodating and willing to mentor you if you approach them early in the process. They will tell you what to do next. This is a valuable resource,” Ms. Ham says.

The schedule of events usually goes like this:

- The center receives a visit from the local building inspector and fire marshal, after which an occupancy permit is issued;
- The state inspects the facility and grants a license;
- The center performs about 10 surgeries;
- The Medicare survey is performed and certification is given;
- The center seeks accreditation;
- The center informs health plans and insurers that it is certified and/or accredited, as appropriate;
- The center can at last perform procedures and seek reimbursement from Medicare and private insurers.

This sounds like a logical train of events, but preparing for the inspections and surveys is not such a simple matter. For the state inspection and Medicare survey, you need to prepare documentation on every aspect of the center's operations.

“Go ahead and fill your trunk with three-ring binders; you're going to need them,” says Ms. Broadwater.

She notes that along with all the documents specified above for licensure, you will also need a human resources plan, policies and records. Document the various in-services required by the state and Medicare, such as “Controlling a Fire in an Oxygen-Rich Environment.” Dr. Schutz points out that QA studies and chart reviews must be in place.

“You really need six months to prepare for your survey, so you have to be starting long before the center opens. You have to be asking, ‘Do we have enough data or documentation?’ in any given area,” he says.

The state usually will give a date on which its survey will be performed. Medicare will not; the agency does its surveys unannounced.

“You never know when Medicare is coming. The irony is that the inspector usually is the state inspector who already gave you a license, but he has to come back and do the Medicare survey all over. If you pass one survey, you usually pass the other, but no one knows how long you will wait in between. During that time, you can’t get reimbursed,” Dr. Schutz notes.

### **Details, details**

If you plan to have your center accredited and you are unfamiliar with the process, brace yourself. Your center is about to be examined thoroughly for evidence that you are doing things “by the book.”

It works like this. An examiner—either a board-certified surgeon, a nurse, practice manager, anesthesiologist, or physician of any specialty—will visit your center on a “typical” (i.e. surgery) day of your choice. He or she will be examining your records and interviewing your staff to learn how your center is doing things.

No detail is too picayune. Among the paperwork a surveyor might check:

- Patient charts. They should be neat and clean, with crisp chronologies, no crossouts, and a minimum of blank spaces.

- Policy and procedure manuals;

- Personnel files, including staff inoculation records for hepatitis B and tuberculosis;

- Physician licensure and credentialing records;

- Written policies on transfer procedures;

- Quality assurance studies;

- Patient exit surveys;

- Vendor agreements;

- Narcotics logs;

- CME documentation;

- Relevant licenses and permits;

- Insurance documents;

- Biomedical equipment calibration books; and

- Minutes of the governing board meetings.

The surveyor will want to observe at least one case. He may ask you questions about procedures such as your peer review processes. He wants to know that you have reviewed the surgeon’s charts, looked over patient satisfaction surveys and analyzed complication rates before offering privileges. He may want to know about risk management protocols—the policies and people you have in place to address patient

## Accreditation

To avoid this delay, you may choose to seek accreditation right away. The accrediting bodies (see sidebars) can do the Medicare survey when they do the accrediting survey.

“The accrediting surveyor will give you a firm date for the survey, within two weeks of opening. The accreditor also provides a book to guide you through the survey,” says Dr. Schutz, who is an AAAHC surveyor.

He says the step-by-step approach will get you through. Make sure you have:

- Gone through every item in the book
- Completed every item
- Done it in the order specified
- Created the ability to update data and documentation as required

“As you prepare your book, you will be preparing for the survey. As long as you follow every step, you’ll be in good shape. If you haven’t performed enough cases to meet some of the requirements, you’ll get a six-month approval, and then just have to send in the data for a full accreditation. But during that time, you can get reimbursed for cases,” Dr. Schutz says.

Other experts agree that working through an accrediting organization can save valuable time.

“The Medicare surveyors are often behind, and the survey is unannounced. It’s better to go with ‘deemed status’ with an accreditor, which means they will do the Medicare survey, too. Just be sure to let them know you are doing the Medicare survey through them,” says Ms. Broadwater.

## A few more things

Before opening, there are a few more things to take care of. Ms. Broadwater suggests that you:

- Apply for a CLIA waiver through the state department of health. This will allow you to perform lab tests on an outpatient basis.
- Apply for a DEA license. This federal license will enable you to order pharmaceuticals. Even though you don’t dispense drugs, you may be required to have a drug inventory on hand.
- Develop a consensus among physicians regarding equipment and supplies, then seek your best volume discount on these items.

Does it sound like the details of complying with regulations and opening your ASC are endless? Experts say that’s pretty much the case.

“This is a very complicated process. You must be organized, assertive and experienced,” Ms. Broadwater says. “And you have to be working on all this back when the mud is on the ground.” ■

complaints and correct medical errors. He may ask staff members if they have “walked through” the contingency plans you have for emergencies such as malignant hyperthermia. He may fault you if you are not doing enough to protect patient confidentiality—for example, if you do not have a separate sign-in sheet at the front desk. He may want to see that you are regularly exploring ways to improve efficiency, economy and quality via QA studies.

At day’s end, the surveyor will present his findings and ask any remaining questions. You will have the opportunity to challenge him on any points before he prepares a written report.

If you pass muster, you will typically receive accreditation status within about three months. Depending on the surveyor’s assessment, your accreditation can last as long as three years.