

Your Guide To ASC Development Success

License and Certification

To participate in the Federal ASC program and receive facility fees from governmental payers, the ASC must meet Medicare criteria and approval, known as Certification. This Certification is also mandatory in order to contract with “other” payers for facility fees.

A pre-requisite to Medicare Certification is compliance with State Licensure Law. Although Medicare governs the ASC program, each State Department of Health is their own authority having jurisdiction over the program. Forty-three states require a state licensure for ASC’s. These states specify the criteria that ASC’s must meet for licensure prior to Certification. Information can be found on the individual State Department of Health’s website, many of which publish their rules and regulations such as patient rights, incidence reporting and safety programs. This pre-requisite of State Licensure, however, may exempt some single specialty facilities in some States.

The process of Licensure and Certification includes surveys and approval by the Medicare program as a provider of surgical services. Typically, the survey is performed by the individual State Department of Health or by a third party Accrediting Body. In return for making increased payments to ASCs, federal and state governments have specific requirements for the physical environment as well as a whole host of rules and regulations covering procedures performed, staffing and administrative function.

Certificate of Need

Some states require a Certificate of Need (commonly referred to as CON, Certificate of Public Need (COPN) or Determination of Need (DON) but certainly not all, or even a majority to establish a new ASC. CON is State regulatory program intended to balance cost, quality, and access issues and ensure that only needed services and facilities are developed as needed. It may be possible to obtain an exemption in some states for single specialty ASC’s or for just one operating room or for wholly physician owned ASC’s. The process of CON or an exemption varies per State such as:

- A petition may be filed in some states for exemption
- Some states have a number of rooms exemption – such as one operating room facilities
- Some states have a cost of the project threshold for exemption

Accreditation

Many surgery centers choose to go through a voluntary accreditation processes conducted by their peers. This accreditation is sometimes referred to as a “third party survey” and may be mandatory in some states or with some payers. ASC’s can seek accreditation from one of three accrediting bodies: Accreditation Association for Ambulatory Health Care, Inc (AAAHC), Joint Commission on Accreditation of Healthcare Organizations (JCAHO), or The American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF).

Twenty one states and DC require or recognize accreditation of certain types of ambulatory surgical facilities: AZ, CA, DE, DC, FL, GA, IN, KS, MD, MT, NE, NV, NH, NM, NY, NC, OH, OR, PA, TN, UT and WY.

All accredited ASCs must meet specific standards that are evaluated during on-site inspections. These accrediting bodies also have deemed status by CMS to survey for Medicare Certification. Typically this survey is after the facility has been open for 6 months; however, an early option is available to satisfy State and/or payer requirements. Proof of State License or exemption letter will be needed before they will schedule survey. Medicare Certification survey through an Accrediting Body is unannounced. Accrediting bodies will typically give a 1 month window for survey.

Conditions for Coverage

The State Operations Manual published by CMS can be found on the Federal Register, 42 CFR 416, and contains the parameters that must be met in order to apply for Medicare Certification. Once the State Licensure Law has been determined, the next condition that must be met is to assure that the ASC is a distinct entity that operates exclusively to furnish outpatient surgical services. It can be either an independent freestanding facility, or under the common ownership, licensure or control of a hospital.

With many specialties, it may be more advantageous for efficiency, for the physician’s practice to be in the same environment as the ASC. This would require that it be separated from the ASC by at least semi-permanent walls. State Interpretation of this regulation varies. Some states will allow some shared spaces but would require that the two entities not run concurrently and that the staff is exclusive to the ASC.

Specific Conditions for Coverage include:

- **Governing Body and Management: Assumes full legal responsibility for total operations**
- **Surgical Services: Physicians must be fully credentialed and approved by the Governing Board**

- Evaluation of Quality: **Ongoing Continuous Quality Improvement & Risk Management programs, Peer Review, Chart Review, Credentialing with primary verification source**
- Safety: **Many states require a separate Safety Plan with Officer and incidence reporting**
- Medical Staff: **legally and professionally qualified for appointment**
- Nursing Services: **RN trained in CPR must be available whenever a patient is the ASC (ACLS - Recovery Room)**
- Medical Records: **Complete, comprehensive and accurate**
- Pharmaceutical Services: **DEA license to dispense narcotics**
- Laboratory: **CLIA license to perform lab services or CLIA waiver to perform limited tests**
- Radiological Services: **must be supervised by a radiologist or radiation oncologist (C'arm for needle localization or interpretive report only is usually approved to be supervised by a physician on staff)**

Physical Environment

All ASC's must meet requirements of the Federal and State Fire Safety Codes: Safe, sanitary and appropriate environment for an ASC. It is crucial to determine the individual State regulations prior to any construction, as the source and year version of the requirements holds different requirements. Codes used by the individual states can be from the Centers for Medicare and Medicaid Services (CMS, formerly, HCFA), the National Fire Protection Association and/or from the American Institute of Architects. Some States have their own individual building code as well. These codes include specifics on construction type, engineering, electrical, mechanical as well as storage and monitoring and alarm systems. Parameters include regulations on:

- Fire resistance/sprinklers
- Functional Zoning
- Public/Administrative
- Prep Area
- Procedure Suites
- Recovery Suite
- Staff "amenities"
- ADA compliant
- Specific Rooms and Functions
- Minimum Areas and/or Dimensions
- Accessibility

It is vitally important in creating physical environments (the planning and spatial design of your facilities) that you meet regulatory standards, while facilitating efficient use of staff (the only truly vital aspect of your cash flow model), maximum procedural volume, and patient centered care. Utilizing a Medical Facility Design Planner who specializes in ASC Design is the best avenue for success on design plan approval.

Minimal Emergency Equipment

- Oxygen
- Mechanical ventilatory equipment
- Defibrillator and cardiac monitoring
- Tracheostomy set
- Laryngoscopes and endotracheal tubes
- Suction
- Break away lock on crash cart
- MHA cart as applicable

Feasibility for Starting for an ASC

Begin by creating a spreadsheet to calculate projected revenue and costs. Include all of the following:

1. Type of facility and services provided
2. Geographical market research and area competition
3. **Procedure types and volumes performed**
4. **Payer mix: determine rates of facility fees from Managed Care, Commercial and Workers Compensation**
5. CON/Licensing/Surveys and Permits as applicable
6. Architectural/Construction/Electrical/Mechanical
7. Equipment and supplies: Medical and Administrative
8. Contracted services
9. Legal/Accounting
10. Staffing
11. Rent or mortgage
12. Interest and principal payments (Cash flow, first three-six months)

Itemized Task List

Realizing that an ASC is one the most highly regulated Health Care Entities with many regulations to meet, it is most efficient to create a detailed task list and develop a team to work together toward your goal. Assignment of tasks should include-

Research and determination of individual State requirements
CON filing or exemption?
Legal issues- stark, anti kick-back?
Design and construction plans
Name of Facility/Tax ID number
Articles of Incorporation or operating agreement
Shareholders agreement
Determine Governing Body and Organizational Chart
By-Laws
Medical Staff Rules and Regulations

Loan and Line of Credit
Billing Service or in-house
Staff Recruitment
Proposals on equipment and supplies
State License application, Medicare applications and AAAHC applications filed minimum of 90 days prior to construction finish out

Begin requesting all other payor applications

Phase 2 Tasks

Develop detailed policies and procedures to comply with Medicare Conditions for Coverage and State Provisions for Licensure (Note: many State Departments of Health publish their provisions for ASC Licensure on their website). Perform Credentialing with primary verification source for all Clinical Staff through The National Practitioners Data Bank and the American Medical Association. Stocking and Storage of equipment and supplies is next, all equipment must be inspected, tagged and an in-service documented.

Preparation for surveys starts with early staff training in all ASC policies and procedures. Successful surveys starts with early research and implementation. If you don't know, don't guess! Never be afraid to ask!

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