

010-144 DEPARTMENT OF HUMAN SERVICES

BUREAU OF MEDICAL SERVICES
DIVISION OF LICENSING AND CERTIFICATION

Chapter 125: REGULATIONS GOVERNING THE LICENSING OF AMBULATORY SURGICAL FACILITIES

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CHAPTER 1: STATUTORY BASIS

The following rules and regulations are promulgated by the Maine Department of Human Services by virtue of the authority granted to the Department pursuant to 22 M.R.S.A. §1812-E.

Section 1. 22 M.R.S.A. §1812-E Ambulatory surgical facility

1. Definition. As used in this chapter, unless the context otherwise indicates, "ambulatory surgical facility" means a facility with a primary purpose of providing elective surgical care to a patient who is admitted to and discharged from the facility within the same day. In order to meet this primary purpose, a facility must at least administer anesthetic agents, maintain a sterile environment in a surgical suite and charge a facility fee separate from the professional fee. "Ambulatory surgical facility" does not include:
 - A. A facility that is licensed as part of a hospital;
 - B. A facility that provides services or accommodations for patients who stay overnight;
 - C. A facility existing for the primary purpose of performing terminations of pregnancies; or
 - D. The private office of a physician or dentist in individual or group practice, unless that facility or office is certified as a Medicare ambulatory surgical center.
2. Standards. The department shall establish standards for the licensure of ambulatory surgical facilities effective July 1, 1992. The standards must provide that ambulatory surgical facilities that are certified for the federal Medicare and Medicaid programs meet the requirements for state licensure.
3. Annual Inspection. The department shall annually inspect ambulatory surgical facility, except that state inspections need not be performed during a year when a Medicare inspection is performed.

Section 2. 22 M.R.S.A. §1815 Fees

Each application for a license to operate a hospital, convalescent home or nursing home shall be accompanied by a nonrefundable fee of \$10 for each bed contained within the facility. Each application for a license to operate an ambulatory surgical facility must be accompanied by the fee established by the department. The department shall establish the fee for an ambulatory surgical facility, not to exceed \$500, on the basis of a sliding scale representing size, number of employees and scope of operations. AU licenses issued must be renewed annually upon payment of a like fee. The State's share of all fees received by the department under this chapter must be deposited in the General Fund. A license granted may not be assignable or transferable. State hospitals are not required to pay licensing fees.

CHAPTER 2: LICENSURE PROCEDURES

2.A. Types of Licenses

The Department shall issue the following types of licenses:

- 2.A.1. The Department shall issue a full license to an applicant who complies with all applicable laws and rules.
- 2.A.2. A conditional license may be issued by the Department, when a provider fails to comply with applicable laws and rules, and in the judgement of the commissioner, the best interest of the public would be so served by issuing a conditional license. The conditional license shall specify when and what corrections shall be made during the term of the conditional license.
- 2.A.3. The commissioner may grant a full or conditional license under this chapter to those entities otherwise regulated by the State Government or the Federal Government, if he determines that those regulations meet the purpose and intent of this chapter.

2.B. Licenses Not Assignable or Transferable

No license may be assignable or transferable. A license shall be immediately void if ownership or control of the provider changes.

2.C. Term of Licenses

Licenses shall be issued for the following terms:

- 2.C.1. Full licenses shall be issued annually for a period of twelve months.
- 2.C.2. The Conditional licenses shall be issued for a specific period, not to exceed one year, or the remaining period of the previous full license, whichever the Department determines appropriate based on the laws and rules violated.
- 2.C.3. Regardless of the term of the license, the Department shall monitor for continued compliance with applicable laws and rules on at least an annual basis.

2.D. Failure to Comply with Applicable Laws and Rules

The following shall apply for failure to comply with applicable laws and rules:

- 2.D.1. When an applicant fails to comply with applicable laws and rules, the Department shall refuse to issue or renew the license.
- 2.D.2. If, at the expiration of a full license, or during the term of a full license, the facility fails to comply with applicable laws and rules and, in the judgement of the commissioner, the best interest of the public will be so served, the Department may issue a conditional license or change a full license to a conditional license.

2.D.3. Any license issued under this chapter may be suspended or revoked for violation of applicable laws and rules which prohibit the committing, permitting, aiding or abetting of any illegal practices in the providers' operations or when the conduct or practices of the provider are detrimental to the welfare, of persons to whom Ambulatory Surgical Facilities are provided. When the Department has reasonable grounds to believe that a license shall be suspended or revoked, it shall file a complaint with the Administration Court in accordance with Title 4, 1153 or commence administrative action pursuant to the Maine Administrative Procedure Act, Title 5, Section 8001 *et seq.*, as appropriate to the circumstances.

2.D.4. Receivership

Pursuant to 22 M.R.S.A., Section 7931 *et seq.*, the Department may petition the Superior Court to appoint a receiver to operate Ambulatory Surgical Facility in the following circumstances:

1. When the Ambulatory Surgical Facility intends to close, but has not arranged at least thirty (30) days prior to closure for the orderly transfer of its patients/clients;
2. When an emergency exists in an Ambulatory Surgical Facility which threatens the health, security or welfare of patient/clients;
3. When the Ambulatory Surgical Facility is in substantial or habitual violation of the standards of health, safety or patient/client care established under State or Federal regulations to the detriment of the welfare of the patient/client.

Eff. April 1,
2000

2.E. Appeals

Any person aggrieved by the Department's decision to take any of the following actions may request an administrative hearing as provided by the Maine Administrative Procedure Act, Title 5, Section 8001 *et seq.*

- 2.E.1. Issue a conditional license;
- 2.E.2. Amend or modify a license;
- 2.E.3. Refuse to issue or renew a full license.

CHAPTER 3: ADMINISTRATIVE REQUIREMENTS

3.A. Fees

Each application for a license under this chapter shall be accompanied by the fee established by the Department. No such fee may be refunded. The fee shall not exceed \$500 annually. All fees received by the Department under this chapter shall be paid into the State Treasury to the credit of the Department for the purpose of reducing the costs of carrying out this chapter.

3.A.1. Each application under this chapter shall be accompanied by the following fee(s):

- a. A basic fee of \$250 for all licensure applicants;
- b. An additional fee based on an agency's total full time equivalent staff. This additional fee will be calculated as follows:

0-10 total full time equivalent employees	\$100
10-25 total full time equivalent employees	\$175
25 or more full time equivalent employees	\$250
- c. In order to calculate the number of full time equivalent employees, a standard of at least 37 1/2 hours per week will be utilized. All full and part time employees of the Ambulatory Surgical Facility, including administrative, business clerical and direct service providers, will be included in the calculation of an agency's full time equivalency figure.
- d. All licenses issued shall be renewed annually upon payment of the appropriate fee and demonstration of continued compliance with these rules and regulations. The renewal fee shall be calculated utilizing information supplied in the Ambulatory Surgical Facility's annual statistical report and/or renewal application.
- e. No such fee shall be refunded.

3.A.2. Any license re-issued as a result of a change of administrator, change of ownership or modification to a conditional license status will be charged an additional \$25 fee.

3.B. Right of Entry and Inspection

The Department and any duly designated officer or employee thereof shall have the right to enter upon and into the premises of any Ambulatory Surgical Facility provider who has applied for a license or who is licensed pursuant to this chapter at any reasonable time and, upon demand, have the right to inspect and copy books, accounts, papers, records and other documents in order to determine the state of compliance with this chapter and any rules in force pursuant thereto. The right of reasonable entry and inspection shall extend to any premises and documents of providers whom the Department has reason to believe are providing Ambulatory Surgical Facility services without a license, but no such entry or inspection may be unreasonable or made without the permission of the

owner or person in charge thereof, unless a warrant is first obtained from a court of competent jurisdiction authorizing that entry or inspection.

3.C. Requirements

3.C.1. No Ambulatory Surgical Facility may provide services without receiving a license from the Department, authorizing such services or operation.

3.C.2. The applicant shall comply with all applicable Maine Statutes and rules and regulations.

3.C.3. No Ambulatory Surgical Facility shall accept any remuneration for delivering ambulatory surgical facilities without having first secured a license authorizing its operation in accordance with these regulations.

3.D. Application Procedures

3.D.1. Filing of Application

Any person, partnership, association or corporation desiring a license to engage in ambulatory surgical facilities shall, prior to the commencement of such operation, file an application with the Department. Applications submitted on behalf of a corporation or association shall be made by any two officers thereof or by its administrator. (All applicants shall comply with these rules and regulations.)

3.D.2. Contents of Application

Each application shall contain:

- a. The name by which the Ambulatory Surgical Facility is to be legally known and the name under which it shall be doing business.
- b. A description of all facilities utilized by the Ambulatory Surgical Facility. This will include the address(es), telephone number(s) and name(s) of owner(s) of all buildings utilized by the Ambulatory Surgical Facility.
- c. A listing of surgical procedures provided by the agency.

3.D.3. Change in Ownership of Ambulatory Surgical Facility

- a. No license shall be assigned or transferred.
- b. At least thirty (30) days advance written notice shall be given to the Division of Program Analysis and Development, Office of Health Planning and Development and the Division of Licensing and Certification, Bureau of Medical Services, prior to the transfer of ownership of any Ambulatory Surgical Facility.
- c. Each application for a license from a new owner shall be accompanied by a statement from the previous owner or his duly authorized

representative concerning the change of ownership. In lieu of this statement, a copy of the deed or other validating document shall be submitted. In addition, an application fee, calculated in accordance with Section 3.A. 1. of this chapter, shall be submitted to the Department. When the ownership of an Ambulatory Surgical Facility provider changes, upon receipt of a completed application and fee the Department may issue a license for a period of one year. The new owner's application must demonstrate that the agency will continue to comply with the requirements for licensure.

3.E. Certificate of Need

- 3.E.1. Any applicant desiring a license to engage in providing Ambulatory Surgical Facility services shall assure the Department that their facility does not need a Certificate of Need as determined by submitting a letter of intent as described in the Procedures Manual Maine Certificate of Need Act to:

Director, Division of Program Analysis and Development
Office of Health Planning and Development
35 Anthony Avenue, 11 State House Station
Augusta, Maine 04333

- 3.E.2. All Ambulatory Surgical Facilities shall submit a letter of intent to the Director, Division of Program Analysis and Development, as a part of the initial Ambulatory Surgical Facility process for the agency. This letter should state:

- a. The types of Ambulatory Surgical Facility services provided by the facility; and
- b. The date that each of these Ambulatory Surgical Facility services was initiated by the agency.

- 3.E.3. Utilizing the information supplied in the letter referenced in 3.E.2., the Division of Program Analysis and Development staff will make a determination as to whether a Certificate of Need is required by the agency, and will notify the agency (in writing) of its decision. The Division of Program Analysis and Development will also forward a copy of its determination to the Division of Licensing and Certification.

- 3.E.4. If an Ambulatory Surgical Facility desires to add any new services, a separate letter of intent should be forwarded to the Division of Program Analysis and Development.

3.F. Compliance with All Local Ordinances

The applicant shall submit a letter from the appropriate municipal official(s) that demonstrates compliance with all local ordinances relative to zoning and building code requirements.

3.G. Posting of License

The license granted by the Department shall be conspicuously posted in an area where business is conducted/coordinated for Ambulatory Surgical Facilities.

3.H. Identification Badges

All health care provider employees providing direct patient care must wear an identification badge that includes at least the following information:

1. Name of health care provider;
2. Employee's first name with first initial of the employee's last name;
3. Initials identifying the employee's registration/ licensure/certification;
4. Employee's job title.

Eff. April 1,
2000

Health care providers will develop policies and procedures which will define the situations and criteria when the wearing of an identification badge will be waived.

CHAPTER 4: COMPLIANCE REQUIREMENTS

4.A. Compliance with State Licensure Laws

The Ambulatory Surgical Facility must comply with all State licensure requirements

4.B. [RESERVE]

Effective
02/01/04

4.C. Governing Body and Management

The Ambulatory Surgical Facility must have a governing body that assumes full legal responsibility for determining, implementing and monitoring policies governing the Ambulatory Surgical Facility's total operation and for ensuring that these policies are administered so as to provide quality health care in a safe environment. When services are provided through a contract with an outside resource, the Ambulatory Surgical Facility must assure that these services are provided in a safe and effective manner.

Effective
02/01/04

4.C.1. Hospitalization

The Ambulatory Surgical Facility must have an effective procedure for the immediate transfer, to a hospital, of patients requiring emergency care beyond the capabilities of the Ambulatory Surgical Facility. This hospital must be a local, Medicare participating hospital or a local, non-participating hospital that meets the requirements for payment for emergency services under 42 Code of Federal Regulations, Section 482.2. The Ambulatory Surgical Facility must have a written transfer agreement with such a hospital, or all physicians performing surgery in the Ambulatory Surgical Facility must have admitting privileges at such a hospital. The Ambulatory Surgical Facility must also have a written agreement with an ambulance service.

Effective
02/01/04

4.D. Surgical Services

Surgical procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the Ambulatory Surgical Facility in accordance with approved policies and procedures of the Ambulatory Surgical Facility.

Effective
02/01/04

4.D.1. Anesthetic Risk and Evaluation

A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed. Before discharge from the Ambulatory Surgical Facility, each patient must be evaluated by a physician for proper anesthesia recovery.

Effective
02/01/04

4.D.2. Administration of Anesthesia

Anesthetics must be administered by only:

- a. A qualified anesthesiologist; or

- b. A physician qualified to administer anesthesia, a certified nurse anesthetist, a supervised trainee in an approved educational program. In those cases where a non-physician administers the anesthesia, the anesthetist must be under the supervision of the operating physician.

Effective
02/01/04

4.D.3. Discharge

All patients are discharged in the company of a responsible adult, except those exempted by the attending physician.

Effective
02/01/04

4.E. Evaluation of Quality

The Ambulatory Surgical Facility, with the active participation of the medical staff, must conduct an ongoing, comprehensive self-assessment of the quality of care provided, including medical necessity of procedures performed and appropriateness of care, and use findings, when appropriate, in the revision of center policies and consideration of clinical privileges.

Effective
02/01/04

4.F. Environment

The Ambulatory Surgical Facility must have a safe and sanitary environment, properly constructed, equipped and maintained to protect the health and safety of patients.

Effective
02/01/04

4.F.1. Physical Environment

The Ambulatory Surgical Facility must provide a functional and sanitary environment for the provision of surgical services.

- a. Each operating room must be designed and equipped so that the types of surgery conducted can be performed in a manner that protects the lives and assures the physical safety of all individuals in the area.
- b. The Ambulatory Surgical Facility must have a separate recovery room and waiting area.
- c. The Ambulatory Surgical Facility must establish a program for identifying and preventing infections, maintaining a sanitary environment and reporting the results to appropriate authorities.

Effective
02/01/04

4.F.2. Safety From Fire

- a. Except as provided in paragraphs 4.E.2.b. and 4.E.2.c. of this section, the Ambulatory Surgical Facility must meet the provisions of the 1985 edition of the Life Safety Code of the National Fire Protection Association (which is incorporated by reference) that are applicable to Ambulatory Surgical Facilities.
- b. In consideration of a recommendation by the State survey agency, HCFA may waive, for periods deemed appropriate, specific provisions of the Life Safety Code which, if rigidly applied, would result in unreasonable

hardship upon an Ambulatory Surgical Facility, but only if the waiver will not adversely affect the health and safety of the patients.

- c. Any Ambulatory Surgical Facility that, on May 9, 1988, complies with the requirements of the 1981 edition of the Life Safety Code, with or without waivers, will be considered to be in compliance with this standard, so long as the Ambulatory Surgical Facility continues to remain in compliance with that edition of the Life Safety Code.

Effective
02/01/04

4.F.3. Emergency Equipment

Emergency equipment available to the operating rooms must include at least the following.

- a. Emergency call system
- b. Oxygen (both portable and stationary) to include oxygen delivery devices such as tubing, masks and nasal cannulae
- c. Mechanical ventilator assistance equipment, including airways, manual breathing bag and ventilator
- d. Cardiac monitoring equipment, including cardiac defibrillation equipment
- e. Tracheostomy set
- f. Laryngoscopes and endotracheal tubes
- g. Suction equipment
- h. Emergency medical equipment and supplies specified by the medical staff.

Effective
02/01/04

4.F.4. Emergency Personnel

Personnel trained in the use of emergency equipment and in cardiopulmonary resuscitation must be available whenever there is a patient in the Ambulatory Surgical Facility.

Effective
02/01/04

4.G. Medical Staff

The medical staff of the Ambulatory Surgical Facility must be accountable to the governing body.

Effective
02/01/04

4.G.I. Membership and Clinical Privileges

Members of the medical staff must be legally and professionally qualified for the positions to which they are appointed and for the performance of privileges granted. The Ambulatory Surgical Facility grants privileges in accordance with recommendations from qualified medical personnel.

Effective
02/01/04

4.G.2. Reappraisals

Medical staff privileges must be periodically reappraised by the Ambulatory Surgical Facility. The scope of procedures performed in the Ambulatory Surgical Facility must be periodically reviewed and amended as appropriate.

Effective
02/01/04

4.G.3. Other Practitioners

If the Ambulatory Surgical Facility assigns patient care responsibilities to practitioners other than physicians, it must have established policies and procedures, approved by the governing body, for overseeing and evaluating their clinical activities.

Effective
02/01/04

4.H. Nursing Services

The nursing services of Ambulatory Surgical Facilities must be directed and staffed to assure that the nursing needs of all patients are met.

Effective
02/01/04

4.H.1. Organization and Staffing

Patient care responsibilities must be delineated for all nursing and service personnel. Nursing services must be provided in accordance with recognized standards of practice. There must be a registered nurse available for emergency treatment whenever there is a patient in the Ambulatory Surgical Facility.

Effective
02/01/04

4.I. Medical Records

The Ambulatory Surgical Facility must maintain complete, comprehensive and accurate medical records to ensure adequate patient care.

Effective
02/01/04

4.I.1. Organization

The Ambulatory Surgical Facility must develop and maintain a system for the proper collection, storage and use of patient records.

Effective
02/01/04

4.I.2. Form and Content of Record

The Ambulatory Surgical Facility must maintain a medical record for each patient. Every record must be accurate, legible and promptly completed. Medical records must include at least the following:

- a. Patient identification
- b. Significant medical history and results of physical examination
- c. Pre-operative diagnostic studies (entered before surgery, if performed).

- d. Findings and techniques of the operation, including a pathologist's report on all times removed during surgery, except those exempted by the governing body
- e. Any allergies and abnormal drug reactions
- f. Entries related to anesthesia administration
- g. Documentation of properly executed informed patient consent
- h. Discharge diagnosis.

Effective
02/01/04

4.J. Pharmaceutical Services

The Ambulatory Surgical Facility must provide drugs and biologicals in a safe and effective manner, in accordance with accepted professional practice, and under the direction of an individual designated responsible for pharmaceutical services.

Effective
02/01/04

4.J.I. Administration of Drugs

Drugs must be prepared and administered according to established policies and acceptable standards of practice.

- a. Adverse reactions must be reported to the physician responsible for the patient and must be documented in the record.
- b. Blood and blood products must be administered by only physicians or registered nurses.
- c. Orders given orally for drugs and biologicals must be followed by a written order, signed by the prescribing physician.

Effective
02/01/04

4.K. Laboratory and Radiologic Services

The Ambulatory Surgical Facility must have procedures for obtaining routine and emergency laboratory and radiologic services, from Medicare approved facilities, to meet the needs of patients.

STATUTORY AUTHORITY: 22 M.R.S.A., Sections 1812-E and 1815

EFFECTIVE DATE:

November 5, 1992

EFFECTIVE DATE (ELECTRONIC CONVERSION):

May 5, 1996

AMENDED:

April 1, 2000 - Sec. 2.D.4. and 3.H. added

February 11, 2004 - Sec. 4.B added, successive subsections in Ch. 4 renumbered - filing 2004-55

AMENDED:

Chapter 4.B Mandatory Reporting of Sentinel Events is repealed and replaced by 10-144 C.M.R. Chapter 114, Rules Governing the Reporting of Sentinel Events.