

Chapter 45. Ambulatory Surgical Center

Subchapter A. General Provisions

Ambulatory Surgical Center (ASC)—a distinct entity that is wholly separate and clearly distinguishable from any other healthcare facility or office-based physician's practice. An ASC shall be composed of operating room(s) and/or procedure room(s) with an organized medical staff of physicians and permanent facilities that are equipped and operated primarily for the purpose of performing surgical procedures. An ASC provides continuous physician and professional nursing services to patients whenever a patient is in the ASC, but does not provide services or accommodations for patients to stay overnight.

1. The following services shall be offered by the ASC when a patient is in the center:

- a. drug services as needed for medical operations and procedures performed;
- b. provisions for the physical and emotional well-being of patients;
- c. provision of emergency services;
- d. organized administrative structure; and
- e. administrative, statistical and medical records.

2. An ASC may also be defined as a treatment center that is organized primarily for the purpose of offering stereotactic radiosurgery by use of a gamma knife or similar neurosurgical tool.

3. An ASC that enters into a use agreement with another entity/individual shall have separate, designated hours of operation.

Certified Registered Nurse Anesthetist (CRNA)—an advanced practice registered nurse who administers anesthetics or ancillary services in accordance with the licensing requirements of the State Board of Nursing (LSBN) and under the supervision of a physician or dentist who is licensed under the laws of the state of Louisiana. The CRNA determines and implements the anesthesia care plan for a patient during a procedure and, for the safety of the patient, shall not be involved in other aspects of the procedure.

Cessation of Business—when an ASC is non-operational and voluntarily stops rendering services to the community.

Controlled Dangerous Substance (CDS)—a drug, substance or immediate precursor in schedule I through V of R.S. 40:964.

Department (LDH)—the Louisiana Department of Health.

Division of Administrative Law (DAL)—the agency authorized to conduct fair hearings and take actions on appeals of departmental decisions as provided for in the Administrative Procedure Act, or its successor.

Endoscopic Retrograde Cholangiopancreatography (ERCP)—a procedure used to diagnose diseases of the gallbladder, biliary system, pancreas and liver.

Endoscopic Ultrasound/Fine Needle Aspiration (EUS/FNA)—a technique using sound waves during an

§4503. Definitions

Administrator—the person responsible for the on-site, daily implementation and supervision of the overall ASC's operation commensurate with the authority conferred by the governing body.

endoscopic procedure to look at, or through, the wall of the gastrointestinal tract.

Governing Body—the individual or group of individuals who are legally responsible for the operation of the ASC, including management, control, conduct and functioning of the ASC, also known as the governing authority.

Immediately Available—a person that is not assigned to any uninterrupted tasks.

Invasive Procedure—a procedure that:

1. penetrates the protective surfaces of a patient's body;
2. is performed in an aseptic surgical field;
3. generally requires entry into a body cavity; and
4. may involve insertion of an indwelling foreign body.

NOTE: The intent is to differentiate those procedures that carry a high risk of infection, either by exposure of a usually sterile body cavity to the external environment or by implantation of a foreign object(s) into a normally sterile site. Procedures performed through orifices normally colonized with bacteria and percutaneous procedures that do not involve an incision deeper than skin would not be included.

Length of Patient Stay—the period of time that begins with the admission of the patient to the ASC and ends with the discharge of the patient from the ASC. The time of admission shall be calculated in accordance with the ASC's written policy. The length of any patient stay shall be documented.

Licensing Agency—the Louisiana Department of Health.

Medical Staff—physicians, dentists, podiatrists and other professional licensed medical practitioners who are authorized to practice in the ASC according to these standards and the requirements of the governing authority.

Minimal Sedation—as defined by the American Society of Anesthesiology (ASA), a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, ventilatory and cardiovascular functions are unaffected.

Minor Alterations—the painting of walls, changing of flooring products or any other cosmetic changes to the ASC which do not involve moving structural walls, doors, windows, electrical or plumbing.

Miscarried Child—the fetal remains resulting from a spontaneous fetal death that does not require compulsory registration pursuant to the provisions of R.S. 40:47.

New Construction—any of the following structures that will be started after promulgation of these provisions shall be considered new construction:

1. newly constructed buildings;
2. additions to existing buildings;

3. conversions of existing buildings or portions thereof;

4. alterations, other than minor alterations, to an already existing ASC; or

5. any previously licensed ASC that has voluntarily or involuntarily ceased providing ASC services and surrendered its license shall be considered new construction for plan review purposes.

Non-Operational—when the ASC is not open for business operation on designated days and hours as stated on the licensing application.

Operating Room (OR)—a room in the surgical center that meets the requirements of a restricted area and is designated and equipped for performing surgical or other invasive procedures. An aseptic field is required for all procedures performed in an OR. Any form of anesthesia may be administered in an OR if proper anesthesia gas administration devices are present and exhaust systems are provided.

Overnight—the length of admission to an ASC of any patient that exceeds 23 hours, which is calculated as the time of admission to the time of discharge from the ASC.

Physician—a licensed medical practitioner who possesses an unrestricted license and is in good standing with the State Board of Medical Examiners. This includes a doctor of:

1. medicine;
2. osteopathy;
3. podiatry;
4. optometry;
5. dental surgery or dental medicine; or
6. chiropractic.

Procedure Room—a room designated for the performance of a procedure that is not deemed to be an invasive procedure. The procedure may require the use of sterile instruments or supplies but not the use of special ventilation or scavenging equipment for anesthetic agents.

Standards—the rules, regulations and policies duly adopted and promulgated by the Department of Health with the approval of the secretary.

Unlicensed Assistive Personnel (UAP)—any unlicensed trained personnel who cannot practice independently or without supervision by a registered nurse. This may include operating and/or procedure room technicians, instrument cleaning and/or sterilization technicians and nursing assistants or orderlies.

Use Agreement—a written agreement between a licensed ASC and an individual or entity in which the ASC allows the individual or entity to use its facility, or a portion thereof, on a part-time basis to provide the services of an ASC. All use agreements shall comply with applicable federal laws and regulations.

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§4507. Initial Licensure Application Process

A. An initial application for licensing as an ASC shall be obtained from the department. A completed initial license application packet for an ASC shall be submitted to, and approved by the department, prior to an applicant providing services.

B. The initial licensing application packet shall include:

1. a completed licensure application and the non-refundable licensing fee as established by statute;
2. a copy of the approval letter(s) of the architectural and licensing facility plans from the Office of the State Fire Marshal (OSFM) and any other office/entity designated by the department to review and approve the facility's architectural and licensing plan review;
3. a copy of the on-site inspection report with approval for occupancy by the Office of the State Fire Marshal, if applicable;
4. a copy of the on-site health inspection report with approval for occupancy from the Office of Public Health (OPH);
5. proof of each insurance coverage as follows:
 - a. general liability insurance of at least \$300,000 per occurrence;
 - b. worker's compensation insurance as required by state law;
 - c. professional liability insurance of at least \$300,000 per occurrence/\$300,000 per annual aggregate, or proof of self-insurance of at least \$100,000, along with proof of enrollment as a qualified health care provider with the Louisiana Patient's Compensation Fund (PCF):
 - i. if the ASC is not enrolled in the PCF, professional liability limits shall be \$1 million per occurrence/\$3 million per annual aggregate; and
 - d. the LDH Health Standards Section shall specifically be identified as the certificate holder on any policies and any certificates of insurance issued as proof of insurance by the insurer or producer (agent);
6. proof of a line of credit issued from a federally insured, licensed lending institution in the amount of at least \$100,000;
7. disclosure of ownership and control information;
8. the usual and customary days and hours of operation;
9. an organizational chart and names, including position titles, of key administrative personnel and governing body;
10. controlled dangerous substance application;
11. fiscal intermediary, if applicable;
12. Secretary of State's articles of incorporation;

13. clinical laboratory improvement amendments (CLIA) certificate or CLIA certificate of waiver, if applicable;

14. an 8.5 x 11 inch mapped floor plan; and

15. any other documentation or information required by the department for licensure.

C. If the initial licensing packet is incomplete, the applicant shall be notified of the missing information, and shall have 90 days from receipt of the notification to submit the additional requested information. If the additional requested information is not submitted to the department within 90 days, the application shall be closed. If an initial licensing application is closed, an applicant who is still interested in becoming an ASC shall be required to submit a new initial licensing application packet with the required fee to start the initial licensing process.

D. Once the initial licensing application packet has been approved by the department, notification of such approval shall be forwarded to the applicant. Within 90 days of receipt of the approval of the application, the applicant shall notify the department that the ASC is ready and is requesting an initial licensing survey. If an applicant fails to notify the department within 90 days, the initial licensing application shall be closed. After an initial licensing application is closed, an applicant who is still interested in becoming a licensed ASC shall be required to submit a new initial licensing packet with the required fee to start the initial licensing process.

E. Applicants shall be in compliance with all appropriate federal, state, departmental or local statutes, laws, ordinances, rules, regulations and fees before the ASC will be issued an initial license to operate.

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c. professional liability insurance of at least \$300,000 per occurrence/\$300,000 per annual aggregate, or proof of self-insurance of at least \$100,000, along with proof of enrollment as a qualified health care provider with the Louisiana Patient's Compensation Fund (PCF);

i. if the ASC is not enrolled in the PCF, professional liability limits shall be \$1,000,000 per occurrence/\$3,000,000 per annual aggregate;

d. the LDH Health Standards Section shall specifically be identified as the certificate holder on the any policies and any certificates of insurance issued as proof of insurance by the insurer or producer (agent);

7. proof of a line of credit issued from a federally insured, licensed lending institution in the amount of at least \$100,000;

8. statement of attestation of ASC compliance with the provisions of §4581; and

9. any other documentation required by the department or CMS if applicable.

B. The department may perform an on-site survey and inspection upon annual renewal of a license.

C. Failure to submit a completed license renewal application packet prior to the expiration of the current license will result in the voluntary non-renewal of the ASC license. There are no appeal rights for such surrender or non-renewal of the license, as this is a voluntary action on the part of the ASC.

D. If an existing licensed ASC has been issued a notice of license revocation, suspension or termination, and the ASC's license is due for annual renewal, the department shall deny the license renewal application and shall not issue a renewal license.

1. If a timely administrative appeal has been filed by the ASC regarding the license revocation, suspension, or termination, the administrative appeal shall be suspensive, and the ASC shall be allowed to continue to operate and provide services until such time as the administrative tribunal or department issues a decision on the license revocation, suspension, or termination.

2. If the secretary of the department determines that the violations of the ASC pose an imminent or immediate threat to the health, welfare, or safety of a patient, the imposition of such action may be immediate and may be enforced during the pendency of the administrative appeal. If the secretary of the department makes such a determination, the ASC will be notified in writing.

3. The denial of the license renewal application does not affect in any manner the license revocation, suspension, or termination.

E. The renewal of a license does not in any manner affect any sanction, civil monetary penalty or other action imposed by the department against the ASC.

§4515. Renewal of License

A. The ASC shall submit a completed license renewal application packet to the department at least 30 days prior to the expiration of the current license. The license renewal application packet shall include:

1. the license renewal application;
2. the non-refundable license renewal fee;
3. the stated days and hours of operation;
4. a current State Fire Marshal report;
5. a current OPH inspection report;
6. proof of each insurance coverage as follows:

a. general liability insurance of at least \$300,000 per occurrence;

b. worker's compensation insurance of at least \$100,000 as required by state law;

PUBLIC HEALTH—GENERAL

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Subchapter F. Safety, Sanitization and Emergency Preparedness

§4575. General Provisions

A. The ASC shall have policies and procedures, approved and implemented by the medical staff and governing body, that address provisions for:

1. sanitizing, disinfecting and sterilizing supplies, equipment and utensils; and
2. the safe use of cleaning supplies and solutions that are to be used and the directions for use, including:
 - a. terminal cleaning of the OR/procedure rooms; and
 - b. cleaning of the OR/procedure rooms between surgical and nonsurgical procedures.

B. Policies and procedures shall be developed, implemented and approved by the ASC's governing body for the types and numbers of sterilizing equipment and autoclaves sufficient to meet the surgical sterilization needs of the ASC.

1. Procedures for the proper use of sterilizing equipment for the processing of various materials and supplies shall be in writing, according to manufacturer's recommendations, and readily available to personnel responsible for the sterilizing process.

2. All sterilization monitoring logs shall be maintained within the ASC for a minimum of 18 months.

C. All steam sterilizing equipment shall have live bacteriological spore monitoring performed at a frequency according to the manufacturer's instructions.

1. If tests are positive, a system shall be in place to recall supplies that have tested substandard in accordance with the ASC's policies and procedures set forth by the ASC's governing body.

D. All ethylene oxide sterilizing equipment shall have live bacteriological spore monitoring performed with each load and according to manufacturer's recommendation. There shall be ventilation of the room used for this sterilization to the outside atmosphere. There shall be a system in place to monitor trace gases of ethylene oxide with a working alert system which is tested and documented daily.

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