

## Chapter 45. Ambulatory Surgical Center

### Subchapter A. General Provisions

#### §4501. Introduction

A. These regulations contain the minimum licensing standards for ambulatory surgical centers, pursuant to R.S. 40:2131-2141. Ambulatory surgical centers are established for the purpose of rendering surgical procedures to its patients on an outpatient basis.

B. The care and services to be provided by an ambulatory surgical center (ASC) shall include:

1. surgical procedures;
2. medications as needed for medical and surgical procedures rendered;
3. services necessary to provide for the physical and emotional well-being of patients;
4. emergency medical services; and
5. organized administrative structure and support services.

C. Licensed ASCs shall have one year from the date of promulgation of the final Rule to comply with all of the provisions herein.

D. For those ASCs that apply for their initial ASC license after the effective date of the promulgation of this Rule, or receive plan review approval for initial construction or major renovations after the effective date of the promulgation of this Rule, or change their geographic address after the effective date of the promulgation of this Rule, such shall be required to comply with all of the provisions herein.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:1732 (September 2017).

#### §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.

*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 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 uninterruptible 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.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:1732 (September 2017).

C. An ASC shall ensure that each patient has the appropriate pre-surgical and post-surgical assessments completed, inclusive of suitability for less than 23-hour timeframe of patient stay, ability of the ASC to provide services needed in the post-operative period in accordance with prescribed plan of care, and discharge plans to home or another licensed facility setting.

D. Within 30 days prior to the date of the scheduled surgery, each patient shall have a comprehensive medical history and physical assessment completed by a physician or other qualified licensed professional practitioner in accordance with applicable state health and safety laws, ASC policies, and standards of practice.

E. The history and physical assessment prior to surgery shall specify that the patient is medically cleared for surgery in an ambulatory setting and is required on all patients regardless of whether the patient is referred for surgery on the same day that the referral is made and the referring physician has indicated that it is medically necessary for the patient to have the surgery on the same day.

F. Upon admission, each patient shall have a pre-surgical assessment completed by a physician or other qualified licensed health practitioner. The pre-surgical assessment shall include, at a minimum:

1. an updated medical record entry documenting an examination for any changes in the patient's condition since completion of the most recently documented medical history and physical assessment; and

2. documentation of any known allergies to drugs and/or biological agents.

G. The patient's medical history and physical assessment shall be placed in the patient's medical record prior to the surgical procedure.

H. The patient's post-surgical condition shall be assessed and documented in the medical record by a physician, other licensed medical practitioner, or a registered nurse (RN) with, at a minimum, the required post-operative care experience in accordance with applicable state health and safety laws, ASC policies and standards of practice.

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HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:1741 (September 2017).

#### **§4541. Transfer Agreements and Patient Transfers**

A. The ASC shall secure a written transfer agreement with at least one hospital in the community. A transfer agreement shall serve as evidence of a procedure whereby patients can be transferred to a hospital should an emergency arise which would necessitate hospital admission.

1. If a written transfer agreement is established with a hospital in the community, medical staff at the ASC shall still be required to adhere to the provisions of §4541.B and C.

## **Subchapter C. Admissions, Transfers and Discharges**

### **§4539. Admissions and Assessments**

A. Each ASC shall have written admission and assessment policies and criteria.

B. An individual or entity that enters into a use agreement with a licensed ASC shall be required to adhere to all of the provisions of this Section.

2. If the ASC is not able to secure a written transfer agreement, the ASC's compliance with §4541.C shall substantiate the ASC's capability to obtain hospital care for a patient if the need arises.

B. Each member of the medical staff of the ASC, including physicians who practice under a use agreement, shall be a member in good standing on the medical staff of at least one hospital in the community and that hospital shall be licensed by the department. Members of the ASC medical staff shall be granted surgical privileges compatible with privileges granted by the hospital for that physician.

C. The admitting physician of the ASC shall be responsible for effecting the safe and immediate transfer of patients from the ASC to a hospital when, in his/her medical opinion, hospital care is indicated.

D. The ASC is responsible for developing written policies and procedures for the safe transfer of patients and coordination of admission, when necessary, into an inpatient facility. The written policy shall include, but is not limited to:

1. identification of the ASC personnel who shall be responsible for the coordination of admission into an inpatient facility;
2. procedures for securing inpatient services; and
3. procedures for the procurement of pertinent and necessary copies of the patient's medical record that will be sent with the transferring patient so that the information may be included in the patient's inpatient medical record.

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