

Chapter 2 – Hospital and Medications Rules

Subchapter 8 –

Ambulatory Surgical Center Licensing Rule

1.0 Authority

This rule is adopted pursuant to 18 V.S.A. § 2159.

2.0 Purpose

This rule sets forth the standards that apply to the licensing of Ambulatory Surgical Centers in Vermont. This rule applies to all Ambulatory Surgical Centers in Vermont as defined in 18 V.S.A. Chapter 49.

3.0 Definitions

3.1 “Accreditation” means the formal recognition by an CMS-approved accrediting body such as the Joint Commission that indicates conformity with the accrediting body’s required set of standards and criteria.

3.2 “Ambulatory Surgical Center” means any distinct entity that operates primarily for the purpose of providing surgical services to patients not requiring hospitalization and for which the expected duration of services would not exceed 24 hours following an admission. The term does not include:

3.2.1 A facility that is licensed as part of a hospital; or

3.2.2 A facility that is used exclusively as an office or clinic for the private practice of one or more licensed health care professionals, unless one or more of the following descriptions apply:

3.2.2.1 The facility holds itself out to the public or to other health care providers as an ambulatory surgical center, surgical center, surgery center, surgicenter, or similar facility using a similar name or a variation thereof;

3.2.2.2 Procedures are carried out at the facility using general anesthesia, except as used in oral or maxillofacial surgery or used as used by a dentist with a general anesthesia endorsement from the Board of Dental Examiners; or

3.2.2.3 Patients are charged a fee for the use of the facility in addition to the fee for the professional services of one or more of the health care professionals practicing at the facility.

3.3 “CMS” means the Centers for Medicare and Medicaid Services of the U.S. Department of Health and Human Services.

3.4 “CMS Conditions for Coverage for Ambulatory Surgical Center” or “CfCs” means the following current Centers for Medicare and Medicaid Services rules

from the Code of Federal Regulations (CFR) and related laws and regulations, interpretive guidelines, appendices and requirements, including 42 CFR § 416.40-416.54.

- 3.5 “Commissioner” means the Commissioner of the Vermont Department of Health.
- 3.6 “Deemed Status” means the status granted to an Ambulatory Surgical Center by a CMS-approved national accrediting body, such as The Joint Commission, after it has surveyed the Ambulatory Surgical Center and determined it is in compliance with all CMS Conditions for Coverage.
- 3.7 “Deficiency” means a policy, procedure, practice or any other action by an Ambulatory Surgical Center that results in the Ambulatory Surgical Center not being in compliance with this rule or with the CMS Conditions for Coverage.
- 3.8 “Department” means the Vermont Department of Health.
- 3.9 “The Joint Commission” means the independent not for profit organization that accredits and certifies that healthcare organizations meet certain performance standards.
- 3.10 “Patient Complaint” means any expression of dissatisfaction related to the care and treatment provided by an Ambulatory Surgical Center, from a patient or the patient’s representative. In this Rule, the term includes patient “grievance” which in the CfCs and CMS State Operations Manual specifically refers to complaints presented to and resolved or attempted to be resolved within the Ambulatory Surgical Center’s internal system.
- 3.11 “Plan of Correction” means a written plan that a licensee is required to submit to address any identified Deficiency to bring an Ambulatory Surgical Center into compliance with this rule.
- 3.12 “State Survey Agency” means the unit of Vermont state government designated by CMS to enforce the federal CfC for Ambulatory Surgical Centers in Vermont.
- 3.13 “Validation Survey” means a survey conducted by the State Survey Agency on behalf of CMS to ensure that an Ambulatory Surgical Center with Deemed Status is in compliance with the Conditions for Coverage.

4.0 Application for an Ambulatory Surgical Center License

- 4.1 No organization or individual may establish, conduct, or maintain operation of an Ambulatory Surgical Center in Vermont without being granted a license by the Department.

- 4.2 Every Vermont Ambulatory Surgical Center license shall expire on December 31 of each year unless otherwise revoked.
- 4.3 An application for an Ambulatory Surgical Center license or license renewal must be submitted in the form required by the Department and available on its webpage. Renewal applications must be submitted on or before the deadline set by the Department.
- 4.4 The application must contain all information required by the Department and be accompanied by a license fee in the amount required by law and posted on the Department webpage. The required information must include:
 - 4.4.1 Identifying information and all facility locations.
 - 4.4.2 Administrative officers and contact information for the person completing the application.
 - 4.4.3 Type of Ambulatory Surgical Center, form of organization, and CMS designation.
 - 4.4.4 Certification and accreditation status.
 - 4.4.5 Number of surgical procedure rooms.
 - 4.4.6 The Ambulatory Surgical Center's publicly accessible policy for providing charity care to eligible patients.
 - 4.4.6.1 At a minimum, such a policy must inform patients of how to apply and identify the criteria used for making decisions on applications.
 - 4.4.7 Documentation of at least one emergency medical service transportation agreement.
 - 4.4.8 Any other information as required by the Department.
- 4.5 Unless the Department specifies a different time or format for response, an Ambulatory Surgical Center must furnish all information requested by the Department within ten (10) working days of receipt, including any documents necessary to verify that the applicant Ambulatory Surgical Center has met the requirements of the CfCs.

5.0 Requirements for Ambulatory Surgical Center Licensure

- 5.1 42 CFR § 416.40-416.54 is hereby incorporated by reference.**

To be licensed and retain licensure in Vermont, each Ambulatory Surgical Center must comply with all applicable CMS Conditions for Coverage or be operating under a Plan of Correction as described in Section 7.0 of this rule.

5.2 Compliance with CMS Conditions for Coverage for entities without Deemed Status

5.2.1 A Vermont Ambulatory Surgical Center that does not have deemed status must be available for a comprehensive, on-site and unannounced survey by the State Survey Agency to demonstrate compliance with CfCs:

5.2.1.1 Occurring on average once every three years or at a frequency determined by CMS for ambulatory surgical centers without deemed status.

5.2.1.2 Whenever the Department or its designee determines that a survey is required as referenced in Section 7 of this rule.

5.3 Demonstrating Compliance with CMS CfCs through Deemed Status

5.3.1 Ambulatory Surgical Centers accredited by a CMS-approved accrediting body and with Deemed Status meet the compliance requirements of the CfCs; each Accredited Ambulatory Surgical Center with Deemed Status shall be considered by the State Survey Agency and the Department to have met the CfCs unless and until their accreditation is revoked or cancelled or there is a finding made pursuant to Section 7 of this rule.

5.3.2 An Ambulatory Surgical Center with Deemed Status must make the institution available for a Validation Survey by the State Survey Agency when CMS requires a Validation Survey.

5.4 Safety and Quality Programs

5.4.1 Each applicant for an Ambulatory Surgical Center license or renewal must certify compliance with the Patient Safety Surveillance and Improvement System regulations adopted by the Commissioner pursuant to 18 V.S.A. Ch. 43a.

5.4.2 Each Ambulatory Surgical Center must participate in the CMS Ambulatory Surgical Center Quality Reporting Program.

5.4.3 Any Ambulatory Surgical Center that is notified by CMS of a reduction in the ASC annual payment rate or denial of the full annual update to the ASC annual payment rate must submit notice of such action to the Department within fifteen days of receipt of notice from CMS.

5.5 Emergency Preparedness Planning

All Vermont Ambulatory Surgical Centers must comply with CMS regulations for Emergency Preparedness. An Ambulatory Surgical Center must provide a copy of its Emergency Preparedness Plan to the Department for review if requested.

5.6 License Transfer and Posting

5.6.1 An Ambulatory Surgical Center license is not transferable or assignable and must be issued only for the premises and persons named in the application. A licensed Ambulatory Surgical Center changing ownership or eliminating or significantly reducing clinical services must provide at least ninety (90) days advance notice to the Department.

5.6.2 The Ambulatory Surgical Center license must be posted in a conspicuous place on the licensed facility's premises.

6.0 Ambulatory Surgical Center Response and Management of Complaints

6.1 Patients' Rights

Each Vermont Ambulatory Surgical Center must:

6.1.1 Distribute to all patients registered for a procedure a clear language and easily readable print copy of the patient's rights required by 42 CFR 416.50.

6.1.2 Post conspicuously a written version of the patient's rights in areas frequented by patients and patient representatives and on its website.

6.2 Procedures for Responding to Patient Complaints

The following information must be included with the patient's rights distributed to each patient receiving care at a Vermont Ambulatory Surgical Center:

6.2.1 A description of the procedure for filing and appealing a complaint to the Ambulatory Surgical Center, clearly labeled, "To file a complaint" or "What to do if you are not satisfied with our response to your complaint". Other descriptors such as "patient concerns" or "consumer feedback" may be used, but only in addition to "To file a complaint" or "What to do if you are not satisfied with our response to your complaint."

6.2.2 A notice that a complainant may also contact the Department, the Vermont Office of the Healthcare Advocate, the Board of Medical Practice, or the licensing authorities for other health care professions as an alternative. The notice must include the address and phone numbers for the Department, the Board of Medical Practice, the Vermont Office of the Healthcare Advocate, and the Office of Professional Regulation.

- 6.2.3 A published time frame for processing and resolving complaints and appeals within the Ambulatory Surgical Center.
- 6.2.4 A description of internal procedures for receiving, processing and resolving complaints from or filed on behalf of patients. Such procedures must ensure that the Ambulatory Surgical Center complies with the CfC requirements for grievances.
- 6.2.5 Each Ambulatory Surgical Center applicant shall demonstrate to the Department that the Ambulatory Surgical Center meets the following:
 - 6.2.5.3 Maintains adequate records of patient complaints and their resolution; and
 - 6.2.5.4 Documentation that the Ambulatory Surgical Center complies with all other applicable requirements pertaining to patients' rights.

6.2 Reporting Complaint Data

No less frequently than annually, on a schedule and in a format determined to the Commissioner, an Ambulatory Surgical Center must submit to the Department a report summarizing, in aggregate, the types of complaints filed with the Ambulatory Surgical Center by patients or their representatives in the past year. The report must contain:

- 6.2.1 The number of patients served during the reporting period;
- 6.2.2 The total number of complaints received;
- 6.2.3 The total number of complaints in each of the categories the Ambulatory Surgical Center uses to track complaints; and
- 6.2.4 A brief narrative report describing examples of actions taken to resolve complaints in the past year.

7.0 Compliance

- 7.1 Notwithstanding a CMS-approved national accrediting body's determination that an Ambulatory Surgical Center has met CfCs through surveys or Deemed Status, the Department or its designee may independently review or investigate an Ambulatory Surgical Center and determine whether it is in compliance with requirements for Ambulatory Surgical Center licensure under Vermont law.
- 7.2 When notified of a Deficiency, an Ambulatory Surgical Center must within 30 days, or such shorter period as may be specified in the notice for good cause, develop and submit a Plan of Correction for addressing any identified Deficiency and for achieving compliance with this rule.
- 7.3 Department Review and Response to Plan of Correction

- 7.3.1 Within thirty (30) days after receipt of a Plan of Correction, the Department must notify the Ambulatory Surgical Center of one of the following actions related to each identified Deficiency:
 - 7.3.1.1 Accept the Plan of Correction
 - 7.3.1.2 Request a revision to the Plan of Correction specifying the reasons for the request.
- 7.3.2 An Ambulatory Surgical Center required to submit a revised Plan of Correction pursuant to Section 7.3.1.2 of this rule must develop and submit the revision within thirty (30) days.
- 7.3.3 If, after reviewing a revised Plan of Correction, the Department determines that an Ambulatory Surgical Center is not in full compliance with this rule or cannot comply with this rule or the Ambulatory Surgical Center's Plan of Correction, the Department may find that it is in violation of this regulation and proceed with a compliance action.

8.0 Process for Compliance Actions

- 8.1 The Department may condition, suspend, or revoke the license of an Ambulatory Surgical Center upon due notice and opportunity for hearing with the Commissioner or designee for violation of any provision of this rule or applicable state regulation, municipal ordinance or state statute, pursuant to the provisions of 3 V.S.A. § 814.
- 8.2 The Department must notice the licensee by registered mail or personal service of the facts that warrant conditioning, suspending, or revoking the license and the right to a hearing. A hearing must be set not less than 60 days from the date of the mailing to or service on the licensee, however a hearing may take place earlier upon agreement of all parties.

9.0 Process for Conditioning or Denying a License Application

- 9.1 When the Department determines that a license should not be granted without the imposition of specified conditions it may notify the applicant and, if the applicant consents, a license may be issued subject to such conditions.
- 9.2 When the Department denies an application for licensure, the applicant must be afforded an opportunity for a hearing with the Commissioner or designee pursuant to the provisions of 3 V.S.A. § 814.
- 9.3 The Department must provide an applicant with notice of denial by mail or by personal service that explains the facts that warrant the denial of the application and the right to a hearing. The Department must set a date for the hearing not less than 60 days from the date of the mailing or service, however a hearing may take place earlier upon agreement of all parties.

10.0 Hearing Process for License Denial and Compliance Actions

- 10.1 Hearings must be conducted according to the hearing provisions of the Administrative Procedure Act, 3 V.S.A. § 809-815.
- 10.2 The Commissioner's decision may be appealed to the Vermont Superior Court for the district in which the appellant is located. Appeals from the decision of the Superior Court must be to the Vermont Supreme Court.

11.0 Informing Patients of Investigation Completion

- 11.1 Upon completion of an investigation initiated upon a patient complaint, and determination as to whether an action is to be pursued under subsections 7.0 or 8.0 of this rule, the complainant or their representative must be provided notice in writing.
- 11.2 The notice must state that the investigation is complete and whether a public proceeding regarding the license of the subject facility has resulted.
- 11.3 Notice must be sent promptly and in no case more than 14 days after the determination is made and must include the time and place of any public proceeding.