Standards for Licensing Ambulatory Surgical Facilities

Regulation 61-91

Effective June 28, 2024

SECTION 100 - DEFINITIONS, REFERENCES, AND LICENSE REQUIREMENTS

B. Adjusted Gross Revenue. Total Gross Revenue minus Medicaid and Medicare contractual adjustments only and bad debt. (This definition was added, causing subsequent letter designations for the definitions in this section to be adjusted).

J. Bad Debt. The amount a party has an obligation to pay, but that is considered uncollectible. Bad debt represents the portion of a patient's account not expected to be collected from the patient or other responsible party (the patient's portion). The patient's portion of a bill should not be categorized as bad debt for medically indigent patients. Bad debt must be differentiated from charity services. Patient charges otherwise eligible for classification as charity care should only be treated as bad debt if all conditions of your facility's charity care criteria are not met.

DEFINITIONS, REFERENCES, AND LICENSE REQUIREMENTS CONT'D

M. Charity Care. Any unpaid charges for services to patients as defined in S.C. Code Ann. Section 44 6 5(5). Only the portion of a patient's account that meets the facility's charity care criteria is recognized as charity.

N. Contractual Adjustments. Any charges that are not paid by third party payers and cannot be billed to the patient pursuant to contractual agreements. Contractual adjustments for Medicare, Medicaid and other payers should be captured separately.

DEFINITIONS, REFERENCES, AND LICENSE REQUIREMENTS CONT'D

W. Gross Indigent and Charity Care Patient Charges. The total uncompensated charges for patients who qualify as indigent or charity under the relevant definitions.

X. Gross Patient Revenue. Includes charges generated by all patients at full established rates before provisions for contractual and other adjustments are applied. Include any revenue forgone for provision of care for indigent/charity patients at full established rates.

DEFINITIONS, REFERENCES, AND LICENSE REQUIREMENTS CONT'D

Z. Indigent and Charity Care Write Offs. Unpaid charges for indigent and charity care cases should be related only to the provision of ambulatory surgical facility services that are licensed and regulated by the Department. Unpaid charges from other lines of business should not be included.

AA. Indigent Care. Any unpaid charges for services to medically indigent patients as defined in S.C. Code Ann. Section 44 6 5(5). Unpaid charges for patients who were eligible for Medicare, Medicaid, Third Party, or patients provided other free care are not included in Indigent Care.

DEFINITIONS, REFERENCES, AND LICENSE REQUIREMENTS CONT'D

MM. Other Free Care. Other uncompensated care provided as a result of employee discounts, administrative adjustments, courtesy discounts, small bill write-offs, or other similar write-offs not based on a patient's inability to pay. Should not include amounts properly classified as "contractual adjustments."

NN. Other Revenue. Other revenues or gains are derived from services other than providing services to patients. This may include revenues shared with the facility from another organizational entity.

DEFINITIONS, REFERENCES, AND LICENSE REQUIREMENTS CONT'D

HHH. Total Expenses. The sum of resources consumed in fulfillment of a facility's ongoing major or central operations. Expenses may result from current expenditures, incurring obligations to make future expenditures, or consuming resources obtained from previous expenditures. Expenses related to activities shared with entities other than the ambulatory surgical facility should be allocated between the entities. The expense component not allocated to the ambulatory surgical facility should not be included in the report. Appropriate matching of revenues and expenses excluded from the report should be made. Do not include bad debt as a total expense, but as a deduction from revenue.

DEFINITIONS, REFERENCES, AND LICENSE REQUIREMENTS CONT'D

III. Total Gross Revenue. The total revenue for the facility from all patient revenue and from other revenues or gains derived from services other than providing services to patients.

JJJ. Total Indigent and Charity Compensation. Funds provided by all public and private sources that are earmarked as compensation to offset uncompensated charges from indigent or charity care cases.

SECTION 103 - LICENSE REQUIREMENTS

G. Application. Applicants for a license shall submit to the Department…**Applicants shall make payment of all outstanding fees (initial licensure fees, annual licensure fees, inspection fees, construction fees, etc.) prior to the Department's issuance of a license.**

H. Fees. The initial and annual license fee shall be $150.00 per operating/procedure room or $600.00, whichever is greater. **(Such fee shall be made payable by check or money order to the Department and is not refundable. The Department may charge a fee for plan reviews, construction inspections and licensing inspections – deleted). All fees are non-refundable and shall be made payable to the Department via a secured portal or specific website.**

LICENSE REQUIREMENTS CONT'D

N. **Indigent/Charity Care. Any Facility established or constructed after May 16, 2023, and which did not require a Certificate of Need, must provide indigent charity care as described below in Section 103.N.2 after it has been in operation for two calendar years:**

1. **Annual Reports: After being in operation for two calendar years, a Facility subject to Section 103.N shall submit annual reports in a form prescribed by the Department and located on the Department's website. Further, a Facility subject to Section 103.N shall submit the annual reports by a deadline set by the Department and indicated on the Department's website. The annual reports shall include, but not be limited to the following information:**

LICENSE REQUIREMENTS CONT'D

a. **Gross patient revenue;**

b. **Medicare contractual adjustments;**

c. **Medicaid contractual adjustments;**

d. **Other contractual adjustments;**

e. **Bad debt;**

LICENSE REQUIREMENTS CONT'D

f. **Indigent care gross charges;**

g. **Indigent care compensation;**

h. **Charity care gross charges;**

i. **Charity care compensation;**

j. **Other free care;**

LICENSE REQUIREMENTS CONT'D

k. **Other revenue; and**

l. **Total expenses.**

2. **Indigent/Charity Care requirements:**

a. **If the Facility provides care to Medicaid beneficiaries, it must provide uncompensated indigent/charity care to the underinsured or medically indigent in an amount equal to or greater than 2% of its adjusted gross revenue; or**

LICENSE REQUIREMENTS CONT'D

b. If the Facility does not provide care to Medicaid beneficiaries, it must provide uncompensated indigent/charity care to the underinsured or medically indigent in an amount equal to or greater than 3% of its adjusted gross revenue.

c. Noncompliance with Section 103.N.2.a or -b shall result in a monetary penalty in the amount of the difference between the services which the Facility is required to provide and the amount it actually provided.

SECTION 200 - ENFORCING REGULATIONS

202. F. **Inspection Fees. The Facility shall pay the inspection fee for initial, relocation, routine inspection, and routine follow up. The Facility shall pay a fee for unit increase of service modification or follow up.**

Initial/Relocation Inspection Fee	Calculated - $350 + $45 per operating, endoscopy, and procedure room
Initial/Relocation Inspection Fee	Calculated - $200 + $45 per operating, endoscopy, and procedure room
Routine Inspection Fee	Calculated - $350 + $45 per operating, endoscopy, and procedure room
Routine Follow-Up Fee	Calculated - $350 + $45 per operating, endoscopy, and procedure room
Unit Increase or Service Modification Fee	Calculated - $200 + $45 per operating, endoscopy, and procedure room
Unit Increase of Service Modification Follow-Up	Calculated - $200 + $45 per operating, endoscopy, and procedure room

ENFORCING REGULATIONS CONT'D

G. **Construction Fees. The Facility shall pay the following inspection fees during the construction phase of the project.**

Construction Inspection Fees	
Plan Inspection	
Total Project Cost	**Fee**
< $10,001	**$750**
$10,001 -$100,000	**$1,500**
$100,001 - $500,00	**$2,000**
> $500,000	**$2,500 plus $100 for each additional $100,000 in project costs**
Site Inspection	**$500**

SECTION 400 - POLICIES AND PROCEDURES

401.A. **The Facility shall maintain and adhere to** policies and procedures addressing each section of this regulation regarding care, treatment, procedures, surgery, and/or services, patient rights, and the operation of the facility **(shall be developed and implemented, and revised as required in order to accurately reflect actual facility operation - deleted). The policies and procedures shall follow current accepted standards of medical and surgical practice to ensure services are provided in a manner which protects the health and safety of patients. The Facility shall be in full compliance with the policies and procedures**. **(The licensee shall establish a time period for review of all policies and procedures. These policies and procedures shall be accessible in each facility at all times, either by hard copy or electronically – deleted)**

POLICIES AND PROCEDURES CONT'D

B.(Policies and procedures shall describe the means by which the facility shall assure that the standards described in this regulation that the licensee has agreed to meet, as confirmed by signature on the application for licensing, will be met (see Section 1601.B) – deleted). **The Facility shall establish a time period for review, not to exceed two (2) years, of all policies and procedures, and such reviews shall be documented. The Facility shall ensure all policies and procedures are accessible to staff at all times, either by hard copy or electronically.**

SECTION 500 - STAFF

503. Control

The Facility must have a governing body designated in writing by the licensee that assumes full responsibility for determining, implementing, and monitoring policies governing the Facility's total operations. The governing body has oversight and accountability for the quality improvement program, and ensures that Facility policies and programs are administered so as to provide quality health care in a safe environment.

STAFF CONT'D

507. B. An individual who possesses a valid Pediatric Advanced Life Support credential shall be on duty in the facility whenever pediatric patients are present in the facility.

SECTION 600 - REPORTING

601. B The licensee shall report each accident and/or incident resulting in unexpected death or serious injury to the next of kin or party responsible for each affected individual at the earliest practicable hour, not exceeding twenty-four (24) hours. The licensee shall notify the Department immediately, not to exceed twenty-four (24) hours, via telephone, email or facsimile. The licensee shall submit a report of the licensee's investigation of the accident and/or incident to the Department within five (5) days. Accidents and/or incidents requiring reporting include, but are not limited to:

601. **B 1-14 were deleted**

SECTION 600 - REPORTING

1. **Surgical or Invasive Procedure Events**
   a. **Surgery or other invasive procedure performed on the wrong site;**

   b. **Surgery or other invasive procedure performed on the wrong patient;**

   c. **Wrong surgical or other invasive procedure performed on a patient;**

   d. **Unintended retention of a foreign object in a patient after surgery or other invasive procedure; and**

   e. **Intraoperative or immediately/post procedure death.**

REPORTING CONT'D

2. **Product or Device Events**

   a. **Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the Facility;**

   b. **Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used or functions other than as intended; and**

   c. **Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in the Facility.**

REPORTING CONT'D

3. **Patient Protection Events**

   a. **Discharge or release of a patient of any age, who is unable to make decisions, to other than an authorized person;**

   b. **Patient death or serious injury associated with patient elopement; and**

   c. **Patient suicide, attempted suicide, or self harm that results in serious injury while being cared for in the Facility.**

REPORTING CONT'D

4. **Care Management Events**

   a. **Patient death or serious injury associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration);**

   b. **Patient death or serious injury associated with unsafe administration of blood products;**

   c. **Patient death or serious injury associated with a fall while being cared for in the Facility;**

   d. **Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results.**

REPORTING CONT'D

5. **Environmental Events**

   a. **Patient or staff death or serious injury associated with an electric shock in the course of a patient care process in the Facility;**

   b. **Any incident in which systems designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas, or are contaminated by toxic substances;**

REPORTING CONT'D

c. Patient or staff death or serious injury associated with a burn incurred from any source in the course of a patient care process in the Facility; and

d. Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in the Facility.

REPORTING CONT'D

6. **Potential Criminal Events**

   a. **Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider;**

   b. **Abduction of any patient of any age;**

   c. **Sexual abuse/assault on a patient or staff member within or on the grounds of the Facility; and**

   d. **Death or serious injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of the Facility.**

SECTION - 800 CARE/TREATMENT/ PROCEDURES/SURGERY/SERVICES

801.D. **The Facility shall have a written transfer agreement with one (1) or more hospitals that provides reasonable assurance that transfer of patients will be made between the hospital and the facility. The transfer agreement shall be dated and signed by authorized officials who are a party to the agreement. The agreement shall be updated following a change of Administrator; the agreement shall be updated following changes in licensee or at any other time as deemed advisable to maintain or further improve continuity of care.**

Exception: A facility which has attempted, but has been unable to secure such an agreement shall maintain documentation of its efforts, and shall provide the local hospitals written notice of its hours of operation and patient population.

CARE/TREATMENT/PROCEDURES/ SURGERY/SERVICES CONT'D

804. Anesthesia Services

B. **Immediately before surgery**:

1. **A physician must examine the patient to evaluate the risk of the procedure to be performed; and**

2. **A physician, certified registered nurse anesthetist, or anesthesiologist's assistant must examine the patient to evaluate the risk of anesthesia.**

CARE/TREATMENT/PROCEDURES/ SURGERY/SERVICES CONT'D

807. Cardiovascular Care Services.

A. **Prior to establishing or offering invasive cardiac procedures, including cardiac catheterization services, a facility must have applied for and be in the process of obtaining accreditation for such services from the American College of Cardiologists, Accreditation for Cardiovascular Excellence, or other nationally recognized accrediting organization approved by the Department with standards at least equal to those of the Accreditation for Cardiovascular Excellence or American College of Cardiologists. To continue providing such services, a facility must obtain such accreditation within two years from application unless otherwise approved by the Department.**

CARE/TREATMENT/PROCEDURES/ SURGERY/SERVICES CONT'D

807.A cont'd:

...Facilities must maintain documentation evidencing their application for accreditation and accreditation for such services. If a facility is denied accreditation or has its accreditation revoked, the facility must immediately notify the Department in writing, cease offering such services, and cannot resume offering such services until the facility is accredited or re accredited.

CARE/TREATMENT/PROCEDURES/ SURGERY/SERVICES CONT'D

807.B. **Facilities that offer cardiac catheterization services shall have written protocols ensuring immediate, efficient, and safe transfer of patients to the nearest hospital with onsite cardiac surgery in the case of an emergency.**

SECTION 1200 - EMERGENCY PROCEDURES/DISASTER PREPAREDNESS

1201. Emergency Services

A. Appropriate equipment and services shall be provided to render emergency resuscitative and life-support procedures pending transfer to a hospital. **The emergency equipment must meet the following requirements**:

1. **Be immediately available for use during emergency situations**;

2. **Be appropriate for the facility's patient population; and**

SECTION 1200 - EMERGENCY PROCEDURES/DISASTER PREPAREDNESS CONT'D

1201. Emergency Services cont'd

3. **Be maintained by appropriate personnel in accordance with manufacturer's instructions.**

B. **(The facility shall have the capability of obtaining blood and blood products to meet emergency situations – deleted).**

SECTION 1500 - INFECTION CONTROL AND ENVIROMENT

1504. Sterilization Procedures

E. **Collection, transportation, and storage of contaminated or used equipment must be performed in a safe manner and in accordance with approved policies and procedures of the Facility.**

SECTION 1600 - QUALITY IMPROVEMENT PROGRAM

1601. General

C. **The governing body must ensure the quality improvement program:**

1. **Is defined, implemented, and maintained by the Facility;**

2. **Addresses the Facility's priorities and that all improvements are evaluated for effectiveness;**

SECTION 1600 - QUALITY IMPROVEMENT PROGRAM CONT'D

1601. C . Cont'd

3. **Specifies data collection methods, frequency, and details;**

4. **Clearly establishes its expectations for safety; and**

5. **Adequately allocates sufficient staff, time, information systems, and training to implement the quality improvement program.**

SECTION 2000 – Physical Plant

2006. Restrooms

E. The facility shall have toilet fixtures in restrooms for patient use in ample number, located within or adjacent to the recovery area. The minimum requirement is one toilet fixture for every **(surgical and procedure room- deleted)** **eight pre-operative and post operative beds.**