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**RULES
OF
DEPARTMENT OF COMMUNITY HEALTH**

**CHAPTER 111-8
HEALTHCARE FACILITY REGULATION**

**111-8-4
AMBULATORY SURGICAL TREATMENT CENTERS**

TABLE OF CONTENTS

111-8-4-.01	Definitions.
111-8-4-.02	Exemptions.
111-8-4-.03	Organization and Administration.
111-8-4-.04	Classification of Services.
111-8-4-.05	Application for Permits.
111-8-4-.06	Permits.
111-8-4-.07	Provisional Permits.
111-8-4-.08	Inspections.
111-8-4-.09	Professional Services
111-8-4-.10	Physical Plant and Operational Standards
111-8-4-.11	Personnel
111-8-4-.12	Records
111-8-4-.13	Administrative Area and Waiting Rooms
111-8-4-.14	Clinical Laboratory Services
111-8-4-.15	Housekeeping, Laundry, Maintenance and Sterile Supplies
111-8-4-.16	Drug Storage and Dispensing
111-8-4-.17	Blood Supply and Storage
111-8-4-.18	X-Ray
111-8-4-.19	Electrical Power
111-8-4-.20	Sanitation and Waste Disposal
111-8-4-.21	Advertising
111-8-4-.22	Waiver of Rule
111-8-4-.23	Enforcement
111-8-4-.24	Applicability of Regulations
111-8-4-.25	Severability

111-8-4-.01 Definitions.

Unless a different meaning is required by the context, the following terms as used in these rules and regulations shall have the meaning hereinafter respectively ascribed to them:

(a) "Ambulatory Surgical Treatment Centers" means any institution, building, or facility, or part thereof, devoted primarily to the provision of surgical treatment to patients not requiring hospitalization, as provided under provisions of O.C.G.A. § 31-7-1(4)(c). Such facilities do not admit patients for treatment which normally requires overnight stay, nor provide accommodations for treatment of patients for period of twenty-four (24) hours or longer;

(b) "Governing Body" and/or "Management" means the Board of Directors and/or Trustees, the partnership, the corporation, the association, or the person or group of persons who maintain and control the operation of the ambulatory surgical treatment center and who are legally responsible for its operation;

(c) "Center" means an ambulatory surgical treatment center as defined in these rules and regulations;

(d) "Board," unless otherwise indicated, shall mean the Georgia Board of Community Health;

(e) "Commissioner" means the Commissioner of the Georgia Department of Community Health or his designee;

(f) "Department" means the Georgia Department of Community Health;

(g) "General Anesthesia" means any drug, element or other material administered to eliminate all sensation and which, when administered, is accompanied by a state of unconsciousness;

(h) "Licensee" means the person or body to whom the license or permit is issued and who is held responsible for compliance with all required rules, regulations, and minimum standards;

(i) "Permit" or "license" means an authorization granted by the Department to an applicant to operate an ambulatory surgical treatment center providing one or more types or classifications of services;

(j) "Provisional Permit" means an authorization granted by the Department to an applicant to operate an ambulatory surgical treatment center on a conditional basis to allow a newly established center a reasonable but limited period of time to demonstrate that operational procedures are in satisfactory compliance with these rules and regulations, or to allow an established and operating center a specified length of time to comply with these rules and regulations, provided said center shall first present a plan of improvement which is acceptable to the Department;

(k) "Plan of Improvement" means a written plan submitted to the Department by the person or persons responsible for the center, and acceptable to the Department. The plan shall identify the existing areas of noncompliance of the facility, together with the proposed procedures, methods and period of time to correct the areas of noncompliance;

(l) "Professional Staff" means the group of persons or body appointed by the Governing Body to provide patient services, and who require special licensure or registration. Normally, the professional staff will be restricted to currently licensed medical, dental, and podiatrist practitioners. Other personnel, for example, registered nurses, may be appointed to the professional staff to assist the practitioners in the development, interpretation, and enforcement of patient care policies;

(m) "Practitioner" means a physician, dentist, or podiatrist;

(n) "Physician" means an individual who is currently licensed to practice medicine, surgery or osteopathy in the State of Georgia, under the Georgia Medical Practice Act, O.C.G.A. § 43-34-20 et seq.;

(o) "Dentist" means any person who is currently licensed to practice dentistry in the State of Georgia, under provisions of the Georgia Dentist and Dental Hygienists Act, O.C.G.A. § 43-11-1 et seq.;

(p) "Podiatrist" (Chiropodist) means any person who is currently licensed to practice podiatry (chiroprody) in the State of Georgia, under provisions of the Georgia Podiatry Act, O.C.G.A. § 43-35-1 et seq.;

(q) "Registered Nurse," "Registered Professional Nurse," or "R.N." means a person who is currently licensed to practice as a licensed registered nurse under provisions of O.C.G.A. § 43-26-1 et seq.;

(r) "Licensed Practical Nurse" or "L.P.N." means a person currently licensed to practice as a licensed practical nurse under provisions of O.C.G.A. §43-26-30 et seq.;

(s) "Private Office(s)," "Office(s)," and/or "Treatment Rooms" means any area or place established and maintained by a currently licensed individual practitioner, professional association, or group practice of such practitioners, in his/her/their private individual or private group practice, in which he/she/they primarily see(s), consult(s) with, examine(s), and/or treats private patients on a regular and on-going basis, and in the operation of which such currently licensed practitioners have full control of all financial, administrative, and professional arrangements with said patients;

(t) "Hospital" means any facility which meets the requirements of and is currently licensed as a hospital under Georgia Laws and rules and regulations pertaining thereto;

(u) "Procedure Room" means any room or area of the ambulatory surgical treatment center in which surgical procedures are performed;

(v) "Patient" means any individual who receives medical/surgical treatment in facilities governed by these regulations;

(w) "Qualified Counselor" means a person who assists the professional staff by talking with and informing patients regarding

expectations and probable outcomes associated with services in an ambulatory surgical treatment center, and who possesses the following minimum qualifications: at least a bachelor's degree from an accredited college or university in nursing, psychology or social work, or in some related field, or who has special training in counseling which is deemed acceptable by the Department; provided, however, that any such counselor shall function only under the direct supervision of the responsible practitioner.

Authority: O.C.G.A. §§ 31-2-4 et seq., and 31-7-1 et seq.

111-8-4-.02 Exemptions.

The following types of health care facilities are exempt from the requirements of these regulations:

(a) currently licensed hospitals, or a facility as specified in 111-8-4-.03(12);

(b) a practitioner's private offices or treatment rooms in which a practitioner primarily sees, consults with, and treats patients;

(c) facilities owned and operated by the Federal Government.

Authority: O.C.G.A. §§ 31-2-7 and 31-7-1 et seq.

111-8-4-.03 Organization and Administration.

(1) Each ambulatory surgical treatment center shall be organized with an identifiable governing body that establishes the objectives, sets the policies and assumes full legal responsibilities for the overall conduct of the center and for compliance with all applicable laws and regulations pertaining to the center. The membership of the governing body shall be identified in the application to the Department for licensure.

(2) The ownership of the center shall be fully disclosed in the application to the Department. This disclosure shall include the names and addresses of all corporate officers and any person(s) having a five percent (5.0%) or more financial interest.

(3) The governing body of the center shall be responsible for appointing the professional staff and shall establish effective mechanisms for quality assurance and to ensure the accountability of the center's medical and/or dental staff and other professional personnel.

(4) The organizational objectives of the ambulatory surgical treatment center shall be clearly stated in the procedures and policies of the governing body and on the application for licensure.

(5) The governing body shall inform the Department of the name(s) of the administrator(s) to whom the responsibility for the day-to-day management of the center is delegated, including the implementation of rules and policies adopted by the governing body.

(6) Each center shall be at all times under the immediate personal and daily supervision and control of the administrator or his designated representative, whose authority, duties and responsibilities shall be defined in writing and which shall be available to the Department upon request.

(7) The Department shall be notified with a new application, or written amendment to the current application, when there are changes in location, ownership, management or operational objectives.

(8) Individual patients shall be discharged within twenty-four (24) hours of admission, in an ambulatory condition which will not endanger their continued well-being, or shall be transferred to a licensed hospital or other treatment facility. There shall be written procedures and assigned responsibilities for implementing such procedures, including provisions for transportation. Patients

requiring emergency services shall be accompanied by a member of the professional staff of the center.

(9) Each center shall have an organized professional staff which is responsible for the development of patient care policies and procedures and for maintaining the level of professional performance through a continuing program of staff education, review and evaluation of patient care.

(10) Each center shall at all times have a professional director designated by the governing body, who shall be responsible for the direction and coordination of all professional aspects of the center programs.

(11) The practitioners applying for staff privileges shall be required to sign an agreement to abide by the staff bylaws and required State laws and rules and regulations.

(12) Nothing in these rules and regulations shall prevent a licensed hospital from organizing and providing an ambulatory surgical treatment service as a part of a licensed hospital under the controlling authority of a hospital board, so long as all hospital licensure standards are met and the provided services are included in the application under which the hospital license is granted.

Authority: O.C.G.A. §§ 31-2-4 et seq. and 31-7-1 et seq.

111-8-4-.04 Classifications of Services.

Each ambulatory surgical center, when applying for a permit shall designate the type(s) or classification(s) of services to be provided in or by the center. These classifications may include, but are not necessarily limited to the following: general surgery; eye, ear, nose, and throat; plastic surgery; oral and maxillofacial; obstetrical-gynecological; oncological; ophthalmological; and urological. Provided, however, that any facility providing labor and delivery services must meet the requirements of Rules and

Regulations for Hospitals, Maternity and Obstetrical and Newborn Services, Rule 111-8-40-.34 or as later revised. The permit for a single ambulatory surgical treatment center may cover one or more types of services. Each ambulatory surgical treatment center shall provide only those services listed on the face of its permit.

Authority: O.C.G.A. §§ 31-2-4 et seq. and 31-7-1 et seq.

111-8-5-.05 Application for Permits.

(1) Any person or persons responsible for the operation of an ambulatory surgical treatment center as defined and classified in these regulations, or who may hereafter propose to establish and operate such an institution, shall submit an application to the Department for a permit to operate said institution using forms provided by the Department. No such institution shall be operated in Georgia without a valid permit which shall be displayed in a conspicuous place within the center.

(2) The applicant for a permit to operate an ambulatory surgical treatment center shall submit a completed application with character references and a certification that the applicant is able and willing to comply with the minimum standards for an ambulatory surgical treatment center and with the rules and regulations lawfully promulgated. Each application shall be accompanied by a statement from the local (city or county) fire safety authority stating that an inspection has been made of the premises and that state and local fire safety requirements have been met.

(3) The application shall include full and complete information concerning the name and address of the applicant and the classification(s) of services to be provided; the ownership of the property and operation; in case a center is organized as a corporation, the names and addresses of each officer and director of the corporation; in case the center is organized as a partnership, the names and addresses of each partner; the

identity of the professional director of the facility; the days and hours the center is normally operated; and any other information which the Department may require.

(4) Ambulatory surgical treatment centers are subject to review by the Department, pursuant to the Georgia Certificate of Need Law. Evidence of completion of this review shall be made a part of the application for a permit.

(5) Plans for ambulatory surgical treatment centers shall be submitted to the Department for review and approved in three stages of development:

- (a) schematic drawings;
- (b) design-development drawings; and
- (c) final working drawings and specifications.

(6) A permit shall be issued to the person or persons named only for the premises listed on the application for licensure.

(7) Permits are not transferable or assignable.

(8) Changes in ownership shall be subject to notice requirements as specified in O.C.G.A. § 31-6-40.1. Each planned change of ownership or lease shall be reported to the Department thirty (30) days prior to such change with an application being submitted from the proposed new owners for a new permit.

(9) Separate applications and permits are required for centers maintained in separate premises, even though they are owned or operated by the same person(s), business or corporation, and may be doing business under the same title.

Authority: O.C.G.A. §§ 31-2-4 et seq., 31-6-40.1 and 31-7-1 et seq.

111-8-4-.06 Permits.

(1) Following inspection and classification of the institution for which application for a permit has been made, the Department may issue a permit or a provisional permit or refuse to reissue or continue a permit or provisional permit. Each permit or provisional permit shall indicate the classifications of services to be provided and patient capacity of the center.

(2) Permits issued shall mean that the Department grants authorization to the governing body of the applicant institution to operate an ambulatory surgical treatment center and signifies compliance with these rules and regulations. Permits issued shall remain in force and effect until revoked or suspended.

Authority: O.C.G.A. §§ 31-2-4 et seq. and 31-7-1 et seq.

111-8-4-.07 Provisional Permits.

Provisional permits may be issued for a limited period specified by the Department based on an acceptable written plan for correcting one or more deficiencies (plan of correction) found during an inspection; provisional permits issued shall remain in force and effect for such limited period of time as specified by the Department, unless earlier revoked due to prevailing circumstances which are not acceptable to the Department. Centers which are established and operating prior to adoption of these rules and regulations may be considered for extension of a provisional permit when needed to meet physical plant standards. If the Department's decision is that a deficiency is of such nature that it would jeopardize the life of a patient, a provisional permit will not be issued.

Authority: O.C.G.A. §§ 31-2-4 et seq. and 31-7-1 et seq.

111-8-4-.08 Inspections.

(1) The ambulatory surgical treatment center shall be available at all reasonable and/or scheduled operating hours for observation and examination by properly identified representative of the Department.

(2) The governing body shall notify the Department of the anticipated opening date of a newly constructed center in order that a preopening licensure inspection of the center may be conducted to determine compliance with these rules and regulations.

(3) The administrator or his representative shall accompany the Department representative on all tours of inspection and shall sign the completed checklist.

(4) Each center shall be periodically inspected to determine whether the center is continuing to meet these requirements or is making satisfactory progress on approved plans of correction.

Authority: O.C.G.A. § 31-2-8.

111-8-4-.09 Professional Services.

(1) All services provided by or in the center shall be provided by persons who are currently licensed to perform the services they render when such services require licensure or registration under the laws of the State of Georgia. There shall be a sufficient number of qualified staff members to adequately provide for patient needs based on services provided and the number of patients served.

(2) Each center shall have a professional director who shall be a practitioner currently licensed in Georgia, and who shall be responsible for the direction and coordination of all medical aspects of the center program.

(3) General anesthesia shall be administered by an anesthesiologist, a physician anesthetist, an oral surgeon, or a certified R.N. anesthetist under the direction and responsibility of a currently licensed physician with training and experience in anesthesia, as specified in Georgia Code 84-10A. After administration of a general anesthetic, patients shall be constantly attended (at bedside) by a person qualified as above or by an R.N. until reactive and able to summon aid.

(4) All nursing services shall be under the supervision of a registered nurse (R.N.). Each center shall have a sufficient number of currently licensed nurses present and on duty to attend to patients at all times patients are receiving treatment or recovering from treatment up to and including the time of discharge. Additional staff shall be on duty and available to assist the professional staff to adequately handle routine and emergency patient needs.

(5) Each center shall establish written procedures for emergency services which will insure that a professional staff member who has been trained in emergency resuscitation procedures shall be on duty at all times when there is a patient receiving treatment or recovering from treatment, up to and including the time of discharge.

(6) The written procedures shall provide that an appropriate practitioner be designated on call and available to provide timely response to emergencies which may occur with any patient in the center.

(7) Each center shall have a hospital affiliation agreement and/or the medical staff must have admitting privileges or other acceptable documented arrangements to insure the necessary backup for medical complications. The center must have the capability to transfer a patient immediately to a hospital with adequate emergency room services.

(8) Each center will have effective policies and procedures for handling infection control and for recording complications which occur during or after surgery, which includes a reporting mechanism for patients who develop infections or postoperative complications after discharge.

(9) Either prior to, or at the time of admission, each patient who is admitted to the center without an appointment with a specified practitioner shall be provided (in writing) with the name, address and phone number of the practitioner who is serving him/her. The practitioner or a qualified counselor designated by the practitioner, shall explain the surgical and medical procedures, its potential complications, and postoperative complications and other alternatives to surgery; this shall be confirmed by the patient who shall sign an informed consent form as provided under O.C.G.A. § 31-9-1 et seq. Prior to dismissal, each patient shall be provided with both verbal and written instructions for posttreatment care and procedures for obtaining emergency care, if needed during the period of recuperation.

(10) All ancillary supportive health or medical services such as radiological services, pharmaceutical services, or clinical laboratory services provided in or by the center shall be in accordance with applicable rules and regulations of the State of Georgia.

(11) Each center shall establish policies for patient care and procedures for maintaining these policies.

Authority: O.C.G.A. §§ 31-2-4 et seq. and 31-7-1 et seq.

111-8-4-10 Physical Plant and Operational Standards.

The following minimum physical plant and operational standards shall be met by an applicant or licensee as a prerequisite for the issuance and continuance of a permit to operate an ambulatory surgical treatment center. The failure of any licensee to comply with the minimum standards may result at

any time in the denial, revocation, or suspension of licensure to operate an ambulatory surgical treatment center, pursuant to provisions of O.C.G.A. § 31-2-8, and these rules and regulations.

(a) Rooms and/or areas shall be planned and provided with sufficient space and equipment to provide for patient and visitor waiting area; presurgical examination and treatment; procedure rooms; patient recovery; and staff and administrative areas.

(b) The physical plant of the center shall meet all Federal, State and local laws, codes, ordinances, and regulations which apply to its location, construction, maintenance and operation.

(c) Equipment, electrical appliances, wiring, elevators, heating and cooling systems, surgery rooms and special service areas shall be constructed so as to assure the safety of all occupants. It shall be the responsibility of the governing body to assure that the center is in a safe condition at all times and that a fire inspection record is maintained on equipment, systems, and areas that may present a hazard to occupants.

(d) Except where additional requirements are specified herein, or are required by State or local ordinances or regulations, the construction of an ambulatory surgical treatment center shall meet the requirements for Health Care or Business Occupancies as specified in Chapter 10 and/or Chapter 13, as applicable, of the 1976 Life Safety Code, as currently adopted and amended by regulations of the Georgia Safety Fire Commissioner, Chapter 120-3-3, March 1, 1979, and subsequent revisions thereto.

(e) Entrances for patients shall be connected to the public right-of-way by a hardsurfaced, unobstructed walkway in good repair. Handicapped patients confined to a wheel chair or otherwise impaired shall be able to access the center building without climbing any stairs or steps. A ramp with handrails over existing stairs or steps may be utilized in meeting this requirement. A hard-surfaced, unobstructed road or driveway for use by ambulances or other emergency fire or police vehicles shall run from at least one entrance of the building to the public

right-of-way. The doorway of such entrance shall be immediately adjacent to the road or driveway.

(f) Ambulatory surgical services provided in multistory buildings shall be accessible by an elevator of adequate size to accommodate date a standard wheeled litter patient and two attendants. A stairway or ramp of adequate dimensions shall be available for transfer of a patient in case of power failure.

(g) All procedure rooms shall be constructed, equipped, and maintained to assure the safety of patients and personnel. The following requirements shall apply within the patient treatment/procedure rooms and adjoining areas:

1. Procedure rooms shall be designed and located to prevent traffic through them to any other part of the center;
2. The walls and floors in procedure rooms shall be of material that will permit frequent washing and cleaning;
3. Sterilizing equipment shall be provided within the center and shall be convenient to the procedure rooms;
4. Staff dressing rooms and scrubup facilities shall be convenient to the procedure rooms, and shall include a knee or elbow operated scrub sink, soap dispenser, and brushes;
5. An equipment cleanup area with adequate plumbing, including a sink with counter, shall be provided outside the procedure room;
6. Enclosed storage facilities for sterile supplies and equipment shall be provided within the procedure areas;
7. Scrub clothing worn by personnel outside the procedure area shall be changed before returning to the procedure area;
8. Locations using flammable anesthetic agents shall comply with the following:

(i) Floors, furniture and equipment in operating rooms shall be of electrically conductive material. Conductive flooring shall extend into contiguous rooms and at least ten (10) feet into the entrance traffic area.

(ii) Clean conductive footwear testing device shall be maintained in the procedure rooms.

(iii) An anesthesia supply and equipment storage room shall be provided within the procedure area.

(iv) Separate storage enclosures shall be provided for flammable gases and combustion supporting gases. Such enclosures shall be constructed of building material with a fire resistive rating of at least one hour and shall not communicate directly with anesthetizing locations or each other. Air shall be adequately exhausted by gravity or spark proof forced ventilation from the flammable storage enclosure to the exterior of the building at a rate of not less than two (2) changes per hour. Storage enclosures for combustion supporting gases of less than 1500 cubic feet cylinder capacity need not be vented to the outside. Flammable materials such as fabrics, rubber and wood shall not be stored in these enclosures.

(v) Clothing generating large amounts of static electricity shall be prohibited in the procedure rooms.

9. Locations using flammable anesthetic agents shall be identified by prominently posted signs at all entrances to the procedure room and within the location signifying the type of anesthetics used.

(h) Toilet facilities shall be accessible to patients from the treatment, examining and recovery areas. Convenient handwashing facilities shall be provided for both staff and patients, and shall be provided with soap, disposable towels and dispensers. The use of common towels is prohibited.

(i) Emergency life support equipment shall be available for immediate use, in patient treatment areas. Such equipment shall include, but not necessarily be limited to the following: suction, IV fluids, oxygen, needles, intracatheters, medications, and ventilatory equipment such as ambu bags, oral and nasal airways and endotracheal tubes. Facilities providing general anesthesia shall also have a defibrillator and tracheotomy equipment and supplies.

(j) All medical gases shall be stored in accordance with Bulletin 56A of the National Fire Protection Association.

(k) All plumbing shall be designed and installed in accordance with State laws and local ordinances.

(l) The center shall be arranged and organized in such a manner as to ensure the comfort, safety, hygiene, privacy, and dignity of patients treated therein.

(m) Equipment for sterilizing instruments and supplies shall be conveniently located and of adequate capacity for the workload. Records shall be maintained to assure quality control, including date, time and temperature of each batch of sterilized supplies and equipment.

(n) Medicines shall be stored in a conveniently located cabinet with lock, and only licensed persons shall have access.

(o) Clean and soiled utility rooms shall be arranged and provided with equipment necessary for proper patient care, including sterilizers, storage cabinets and work counters.

(p) Each center shall provide one or more recovery rooms or areas staffed by qualified personnel. The recovery area shall be adequate for the numbers of patients scheduled. Separate recovery areas and/or cubicle curtains shall be provided for patient privacy, when appropriate.

Authority: O.C.G.A. §§ 31-2-4 et seq. and 31-7-1 et seq.

111-8-4-.11 Personnel.

(1) The governing body shall appoint an administrator who is responsible for the day-today management and operation of the center.

(2) The administrator shall designate an individual to act for him in his absence in order to provide the center with administrative direction at all times.

(3) All center personnel shall be currently licensed to perform the services they render when such services require licensure or registration under the laws of the State of Georgia.

(4) Each center shall require that each employee receives a health examination upon employment and a policy shall provide for follow-up examinations. The examination shall be in sufficient detail, including pertinent laboratory and x-ray data, to assure that the employee is physically and mentally qualified to perform the job to which he is assigned.

(5) There shall be a separate personnel folder maintained for each employee. This file shall contain all personnel information concerning the employee, including the application and qualifications for employment, physical examination (including laboratory and x-ray reports, if applicable), job description and attendance record.

(6) Fire and internal disaster drills shall be conducted at least quarterly and the results documented. There shall be an ongoing program of continuing education for all personnel concerning aspects of fire safety and the disaster plan for moving personnel and patients to safety, and for handling patient emergencies.

Authority: O.C.G.A. §§ 31-2-4 et seq. and 31-7-1 et seq.

111-8-4-12 Records.

(1) A full-time employee shall be designated responsible for establishing and maintaining medical records required to be kept by these rules and regulations.

(2) Medical records containing sufficient information to validate the diagnosis and to establish the basis upon which treatment is given shall be maintained on each patient. Contents of individual medical records shall normally contain the following at least:

(a) Admission and discharge data:

1. Name, address, birth date, sex, marital status, race, etc.
2. Date and time of admission.
3. Date and time of discharge.
4. Admitting diagnosis.
5. Final diagnosis.
6. Procedures or operations performed.
7. Condition on discharge.
8. Attending practitioner's signature.

(b) History and physical examination data:

1. Personal medical history (including all current medication that the patient is taking).
2. Family medical history.
3. Physical examination.

4. Psychiatric examination (if applicable).

(c) Treatment data:

1. Practitioner's orders.

2. Progress notes.

3. Nurse notes.

4. Medication.

5. Temperature-Pulse-Respiration (Graphic Chart; surgical purposes only).

6. Special examination(s) and reports (include x-ray and lab reports).

7. Signed informed consent form.

8. Operation record.

9. Anesthesia record (if applicable).

10. Consultation record (if applicable).

11. Tissue findings when performed.

12. Where dental services are rendered, a complete dental chart with dental diagnosis, treatment, prescription and progress notes shall be part of the clinical record.

(3) All orders on patients shall be signed by the practitioner giving them; admitting diagnosis (purpose of admission) shall be recorded prior to or at the time of admission.

(4) Medical records shall be preserved as original records, microfilms or other usable forms and shall be such as to afford a basis for complete audit of professional information. Centers shall

retain all medical records, at least until the sixth anniversary of the patient's discharge. In the case of patients who have not attained majority at the time of the discharge, centers shall retain such records at least six (6) years after patient reaches age of majority. In the event a center shall cease operation, the Department shall be advised of the disposition and/or location of said records.

(5) The center shall collect, retrieve and annually summarize data from the medical record so that it may provide the Department with the following medical statistical information including:

(a) Number of visits by patients.

(b) Number of patients seen.

(c) Basis of treatment (clinical diagnosis and/or problem for which the patient was treated).

(d) Types and number of operative procedures performed.

(e) Age distribution of patients.

(f) Complications and emergencies.

(g) Number of times a patient was transferred from the center to a hospital.

(h) Pathological diagnosis.

(6) Patient records shall be current and shall be entitled to the same protection as provided for any medical records under Georgia law.

Authority: O.C.G.A. §§ 31-2-4 et seq. and 31-7-1 et seq.

111-8-4-13 Administrative Area and Waiting Rooms.

(1) Each center shall provide administrative space and facilities for admitting patients and other service, such as telephone and information office files and supplies, patients' personal belongings, medical records and files.

(2) A waiting room area shall be provided with a seating capacity to accommodate the number of patients and others of the public normally present in the facility at one time.

(3) The center shall have adequate and conveniently located toilets and handwashing facilities for its staff, employees, out-patients and visiting personnel.

Authority: O.G.C.A. §§ 31-2-4 et seq. and 31-7-1 et seq.

111-8-4-14 Clinical Laboratory Services.

(1) Laboratory services utilized by an ambulatory surgical treatment center shall be consistent with requirements of the Clinical Laboratory Licensure Law, O.C.G.A. § 31-22-1 et seq., and applicable amendments and regulations, which provide for clinical laboratory services to be either licensed under Rules and Regulations of the State of Georgia, Chapter 111-8-10, or to be exempt from licensure as specified in the Clinical Laboratory Licensure Law. If exemption is claimed, the application shall state the name(s) of the practitioner(s) responsible for the operation of the clinical laboratory and there shall be an affidavit by the physician that he/she is responsible for the laboratory claims and the exemption.

(2) All removed tissues shall be examined immediately by the practitioner, whose findings shall be recorded in the patient's records, in addition to reports of pathologic examinations which may be obtained later.

(3) Laboratory services shall be provided for each patient, consistent with accepted medical practice and the conditions and needs of the patient. Laboratory reports shall be made a part of patient records.

(4) A system shall be established for the collection of information and all postoperative surgical complications and infections.

(5) The center shall report to the Department all communicable diseases detected or reported for patients.

Authority: O.C.G.A. §§ 31-2-4 et seq., 31-7-1 et seq. and 31-22-1 et seq.

111-8-4.15 Housekeeping, Laundry, Maintenance and Sterile Supplies.

(1) Each center shall provide sufficient space and equipment and ensure that housekeeping and maintenance is sufficient to keep the center and equipment in a clean and tidy condition and state of good repair. Proper maintenance shall be provided as necessary to correct, prevent, or adjust faulty equipment and/or correct other undesirable conditions.

(2) Laundry service shall be provided. Separate space and facilities shall be provided for receiving, sorting and storing soiled laundry, and for sorting, storing and issuing of clean laundry, if reusable items are utilized.

(3) There shall be adequate space and facilities for receiving, packaging and proper sterilizing and storage of supplies and equipment, consistent with the services to be provided.

(4) Special precaution shall be taken to ensure that sterile instruments and supplies are kept separate from non-sterile instruments and supplies. Sterilization records shall be kept and

sterile items shall be dated and utilized, based on established procedures.

(5) A recognized method of checking sterilizer performance shall be adopted.

Authority: O.C.G.A. §§ 31-2-4 et seq. and 31-7-1 et seq.

111-8-4-16 Drug Storage and Dispensing.

Each center shall provide adequate space and equipment and staff to assure that drugs are stored and administered in compliance with State and Federal laws and regulations.

Authority: O.C.G.A. §§ 31-2-4 et seq. and 31-7-1 et seq.

111-8-4-17 Blood Supply and Storage.

Each center which provides service for which blood is needed, shall provide separate refrigeration for the storage of blood and shall have a written agreement with a source for meeting its blood needs. If blood is retained overnight, such refrigeration shall be equipped with a temperature alarm device, and shall be tied in on an automatic emergency electrical power system. In all cases, refrigeration equipment shall be provided with a temperature recording device or the temperature shall be checked and recorded each day of use.

Authority: O.C.G.A. §§ 31-2-4 et seq., 31-7-1 et seq. and 31-22-1 et seq.

111-8-4-18 X-Ray.

All X-Ray facilities in the center shall be registered with and meet the requirements of rules and regulations of governing

radiological health as promulgated by the Department. X-Rays and x-ray reports shall be made a part of the patient's record.

Authority: O.C.G.A. §§ 31-2-4 et seq., 31-7-1 et seq. and 31-13-1 et seq.

111-8-4-19 Electrical Power.

(1) All electrical work and equipment shall be designed and installed in accordance with State and local laws and ordinances.

(2) All areas of the center shall have sufficient artificial lighting for designated purpose.

(3) Centers which utilize general anesthesia shall provide an emergency electrical system so controlled, that, after interruption of the normal electric power supply, an acceptable auxiliary power source is available and capable of being brought into use within ten seconds with sufficient voltage and frequency to reestablish essential in-house services and other emergency equipment needed to effect a prompt and efficient transfer of patients to an appropriate licensed hospital, when needed.

Authority: O.C.G.A. §§ 31-2-4 et seq. and 31-7-1 et seq.

111-8-4-20 Sanitation and Waste Disposal.

(1) All centers shall provide facilities for maintaining sanitary standards throughout the premises, as well as for water supply, sewerage, garbage and refuse, disposal systems. Such facilities shall meet local and State regulations.

(2) All garbage, trash and waste shall be stored and disposed of in a manner, by approved methods, that will not permit the transmission of disease, create a nuisance, or provide a breeding place for insects or rodents.

(3) Arrangements shall be made for proper disposal of all contaminate and/or infection dressings and surgical and obstetrical waste.

(4) Effective means shall be provided at all outside doors, windows and other openings to the center to prevent entrance and harborage of flies, other insects and rodents.

Authority: O.C.G.A. §§ 31-2-4 et seq. and 31-7-1 et seq.

111-8-4-.21 Advertising.

Any advertising of the services provided in or by ambulatory surgical treatment center shall include the full name of the center and its Georgia license number, as shown on the face of the permit.

Authority: O.C.G.A. §§ 31-2-4 et seq. and 31-7-1 et seq.

111-8-4-.22 Waiver of Rule.

The Department may waive any rule for a stated period of time when it is shown that the specific rule is not applicable or when a waiver is needed to permit experimentation and demonstration of new and innovative approaches to the delivery of services which will not jeopardize the health and safety of the patients, staff or others utilizing the center. Results of such experimentation and demonstration projects shall be submitted to the Department as prescribed by the plan under which the waiver is approved. The Department shall maintain a record of and make available to interested persons information on all waivers granted under this rule.

Authority: O.C.G.A. § 31-2-7.

111-8-4-.23 Enforcement.

An ambulatory surgical treatment center which fails to comply with these rules and regulations shall be subject to revocation of its permit or provisional permit and/or other sanctions provided by law. The enforcement and administration of these rules and regulations shall be as prescribed in O.C.G.A. §§ 31-5-8, 31-5-9 and 31-2-8 which includes provision for:

- (a) the misdemeanor penalty for violation of rules and regulations promulgated under this Title;
- (b) injunctive relief under appropriate circumstances; and
- (c) the due process requirements of notice, hearing and appeals.

Authority: O.C.G.A. §§ 31-2-4 et seq., 31-7-1 et seq. and 50-13-1 et seq.

111-8-4-.24 Applicability of Regulations.

These regulations are applicable only to ambulatory surgical treatment centers and the services provided therein, and expressly do not modify or revoke any of the provisions of the published rules of the Department of Community Health, Chapter 111-8-40 (Rules and Regulations for Hospitals), or Chapter 290-5-32 (Rules and Regulations for Performance of Abortions After the First Trimester of Pregnancy and Reporting Requirements for all Abortions), or of revisions which may be made to said regulations.

Authority: O.C.G.A. §§ 31-2-4 et seq. and 31-7-1 et seq.

111-8-4-.25 Severability.

In the event that any rule, sentence, clause or phrase of any of these rules and regulations may be construed by any court of competent jurisdiction to be invalid, illegal, unconstitutional, or otherwise unenforceable, such determination or adjudication shall in no manner affect the remaining rules or portions thereof and such remaining rules or portions thereof shall remain in full force and effect, as if such rule or portions thereof so determined, declared or adjudged invalid or unconstitutional were not originally a part hereof. It is the intent of the Board of Community Health to establish rules and regulations that are constitutional and enforceable so as to safeguard the health and well-being of the people of the State.

Authority: O.C.G.A. §§ 31-2-4 et seq. and 31-7-1 et seq.