Disclaimer: This is an unofficial copy of the rules that has been reformatted for the convenience of the public by the Department of Community Health. The official rules for this program are on record with the Georgia Secretary of State's office. The Secretary of State's website for reviewing the rules is http://rules.sos.state.ga.us/cgi-bin/page.cgi?d=1 . An effort has been made to ensure the accuracy of this unofficial copy. The Department reserves the right to withdraw or correct text in this copy if deviations from the official text as published by the Georgia Secretary of State are found.

RULES
OF
DEPARTMENT OF COMMUNITY HEALTH

CHAPTER 111-8
HEALTHCARE FACILITY REGULATION

111-8-40
RULES AND REGULATIONS FOR HOSPITALS

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111-8-40-.01 Title and Purpose.

These rules shall be known as the Rules and Regulations for Hospitals. The purpose of these rules is to provide for the inspection and issuance of permits for hospitals and to establish minimum requirements for facilities operating under a hospital permit.

Authority: O.C.G.A. §§ 31-2-4, 31-2-5, 31-7-2.1 and 31-7-3.

111-8-40-.02 Definitions.

Unless a context otherwise requires, these identified terms mean the following when used in these rules:

(a) *Board certified* means current certification of a licensed physician by a specialty board recognized by the American Board of Medical Specialties (ABMS) or American Osteopathic Association (AOA) or other nationally recognized specialty's certifying board.

(b) *Board eligible* means a licensed physician who meets the criteria for examination for the designated specialty as published by that nationally recognized specialty's certifying board.

(c) *Bylaws* means a set of laws or rules formally adopted internally by the facility, organization, or specified group of persons to govern internal functions or practices within that group, facility, or organization.

(d) *Department* means the Department of Community Health of the State of Georgia.

(e) *Governing body* means the hospital authority, board of trustees or directors, partnership, corporation, entity, person, or group of persons who maintain and control the hospital.

(f) *Hospital* means any building, facility, or place in which are provided two (2) or more beads and other facilities and services that are used for persons received for examination, diagnosis, treatment, surgery, or maternity care for periods continuing for twenty-four (24) hours or longer and which is classified by the department as a hospital.

(g) *Inpatient* means a person admitted to a hospital for an intended length of stay of twenty-four (24) hours or longer.

(h) *Medical record* means the written or electronic collection of diagnostic and/or treatment information and data pertaining to the patient, including but not limited to identifying information and, as applicable, medical orders, assessment findings, diagnostic test results, progress notes, x-rays films, monitoring data, and details of treatment.

(i) *Medical staff* means the body of licensed physicians, dentists, and/or podiatrists, appointed or approved by the governing body, to which the governing body has assigned responsibility and accountability for the patient care provided at the hospital.

(j) *Organized service(s)* means any inpatient or outpatient service offered by the hospital which functions as an administrative or operational unit under the governing body of the hospital.

(k) *Outpatient* means a person who presents to a hospital for diagnostic or treatment services and who is not admitted to the hospital as an inpatient by a member of the medical staff.

(l) *Patient* means any person presenting at a hospital for the purpose of evaluation, diagnosis, monitoring, or treatment of a medical condition, mental condition, disease, or injury.

(m) *Peer review* means the procedure by which professional health care providers evaluate the quality and efficiency of services ordered or performed by other professional health care providers in the hospital for the purposes of fostering safe and adequate treatment of the patients and compliance with standards set by an association of health care providers and with the laws, rules, and regulations applicable to hospitals.

(n) *Permit* means the authorization granted by the Department to a hospital governing body to operate the hospital's authorized services.

(o) *Physical restraint* means any manual method or physical or mechanical device used with a patient such that the patient's freedom of movement or access to his/her own body is restricted.

(p) *Physician* means any person who is licensed to practice medicine in this state by the Georgia Composite State Board of Medical Examiners.

(q) *Practitioner* means any individual engaged in the practice of the profession for which they are licensed, certified, or otherwise qualified or authorized to practice.

(r) *Professional staff* means a person or persons licensed by the state of Georgia to practice a specified health profession and employed by or contracting with the hospital for the practice of that profession.

(s) *Rules and regulations* means the set of rules formally adopted internally by a specified hospital body to provide guidance for internal functions or practices.

(t) *Seclusion* means the confinement of a person to a room

or an area where the person is prevented from leaving.

(u) *Surveillance* means the systematic method of collecting, consolidating, and analyzing data concerning the distribution and determinants of a given disease or medical event, followed by the dissemination of that information to those who can improve the outcomes.

(v) The singular indicates the plural, the plural indicates the singular, and the masculine the feminine, when consistent with the intent of these rules.

Authority: O.C.G.A. §§ 31-7-1, 31-7-2.1, 31-7-15 and 31-7-131.

111-8-40-.03 Hospital Permit Requirement.

No person, corporation, association, or other entity shall establish, operate, or maintain a hospital in Georgia without a permit or provisional permit.

(a) A permit is required for each hospital. Multi-building hospitals may request a single permit to include all buildings provided that the hospital buildings are in close proximity to each other, the facilities serve patients in the same geographical area, and the facilities are operated under the same ownership, control, and bylaws.

1. Services offered in separate buildings or on separate premises, which do not by themselves meet the definition of a hospital, including, but not limited to, satellite urgent care centers, outpatient or mammography clinics, or hospital-owned physicians' offices, shall be considered organized services of the hospital for the purposes of these rules.

2. Only those services operated by the hospital under the permit as approved by the Department shall be presented to the public as a service of the hospital.

(b) A permit, either continuing or provisional, is required prior to the admission of any patients or initiation of any patient care services in the hospital. A provisional permit may be issued for a limited time to a newly established hospital to allow the hospital to demonstrate that its operational procedures equal standards specified by the rules.

(c) The permit shall designate the classification of the hospital as determined by the Department following evaluation of the hospital's services and in accordance with the Certificate of Need.

1. The classification shall be one of the following:

(i) Classification as a general hospital means a facility meets the definition of a hospital and provides continuous care for a variety of patients who have a variety of medical conditions. A critical access hospital shall fall under the general hospital classification; or

(ii) Classification as a specialized hospital means a facility that meets the definition of a hospital and provides care to a specialized or specified group of patients and/or patients who have specified conditions. The type of specialization shall be designated on the hospital permit.

2. If changes occur in the organized services offered by the hospital, including the addition of any services requiring CON review or off-campus service locations, the hospital's administrator or governing body shall submit to the Department a new description of services at least thirty (30) days prior to the change. Change in the classification of the hospital shall require application for a new permit.

(d) To be eligible for a permit the hospital shall be in substantial compliance with these rules and regulations and any provisions of law as applicable to the construction and operation of the hospital. In its discretion, the Department may issue a provisional permit for a limited time to a new or existing hospital to

allow the hospital a reasonable length of time to come into compliance with these rules provided the Department has received an acceptable plan of correction.

(e) The permit issued to the hospital shall be prominently displayed in a public area of the hospital at all times.

(f) A permit is not transferable from one governing body to another nor from one hospital location to another.

(g) If the hospital anticipates that it will close or cease to operate, the governing body shall notify the Department at least thirty (30) days prior to the anticipated closure.

1. Prior to hospital closure, the hospital shall inform the Department of the planned storage location for patients' medical records, medical staff information, and other critical information after closure. The hospital shall publish in a widely circulated newspaper(s) in the hospital's service area a notice indicating where medical records and other critical information can be retrieved and shall notify the Department of Transportation of the anticipated date of closure for removal of the hospital locator signs. Following closure, the Department shall be notified of any change in location of the patients' medical records, medical staff information, and other critical information from the published location.

2. When the hospital ceases to operate, the permit shall be returned to the Department within ten (10) days of closure. The permit shall be considered revoked, unless placed on inactive status as described in these rules.

3. If the hospital is closing for a period of less than twelve (12) months, and plans to reopen under the same ownership, name, classification, and bed capacity, the hospital may request to have the permit placed on temporary inactive status.

(i) When placed on temporary inactive status, the permit shall be returned to the Department within ten (10) days of closure

and the hospital shall not operate until the permit has been reactivated. The hospital shall notify the Department of Transportation of the intended closure.

(ii) The hospital shall request in writing that the permit be reactivated at least thirty (30) days prior to the desired date of re-opening. Prior to reactivation of the permit, the hospital may be subject to inspection by the Department. If the permit is not reactivated within twelve (12) months, the permit shall be considered revoked.

(h) A new permit may be obtained by application to the Department and is required if the hospital is moved to another location, has a change in operational or trade name, has a change in ownership or classification, or has a change in the authorized bed capacity. The former permit shall be considered revoked upon the issue of a new permit and the former permit shall be returned to the Department.

(i) A permit shall remain in effect unless suspended or revoked or otherwise rescinded or removed as provided in these rules.

Authority: O.C.G.A. §§ 31-7-1, 31-7-2, 31-7-2.1 and 31-7-3.

111-8-40-.04 Facilities Exempt from These Rules.

The following classes of hospitals are exempt from these rules:

(1) **Federally owned and/or operated hospitals.** Hospitals owned or operated by the federal government are exempt from these rules and the requirement for a Georgia hospital permit; and

(2) **Residential Mental Health Facilities for Children and Youth.** A sub-classification of specialized hospitals which are licensed to provide twenty-four (24) hour care and have as their primary function the diagnosing and treating patients to age

twenty-one (21) with psychiatric disorders are exempt from these rules in lieu of meeting the specific regulations under Chapter 111-8-68.

Authority: O.C.G.A. §§ 31-2-7, 31-7-2 and 31-7-5.

111-8-40-.05 Application for a Permit.

An application for a permit to operate a hospital shall be submitted on forms provided by the Department. The application submitted to the Department shall be an original document. No application shall be considered by the Department unless it is complete and accompanied by all required attachments.

(a) **Application for Initial Permit.** The application for an initial permit shall be submitted to the Department not later than thirty (30) days prior to the anticipated date of the opening and initiation of operations by the hospital. The application shall be signed by the hospital administrator or the executive officer of the hospital's governing body and shall include:

1. A listing of the services provided:

2. Proof of hospital ownership. In the case of corporations, partnerships, and other entities authorized by law, the applicant shall provide a copy of its certificate of incorporation, or other acceptable proof of its legal existence together with the names and addresses of all persons owning five (5) percent or more;

3. A list of the locations of any services offered by the hospital on separate premises; and

4. A copy of the Certificate of Need (CON) from the Department.

(b) **Application Due to a Change in Name, Location, or Bed Capacity of a Hospital.** The application for a new permit due to a change in name, location, or authorized bed capacity of a

hospital shall be submitted at least thirty (30) days prior to the proposed effective date of the change.

(c) **Application Due to a Change in Classification of the Hospital.** The application for a new permit due to a change in the classification for the hospital shall be submitted at least thirty (30) days prior to the proposed effective date of the change. The application shall be signed by the hospital administrator or the executive officer of the governing body and shall include:

1. A listing of the service(s) to be provided; and

2. A copy of the required Certificate of Need (CON) from the Department, if applicable.

(d) **Application Due to a Change in Ownership.** The application for a new permit due to a change in ownership shall be submitted at least thirty (30) days prior to the change whenever possible. Proof of ownership documents, as required with the application for the initial permit and any other approvals required by state law, shall be submitted upon the completion of the transaction changing ownership.

Authority: O.C.G.A. § 31-7-3.

111-8-40-.06 Permit Denial and Sanctions.

The Department may refuse to grant an initial permit, revoke a current permit, or impose other sanctions as described herein and in the rules for the "General Licensing and Enforcement Requirements," Chapter 111-8-25.

(a) **Denial of an Application for a Permit.** The Department may refuse to grant an initial permit or provisional permit without the requirement of holding a hearing prior to the action. Denial of an application for a change to a permit from an existing facility shall be subject to notice and opportunity for a hearing following the denial. An application may be refused or denied if:

1. The hospital has failed to demonstrate compliance with these rules and regulations;

2. The applicant or alter ego of the applicant has had a permit denied, revoked, or suspended within one (1) year of the date of a new application;

3. The applicant has transferred ownership or governing authority of a hospital within one (1) year of the date of the new application when such transfer was made in order to avert denial, suspension, or revocation of a permit; or

4. The applicant has knowingly made any verbal or written false statement(s) of material fact in connection with the application for the permit or on documents submitted to the Department as part of any inspection or investigation or in the falsification or alteration of facility records made or maintained by the hospital.

(b) **Sanction of a Permit.**

1. The Department may take an action to sanction the hospital permit holder, subject to notice and opportunity for a hearing, where the Department finds that the hospital has:

(i) Knowingly made any verbal or written false statement of material fact either in connection with the application for the permit or on documents submitted to the Department as part of any inspection or investigation or in the falsification or alteration of hospital records made or maintained by the hospital;

(ii) Failed or refused, without legal cause, to provide the Department with access to the premises subject to regulation or information pertinent to the initial and continued licensing of the hospital;

(iii) Failed to comply with the licensing requirements of this state; or

(iv) Failed to comply with the provisions of O.C.G.A. § 31-2-8 or Rules for General Licensing and Enforcement Requirements, Chapter 111-8-25.

2. Such sanctions may include any one or more of the following:

(i) Administration of a public reprimand;

(ii) Suspension of the permit;

(iii) Prohibition of persons in management or control;

(iv) Imposition of civil penalties as provided by law; and

(v) Revocation of the permit.

(c) If the sanction hearing process results in revocation of the permit, the permit shall be returned to the Department.

Authority: O.C.G.A. §§ 31-2-8 and 31-7-1 et seq., and the Rules for General Licensing and Enforcement Requirements, Chapter 111-8-25.

111-8-40-.07 Hospital Inspections and Required Reports to the Department.

(1) **Inspections by the Department.** The hospital shall be available during all hours of operation for observation and examination by properly identified representatives of the Department.

(a) **Initial Inspection.** There shall be an initial inspection of a hospital prior to the opening date in order to determine that the hospital is in substantial compliance with these rules. Prior to this initial inspection, the hospital shall submit to the Department:

1. A copy of the certificate of occupancy;
2. Verification of building safety and fire safety from local and state authorities; and

3. Evidence of appropriate approvals by the state architect.

(b) **Periodic Inspections.** The hospital shall be subject to periodic inspections to determine that there is continued compliance with these rules, as deemed necessary by the Department.

(c) **Random Inspections.** The hospital may be subject to additional or more frequent inspections by the Department where the Department receives a complaint alleging a rule violation by the hospital or the Department has reason to believe that the hospital is in violation of these rules.

(d) **Plans of Correction.** If violations of these licensing rules are identified, the hospital will be given a written report of the violation that identifies the rules violated. The hospital shall submit to the Department a written plan of correction in response to the report of violation, which states what the hospital will do, and when, to correct each of the violations identified. The hospital may offer an explanation or dispute the findings or violations in the written plan of correction, so long as an acceptable plan of correction is submitted within ten (10) days of the hospital's receipt of the written report of inspection. If the initial plan of correction is unacceptable to the department, the hospital will be provided with at least one (1) opportunity to revise the unacceptable plan of correction. The hospital shall comply with its plan of correction.

(e) **Accreditation in Place of Periodic Inspection.** The Department may accept the accreditation of a hospital by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), the American Osteopathy Association (AOA), or other approved accrediting body, in accordance with specific standards determined by the Department to be substantially equivalent to state standards, as representation that the hospital is or remains

in compliance with these rules.

1. Hospitals accredited by an approved accrediting body shall present to the Department a copy of the full certification or accreditation report each time there is an inspection by the accreditation body and a copy of any reports related to the hospital's accreditation status within thirty (30) days of receipt of the final report of the inspection.

2. Hospitals accredited by an approved accrediting body are excused from periodic inspections. However, these hospitals may be subjected to random inspections by the Department for continuation of the permit when:

(i) A validation study of the accreditation process is necessary;

(ii) There has been a complaint alleging a rule violation which the Department determines requires investigation;

(iii) The Department has reason to believe that there is a patient incident or situation in the hospital that presents a possible threat to the health or safety of patients; or

(iv) There are additions to the services previously offered by the hospital which the Department determines requires an on-site visit.

(2) **Required Reports to the Department.**

(a) **Patient Incidents Requiring Report.**

1. The hospital's duly constituted peer review committee(s) shall report to the Department, as required below, whenever any of the following incidents involving hospital patients occurs or the hospital has reasonable cause to believe that a reportable incident involving a hospital patient has occurred:

(i) Any unanticipated patient death not related to the natural

course of the patient's illness or underlying condition;

(ii) Any rape which occurs in a hospital;

(iii) Any surgery on the wrong patient or the wrong body part of the patient; and

(iv) Effective three (3) months after the Department provides written notification to all hospitals the hospital's duly constituted peer review committee(s) shall also report to the Department, whenever any of the following incidents involving hospital patients occurs or the hospital has reasonable cause to believe that a reportable incident involving a hospital patient has occurred:

(I) Any patient injury which is unrelated to the patient's illness or underlying condition and results in a permanent loss of limb or function;

(II) Second or third degree burns involving twenty (20) percent or more of the body surface of an adult patient or fifteen (15) percent or more of the body surface of a child which burns were acquired by the patient in the hospital;

(III) Serious injury to a patient resulting from the malfunction or intentional or accidental misuse of patient care equipment;

(IV) Discharge of an infant to the wrong family;

(V) Any time an inpatient, or a patient under observation status, cannot be located, where there are circumstances that place the health, safety, or welfare of the patient or others at risk and the patient has been missing for more than eight (8) hours; and

(VI) Any assault on a patient, which results in an injury that requires treatment.

2. The hospital's peer review committee(s) shall make the self-report of the incident within twenty-four (24) hours or by the

next regular business day from when the hospital has reasonable cause to believe an incident has occurred. The self-report shall be received by the Department in confidence and shall include at least:

(i) The name of the hospital;

(ii) The date of the incident and the date the hospital became aware that a reportable incident may have occurred;

(iii) The medical record number of any affected patient(s);

(iv) The type of reportable incident suspected, with a brief description of the incident; and

(v) Any immediate corrective or preventative action taken by the hospital to ensure against the replication of the incident prior to the completion of the hospital's investigation.

3. The hospital's peer review committee(s) shall conduct an investigation of any of the incidents listed above and complete and retain on site a written report of the results of the investigation within forty-five (45) days of the discovery of the incident. The complete report of the investigation shall be available to the Department for inspection at the facility and shall contain at least:

(i) An explanation of the circumstances surrounding the incident, including the results of a root cause analysis or other systematic analysis;

(ii) Any findings or conclusions associated with the review; and

(iii) A summary of any actions taken to correct identified problems associated with the incident and to prevent recurrence of the incident and also any changes in procedures or practices resulting from the internal evaluation using the hospital's peer review and quality management processes.

4. The Department shall hold the self-report made through the hospital's peer review committee(s) concerning a reportable patient incident in confidence as a peer review document or report and not release the self-report to the public. However, where the Department determines that a rule violation related to the reported patient incident has occurred, the Department will initiate a separate complaint investigation of the incident. The Department's complaint investigation and the Department's report of any rule violation(s) arising either from the initial self-report received from the hospital or an independent source shall be public records.

(b) **Other Events/Incidents Requiring Report.**

1. The hospital shall report to the Department whenever any of the following events involving hospital operations occurs or when the hospital becomes aware it is likely to occur, to the extent that the event is expected to cause or causes a significant disruption of patient care:

(i) A labor strike, walk-out, or sick-out;

(ii) An external disaster or other community emergency situation; and

(iii) An interruption of services vital to the continued safe operation of the facility, such as telephone, electricity, gas, or water services.

2. The hospital shall make a report of the event within twenty-four (24) hours or by the next regular business day from when the reportable event occurred or from when the hospital has reasonable cause to anticipate that the event is likely to occur. The report shall include:

(i) The name of the hospital;

(ii) The date of the event, or the anticipated date of the event, and the anticipated duration, if known;

(iii) The anticipated effect on patient care services, including any need for relocation of patients; and

(iv) Any immediate plans the hospital had made regarding patient management during the event.

3. Within forty-five (45) days following the discovery of the event, the hospital shall complete an internal evaluation of the hospital's response to the event where opportunities for improvement relating to the emergency disaster preparedness plan were identified. The hospital shall make changes in the emergency disaster preparedness plan as appropriate. The complete report of the evaluation shall be available to the Department for inspection at the facility.

Authority: O.C.G.A. §§ 31-2-7, 31-2-8, 31-7-2.1, 31-7-15, 31-7-133, 31-7-140 and 50-18-72.

111-8-40-.08 Hospital Ownership.

There shall be full disclosure of hospital ownership to the Department at the time of the initial application and when requested. In the case of corporations and partnerships, the names of all corporate officers, partners, and all others owning five (5) percent or more of corporate stock or ownership shall be made known to the Department.

Authority: O.C.G.A. § 31-7-3.

111-8-40-.09 Governing Body and Hospital Administration.

The hospital shall have an established and functioning governing body that is responsible for the conduct of the hospital as an institution and that provides for effective hospital governance, management, and budget planning.

(a) The governing body shall be organized under bylaws and shall be responsible for ensuring the hospital functions within the classification for which it is permitted by the Department.

(b) The governing body shall appoint members of the medical staff within a reasonable period of time after considering the recommendations of the medical staff, if any, and shall ensure the following:

1. That every inpatient is under the care of a qualified member of the medical staff;

2. That the medical staff is organized and operates under medical staff bylaws and medical staff rules and regulations, which shall become effective when approved by the governing body; and

3. That the medical staff is responsible to the governing body for the quality of all medical care provided to patients in the hospital and for the ethical and professional practices of its members while exercising their hospital privileges.

(c) If the hospital does not provide emergency services as an organized service, the governing body shall ensure that the hospital has written policies and procedures approved by the medical staff for the appraisal of emergencies, the initial treatment of emergencies, and the referral for emergency patients as appropriate.

(d) The governing body shall identify an administrator or chief executive officer who is responsible for the overall management of the hospital. The administrator or chief executive officer shall:

1. Ensure that there are effective mechanisms in the hospital's organization to facilitate communication between the governing body, the medical staff, the nursing staff, and other departments of the hospital;

2. Ensure that patients receive the same quality of care throughout the hospital; and

3. Be responsible for reporting to the appropriate licensing board any member of the medical staff whose privileges at the hospital have been denied, restricted, or revoked, or who has resigned from practice at the hospital, to the extent required by state law.

(e) The hospital shall advise the Department immediately and in writing of a change in the designation of the administrator or chief executive officer.

(f) The governing body shall ensure that the hospital is staffed and equipped adequately to provide the services it offers to patients, whether the services are provided within the facility or under contract. All organized services providing patient care shall be under the supervision of qualified practitioners.

(g) The governing body shall be responsible for compliance with all applicable laws and regulations pertaining to the hospital.

Authority: O.C.G.A. § 31-7-2.1.

111-8-40-.10 Hospital-Patient Communications.

The hospital shall develop, implement, and enforce policies and procedures to ensure that each patient is:

(a) Informed about the hospital's grievance process, including whom to contact to file a grievance or complaint with the hospital and that individual's telephone number, and the name, address, and telephone number of the state regulatory agency;

(b) Provided an opportunity to give informed consent, or have the patient's legally authorized representative give informed consent, as required by state law, with documentation of provision

of such opportunity in the patient's medical record;

(c) Afforded the right to refuse medical and surgical treatment to the extent permitted by law;

(d) Have advance directives honored in accordance with the law and afforded the opportunity to issue advance directives if admitted on inpatient status;

(e) Provided, upon request, a written summary of hospital charge rates, per service, sufficient and timely enough to allow the patient to compare charges and make cost-effective decisions in the purchase of hospital services;

(f) Provided an itemized statement of all charges for which the patient or third-party payer is being billed; and

(g) Provided communication of information in a method that is effective for the recipient, whether the recipient is the patient or the patient's designated representative. If the hospital cannot provide communications in a method that is effective for the recipient, attempts to provide such shall be documented in the patient's medical record.

Authority: O.C.G.A. §§ 10-1-393, 31-7-2.1, 31-7-11, 31-9-2, 31-9-7, 31-11-82, 31-32-1 et seq., 31-33-2, 31-33-3.

111-8-40-.11 Medical Staff.

Each hospital shall have an organized medical staff that operates under bylaws adopted by the medical staff and approved by the governing body. The bylaws may provide for the exercise of the medical staff's authority through committees.

(a) **Organization of the Medical Staff.** The medical staff shall be organized and may operate through defined committees as appropriate.

1. Any physician, podiatrist, or dentist providing patient

care, whether directly or by contract with the hospital, shall obtain clinical privileges through the hospital's medical staff credentialing process.

2. The medical staff shall be responsible for the examination of credentials of any candidate for medical staff membership and for any other individuals seeking clinical privileges and for the recommendations to the governing body concerning appointment of such candidates. Minimum requirements for medical staff appointments and clinical privileges shall include:

(i) Valid and current Georgia license to practice the respective profession;

(ii) Confirmed educational qualifications for the position of appointment;

(iii) References for practice and performance background;

(iv) Current health and mental status sufficient to perform medical and professional duties;

(v) Current Drug Enforcement Agency registration; if applicable;

(vi) Evidence of inquiry through relevant practitioner databases, such as databases maintained by licensing boards and the National Practitioner Data Bank; and

(vii) Congruity of the qualifications and/or training requirements with the privilege requested.

3. The medical staff shall evaluate at least biennially the credentials and professional performance of any individual granted clinical privileges for consideration for reappointment.

4. The medical staff shall establish a system for the approval of temporary or emergency staff privileges when needed.

(b) **Medical Staff Accountability.** The medical staff shall be accountable to the governing body for the quality of medical care provided to all patients.

1. The medical staff shall require that all individuals granted clinical privileges comply with generally accepted standards of practice.

2. The medical staff shall implement measures, including peer review, to monitor the on-going performance of the delivery of patient care by those granted clinical privileges, including monitoring of compliance with the medical staff bylaws, rules and regulations, and hospital policies and procedures.

3. The medical staff shall establish effective systems of accountability for any hospital services ordered by physicians and other practitioners.

4. The medical staff shall review and, when appropriate, recommend to the governing body denial, limitation, suspension, or revocation of the privileges of any practitioner who does not practice in compliance with the scope of privileges, the medical staff bylaws, rules and regulations, generally accepted standards of practice, or hospital policies and procedures.

(c) **Medical Staff Bylaws and Rules and Regulations.** The medical staff of the hospital shall adopt and enforce bylaws and rules and regulations which provide for the self-governance of medical staff activities and accountability to the governing body for the quality of care provided to all patients. The bylaws and rules and regulations shall become effective when approved by the governing body and shall include at a minimum:

1. A mechanism for participation of medical staff in policy decisions related to patient care in all areas of the hospital;

2. A plan for administrative organization of the medical staff and committees thereof, which clearly delineates lines of authority, delegation, and responsibility for various tasks and functions;

3. Description of the qualifications and performance to be met by a candidate in order for the medical staff to recommend appointment or reappointment by the governing body;

4. Criteria and procedures for recommending the privileges to be granted to individual physicians, dentists, or podiatrists;

5. A requirement that members of the medical staff comply with ethical and professional standards;

6. Requirements for regular health screenings for all active members of the medical staff that are developed in consultation with hospital administration, occupational health, and infection control/ safety staff. The health screenings shall be sufficient to identify conditions which may place patients or other personnel at risk for infection, injury, or improper care. There shall be a mechanism for the reporting of the screening results to the hospital, either through the medical staff or otherwise;

7. A mechanism for ensuring physician response to inpatient emergencies twenty-four (24) hours per day;

8. A mechanism for physician coverage of the emergency department and designation of who is qualified to conduct an emergency medical screening examination where emergency services are provided;

9. A requirement that referral for consultations will be provided to patients when a patient's physical or mental condition exceeds the clinical expertise of the attending member of the medical staff;

10. The requirements for the patient's history and physical examination, which must be performed either within twenty-four (24) hours after admission or within the thirty (30) days prior to admission and updated upon admission. See Rule 111-8-40-.28(a)(2) for history and physical requirements when surgery is being performed;

11. Establishment of procedures for the choice and control of all drugs in the hospital;

12. The requirements for the completion of medical records;

13. The requirements for verbal/telephone orders, to include which Georgia-licensed or Georgia-certified personnel or other qualified individuals may receive verbal/telephone orders, and the acceptable timeline for authentication of the orders, not to exceed the timeline requirements of these rules;

14. A mechanism for peer review of the quality of patient care, which includes, but is not limited to, the investigation of reportable patient incidents involving patient care as described in Rule 111-8-40-.07(2)(a); and

15. A procedure for review and/or update of the bylaws and rules and regulations as necessary, but at least once every three (3) years.

(d) **Other Medical Staff Policies.** If not addressed through the medical staff bylaws or rules and regulations, the medical staff shall develop and implement policies to address, at a minimum:

1. Criteria for when an autopsy shall be sought and a requirement that the attending physician be notified when an autopsy is performed; and

2. A requirement that every member of the medical staff provide appropriate medical care for each of their patients until the patient is stable for discharge or until care of the patient has been transferred to another member of the medical staff or to another facility.

Authority: O.C.G.A. §§ 31-7-2.1 and 31-7-15.

111-8-40-.12 Human Resources Management.

The hospital shall select and organize sufficient qualified and competent personnel to meet patients' needs and in a manner appropriate to the scope and complexity of the services offered.

(a) The hospital shall establish and implement human resources policies and procedures to include at least:

1. Procedures for selecting qualified personnel;

2. A system for documenting the current licensure and/or certification status for those personnel whose positions or functions require such licensure or certification;

3. A system for assessing competency of all personnel providing health care services, on a time schedule defined by hospital policy; and

4. Policies and procedures regarding the hospital-approved method for identification of personnel to patients, other staff, and visitors.

(b) **Written Job Descriptions.** The hospital shall have a written description of responsibilities and job duties, with qualification requirements, for each position or job title at the hospital.

(c) **Health Screenings.** The hospital shall have in place a mechanism and requirement for initial, regular, and targeted health screenings of personnel who are employed or under contract with the hospital or providing patient care services within the hospital setting. The screening shall be sufficient in scope to identify conditions that may place patients or other personnel at risk for infection, injury, or improper care. The health-screening program shall be developed in consultation with hospital administration, medical staff, occupational health, and infection control/safety staff.

(d) **Personnel Training Programs.** The hospital shall have and implement a planned program of training for personnel to include at least:

1. Hospital policies and procedures;

2. Fire safety, hazardous materials handling and disposal, and disaster preparedness;

3. Policies and procedures for maintaining patients' medical records;

4. The infection control program and procedures; and

5. The updating of job-specific skills or knowledge.

(e) Personnel records shall be maintained for each employee of the hospital and shall contain, at a minimum:

1. The employment application or resume;

2. Dates of hire and position changes since hiring;

3. The job or position description(s) for the employee;

4. All evaluations of performance or competencies for the employee since the date of hire or at least the last five (5) years;

5. Credible evidence of current registration, licensure, or certification as required for that position by state law;

6. Evidence of completion of in-service training as required by hospital policy; and

7. Evidence of completion of any requirements of the occupational health program at the hospital.

Authority: O.C.G.A. § 31-7-2.1.

111-8-40-.13 Quality Management.

The governing body shall establish and approve a plan for a hospital-wide quality management program, which includes the use of peer review committees. The purpose of the quality management program is to measure, evaluate, and improve the provision of patient care.

(a) The scope and organization of the quality management program shall be defined and shall include all patient services and clinical support services, contracted services, and patient care services provided by the medical staff.

(b) The hospital's quality management program shall be designed to systematically collect and assess performance data, prioritize data, and take appropriate action on important processes or outcomes related to patient care, including but not limited to:

1. Operative procedures and other invasive and non-invasive procedures that place patients at risk;

2. Nosocomial infection rates;

3. Patient mortality;

4. Medication use;

5. Patient injuries, such as, but not limited to, those related to falls and restraint use;

6. Errors in procedures or practices which could compromise patient safety ("near-miss" events);

7. Discrepancies or patterns of discrepancies between preoperative and postoperative diagnosis, including those identified during the pathologic review of specimens removed during surgical or invasive procedures;

8. Significant adverse drug reactions (as identified by the hospital);

9. Adverse events or patterns of adverse events during anesthesia;

10. Equipment malfunctions, for equipment used for patient care; and

11. Reportable patient incidents as required under Rule 111-8-40- .07.

(c) The quality management program shall utilize a defined methodology for implementation, including at least mechanisms and methodology for:

1. Performance measurement including consideration of scope of services;

2. Monitoring, evaluating, and assessing accountability;

3. Setting priorities;

4. Root cause analyses, as appropriate, of problems identified;

5. Process improvement;

6. Identification of expected outcomes;

7. Reporting mechanisms; and

8. Authority for problem resolution.

(d) Results or findings from quality management activities shall be disseminated to the governing body, the medical staff, and any services impacted by the results.

(e) The hospital shall take and document action to address

opportunities for improvement identified through the quality management program.

(f) There shall be an on-going evaluation of the quality management program to determine its effectiveness, which shall be presented at least annually for review and appropriate action to the medical staff and governing body.

Authority: O.C.G.A. §§ 31-7-2.1 and 31-7-15.

111-8-40-.14 Physical Environment.

The hospital shall be equipped and maintained to provide a clean and safe environment for patients, employees, and visitors.

(a) **Safety.** The hospital shall develop and implement an effective hospital-wide safety program that includes the following components:

1. A fire safety program including compliance with the applicable provisions of the *Life Safety Code* (NFPA 101), as enforced by the state fire marshal;

2. An incident monitoring system that promptly identifies, investigates, and takes effective action regarding all incidents that involve injury to patients, employees, or visitors or that involve significant damage to property;

3. A program to inspect, monitor, and maintain biomedical equipment, electrical equipment, and emergency power generators;

4. A program for the monitoring and maintenance of electrical safety;

5. Security procedures for controlling access to sensitive areas, as defined by the hospital, for patients, employees, and visitors;

6. Procedures for the safe management of medical gases;

7. A system for patients or staff to summon assistance, when needed, from patient rooms, bathrooms, and treatment areas;

8. Policies regarding smoking which apply to employees, patients, and visitors; and

9. Procedures for storage and disposal of biohazardous medical waste in accordance with applicable laws.

(b) **Cleanliness and Sanitation.** The hospital shall maintain an environment that is clean and in good repair, through a program that establishes and maintains:

1. Standardized daily, interim, and terminal cleaning routines for all areas;

2. Facilities for convenient and effective hand washing throughout the hospital;

3. Systems for management of linens, including collection, sorting, transport, and washing of soiled linens, and storage and distribution of clean linens;

(i) Collection and sorting procedures shall be designed to prevent contamination of the environment and personnel. Collection procedures shall include bagging of soiled linen at site of use. Sorting and rinsing of soiled linens shall not take place in patient care areas;

(ii) Clean and soiled linens shall be transported in separate containers or carts;

(iii) The laundering process for soiled linens shall be sufficient to remove organic soil and render the linen incapable of causing human illness; and

(iv) Any soiled linen processing area shall be separate from the area used for clean linen storage, from patient care areas, and from areas where clean or sterilized supplies and equipment are stored;

4. Standards regarding the use of hospital disinfectants;

5. Systems for the storage and disposal of garbage, trash, and waste in a manner that will not permit the transmission of disease, create a nuisance, or provide a breeding place for insects or rodents; and

6. Procedures for the prevention of infestation by insects, rodents, or other vermin or vectors.

(c) **Light, Temperature, and Ventilation.** The hospital shall provide adequate lighting, ventilation, and control of temperature and air humidity for optimal patient care and safety of the hospital's patients and staff and shall monitor and maintain such systems to function at least minimally to the design standards current at the time of approved facility construction or renovation.

(d) **Space.** The hospital shall provide sufficient space and equipment for the scope and complexity of services offered.

Authority: O.C.G.A. § 31-7-2.1.

111-8-40-.15 Disaster Preparedness.

The hospital shall prepare for potential emergency situations that may affect patient care by the development of an effective disaster preparedness plan that identifies emergency situations and outlines an appropriate course of action. The plan must be reviewed and revised annually, as appropriate, including any related written agreements.

(a) The disaster preparedness plan shall include at a

minimum plans for the following emergency situations:

1. Local and widespread weather emergencies or natural disasters, such as tornadoes, hurricanes, earthquakes, ice or snowstorms, or floods;

2. Manmade disasters such as acts of terrorism and hazardous materials spills;

3. Unanticipated interruption of service of utilities, including water, gas, or electricity, either within the facility or within a local or widespread area;

4. Loss of heat or air conditioning;

5. Fire, explosion, or other physical damage to the hospital; and

6. Pandemics or other situations where the community's need for services exceeds the availability of beds and services regularly offered by the hospital.

(b) There shall be plans to ensure sufficient staffing and supplies to maintain safe patient care during the emergency situation.

(c) There shall be plans for the emergency transport or relocation of all or a portion of the hospital patients, should it be necessary, in vehicles appropriate to the patient's condition(s) when possible, including written agreements with any facilities which have agreed to receive the hospital's patients in these situations.

(d) The hospital shall document participation of all areas of the hospital in quarterly fire drills.

(e) In addition to fire drills, the hospital shall have its staff rehearse portions of the disaster preparedness plan, with a minimum of two (2) rehearsals each calendar year either in response to an emergency or through planned drills, with

coordination of the drills with the local Emergency Management Agency (EMA) whenever possible.

(f) The plan shall include the notification to the Department of the emergency situation as required by these rules.

(g) The hospital shall provide a copy of the internal disaster preparedness plan to the local Emergency Management Agency (EMA) and shall include the local EMA in development of the hospital's plan for the management of external disasters.

(h) The hospital's disaster preparedness plan shall be made available to the Department for inspection upon request.

(i) The Department may suspend any requirements of these rules and the enforcement of any rules where the Governor of the State of Georgia has declared a public health emergency.

Authority: O.C.G.A. §§ 31-7-2.1, 31-7-3 and 31-12-2.1.

111-8-40-.16 Infection Control.

The hospital shall have an effective infection control system to reduce the risks of nosocomial infections in patients, health care workers, volunteers, and visitors.

(a) The hospital shall designate qualified infection control staff to coordinate the infection control program.

(b) The administrative and medical staff of the hospital, as well as staff from appropriate organized services, shall participate in the infection control program.

(c) The infection control program shall function from a well-designed surveillance plan that is based on accepted epidemiological principles, is tailored to meet the needs of the hospital, and includes both outcome and process surveillance methodologies.

(d) The surveillance plan shall require collection of sufficient baseline data on the incidence of nosocomial infections in order that outbreaks can be identified.

(e) The infection control methodologies for effective investigation and control of outbreaks, once identified, shall include at least:

1. The availability of microbiology laboratory capacity to detect and investigate outbreaks;

2. A system for obtaining appropriate clinical specimens for culture;

3. Access to necessary information in order to investigate infectious outbreaks; and

4. Administrative, physician, and nursing support to direct hospital changes to achieve immediate control of outbreaks and for implementation of corrective actions.

(f) The program shall specify policies and procedures for infection control that apply to all areas of the hospital, and these shall include at least the following:

1. The approved hospital isolation system;

2. The approved procedures for handling and disposing of hazardous waste products;

3. The standards for approved cleaning, disinfection, and sterilization of all areas of the hospital;

4. The standards for hand washing and hand antisepsis; and

5. A communicable disease health-screening plan for the hospital that includes required communicable disease activities,

immunizations, exposure evaluations, tuberculosis surveillance, and work restrictions. There shall be evidence that the plan was developed in consultation with hospital administration, medical staff, and safety staff.

(g) The infection control program shall have an organized and effective on-going education plan for hospital health care workers and volunteers that includes at least:

1. An orientation plan;

2. A plan for on-going training on isolation precautions, aseptic practices, and prevention of blood and body fluid exposure; and

3. Provision of specially designed training programs that result from outcome and process surveillance data.

(h) The hospital shall designate which departments are responsible for the reporting of communicable diseases as required by law.

(i) The infection control program shall be evaluated at least annually to determine the effectiveness of the program at lowering the risks and improving the trends of nosocomial infections in patients, health care workers, and volunteers. Changes in the infection control program shall reflect consideration of the results of the evaluations.

Authority: O.C.G.A. § 31-7-2.1.

111-8-40-.17 Sterile Processing Services.

Each hospital shall designate a sterile processing service area designated for the decontamination, cleaning, sterilizing of reusable equipment, instruments, and supplies.

(a) With the collaboration of the infection control program,

the staff providing sterile processing services shall develop and implement standardized policies and procedures that conform to generally accepted standards of practice for:

1. Decontamination and cleaning of instruments and other items and description of reprocessing protocols for contaminated patient equipment;

2. Disinfecting and/or sterilizing equipment and other items;

3. Monitoring of the systems used for sterilization;

4. Procedures for ensuring the sterility of packaged instruments and supplies;

5. Recall of items; and

6. Mechanisms for protection of workers from exposure to blood and other potentially infectious materials and environmental hazards.

(b) The sterile processing service shall be staffed by qualified personnel.

Authority: O.C.G.A. § 31-7-2.1.

111-8-40-.18 Medical Records.

(1) **Management of Patients' Medical Records.** The hospital shall have an efficient and organized medical records service that establishes the policies and procedures for the maintenance of the medical records for all patients and that is administratively responsible for the management of those records.

(a) The medical records service shall maintain a list of accepted abbreviations, symbols, and medical terminology to be utilized by persons making entries into patients' medical records.

(b) The medical records service shall utilize systems to verify the author(s) of entries in the patients' medical records. Delegation of use of computer codes, signature stamps, or other authentication systems, to persons other than the author of the entry, is prohibited.

(c) The hospital shall utilize systems defined by hospital policies and procedures to ensure that patients' medical records are kept confidential. Medical records shall be accessible only to hospital and medical staff involved in treating the patient and to other individuals as permitted by federal and state laws. The Department, in exercising its licensing authority, shall have the right to review and copy any patients' medical records.

(d) At any time during or after their course of treatment, patients shall be provided with copies of their medical records upon their written requests or the written requests of their authorized representatives in accordance with state law. Copies shall be provided within a reasonable time period not to exceed thirty (30) days after the request, unless the patient agrees to a lengthier delivery time. Copies of records shall be provided to patients for a reasonable fee in accordance with applicable laws.

(e) Copies of the patient's medical records shall be released to persons other than the patient or the patient's legally authorized representative either at the written request of the patient or as otherwise allowed by law. If the individual designated to receive a copy of the record is a health care provider, the copy of the record shall be released by the hospital in a timely manner so as not to interfere with the continuation of the patient's treatment.

(f) Patients' medical records shall be coded and indexed in a manner that allows for timely retrieval by diagnosis or procedure when necessary.

(g) The hospital shall utilize an effective process to ensure that patients' medical records are completed within thirty (30) days after the patients are discharged from the hospital. Records of other parts of patients' records that are not within the control of the

hospital or its medical staff shall be added to the patients' records as soon as they become available to the hospital.

(h) The hospital shall retain all patients' medical records at least until the fifth anniversary of the patients' discharges. If the patient is a minor, the records must be retained for at least five (5) years past the age of majority. Records may be preserved in the hospital's format of choice, including but not limited to paper or electronic format, so long as the records are readable and capable of being reproduced in paper format upon request.

(i) Medical records shall be secured in such a manner as to provide protection from damage or unauthorized access.

(2) **Entries in the Medical Record.** All entries in the patient's medical records shall be accurate and legible and shall contain sufficient information to support the diagnosis and to describe the treatment provided and the patient's progress and response to medications and treatments. Inpatient records shall also contain sufficient information to justify admission and continued hospitalization.

(a) The date of the entry and the signature of the person making the entry, shall accompany all entries in the patient's medical record. Late entries shall be labeled as late entries.

(b) The hospital, through its medical staff policies, shall appropriately limit the use of verbal/telephone orders. Verbal/telephone orders shall be used only in situations where immediate written or electronic communication is not feasible and the patient's condition is determined to warrant immediate action for the benefit of the patient. Verbal/telephone orders shall be received by an appropriately license or otherwise qualified individual as determined by the medical staff in accordance with state law.

(c) The individual receiving the verbal/telephone order shall immediately enter the order into the medical record, sign and date the order, with the time noted, and, where applicable, enter the

dose to be administered.

(d) The individual receiving the order shall immediately repeat the order and the prescribing physician or other authorized practitioner shall verify that the repeated order is correct. The individual receiving the order shall document, in the patient's medical record, that the order was "repeated and verified."

(e) The verbal/telephone order shall be authenticated by the physician or other authorized practitioner giving the order, or by a physician or other authorized practitioner taking responsibility for the order, in accordance with hospital and medical staff policies.

1. Where the procedures outlined in subparagraph (2)(d) of this rule are followed, the hospital shall require authentication of all verbal/telephone orders no later than thirty (30) days after the patient's discharge.

2. As an alternative to meeting the requirements set forth in subparagraph (2)(d) of this rule, the hospital shall require that verbal/ telephone orders be authenticated within forty-eight (48) hours, except where the patient is discharged within forty-eight (48) hours of the time the verbal/telephone order was given, in which case authentication shall occur within thirty (30) days after the patient's discharge.

(f) The hospital's quality improvement plan shall include monitoring of the appropriate use of verbal/telephone orders in accordance with these rules and hospital policy and taking appropriate corrective action as necessary.

(3) **Minimum Requirements for Patients' Medical Records.** Upon completion, medical records for inpatients and outpatients shall contain, at minimum, the documents as specified below. Records for patients at the hospital for other specialized services, such as emergency services or surgical services, shall contain such additional documentation as required for those services.

(a) **Inpatient Records.** Medical records for inpatients shall

contain at least the following:

1. A unique identifying number and a patient identification form, which includes the following when available: name, address, date of birth, sex, and person to be notified in an emergency;

2. The date and time of the patient's admission;

3. The admitting diagnosis and clinical symptoms;

4. The name of the attending physician;

5. Any patient allergies;

6. Documentation regarding advanced directives;

7. The report from the history and physical examination;

8. The report of the nursing assessment performed after admission;

9. Laboratory, radiological, electrocardiogram, and other diagnostic assessment data or reports as indicated;

10. Reports from any consultations;

11. The patient's plan of care;

12. Physician's orders or orders from another practitioner authorized by law to give medical or treatment orders;

13. Progress notes from staff members involved in the patient's care, which describe the patient's response to medications, treatment, procedures, anesthesia, and surgeries;

14. Data, or summary data where appropriate, from routine or special monitoring;

15. Medication, anesthesia, surgical, and treatment records;

16. Documentation that the patient has been offered the opportunity to consent to procedures for which consent is required by law;

17. Date and time of discharge;

18. Description of condition, final diagnosis, and disposition on discharge or transfer;

19. Discharge summary with a summary of the hospitalization and results of treatment; and

20. If applicable, the report of autopsy results.

(b) **Outpatient Records.** Medical reports for outpatients shall contain at least the following:

1. A unique identifying number and a patient identification form, which includes the following if available: name, address, date of birth, sex, and person to be notified in an emergency;

2. Diagnosis of the patient's condition;

3. The name of the physician ordering treatment or procedures;

4. Patient allergies;

5. Physician's orders or orders from another practitioner authorized by law to give medical or treatment orders as applicable;

6. Documentation that the patient has been offered the opportunity to consent to procedures for which consent is required by law;

7. Reports from any diagnostic testing; and

8. Sufficient information to justify any treatment or

procedure provided, report of outcomes of treatment or procedures, and, as appropriate, progress notes and the disposition of the patient after treatment.

Authority: O.C.G.A. § 31-7-2.1.

111-8-40-.19 Patient Assessment and Treatment.

All patient care services provided by the hospital shall be under the direction of a member of the medical staff or a licensed physician, dentist, osteopath, or podiatrist who has been granted hospital privileges.

(a) **Patient Assessment/Screening on Admission.** The hospital shall provide each inpatient with an appropriate assessment of the patient's condition and needs at the time of admission. Such assessments shall be provided by personnel authorized by hospital policy or the medical staff bylaws and/or rules and regulations and shall be designed to trigger referral for further assessment needs.

1. A history and physical examination shall be completed within the first twenty-four (24) hours after admission. A history and physical examination completed by either the patient's physician or the appropriate practitioner operating under the direction of the physician as authorized by law no more than thirty (30) days prior to the admission may be accepted but must be updated to reflect the patient's condition at the time of admission. Where the patient is admitted solely for oromaxillofacial surgery, such history and physical may be completed by the oromaxillofacial surgeon.

2. A basic nursing assessment to include at least evaluation of physical and psychological status sufficient to develop an initial plan of care shall be completed within the first twelve (12) hours after admission. Within twenty-four (24) hours after admission, a comprehensive nursing assessment will be completed to include at least:

(i) Screening and referral for further assessment of patient needs related to social, nutritional, and functional status; and

(ii) Screening of educational and potential post-hospitalization needs.

3. Inquiry as to the status of any advance directives for the patient shall be made at the time of admission.

(i) If a patient has an advance directive in place that the patient wishes to invoke, but the written directive is not available at the time of admission, there shall be a mechanism in place to trigger a recheck by hospital personnel for the document within a reasonable period of time.

(ii) If the patient does not have an advance directive in place, admissions procedures shall require that designated hospital personnel will offer information regarding advance directives according to hospital policy and timelines.

(b) **Patient's Plan of Care .**

1. On admission, the plan of care shall be initiated by the designated hospital staff for each patient to meet the needs identified by the initial assessments. The initial plan of care shall be placed in the patient's record within twelve (12) hours of admission.

2. As the patient's treatment progresses, the plan of care shall be updated to reflect any changes necessary to address new or changing needs.

(c) **Reassessments of the Patient's Condition.** Reassessment of the patient's condition shall be performed periodically at appropriate intervals and defined in hospital policy. In addition, reassessments shall occur at least as follows:

1. During and following an invasive procedure;

2. Following a change in the patient's condition or leve l of care;

3. During and following the administration of blood and blood products;

4. Following any adverse drug reaction or allergic reaction; and

5. During and following any use of physical restraints or seclusion.

(d) **Other Treatment Requirements.**

1. All patients shall be given the opportunity to participate, or have a designated representative participate, in decisions regarding their care.

2. Patients shall be provided treatment free from physical restraints or involuntary seclusion, unless utilized solely for protection during brief transport to a specified destination or authorized by a physician's order, for a limited period of time, to protect the patient or others from injury. Policies and procedures shall be in place to require that a patient's physical comfort and safety needs are addressed during any period of required physical restraint or confinement. A positioning or securing device used to maintain the position, limit mobility, or temporarily immobilize during medical, dental, diagnostic, or surgical procedures is not considered a restraint.

3. Patients shall receive care in a manner free from all forms of abuse or neglect.

4. Patients shall receive treatment in an environment that respects their personal privacy, both of their physical person and their treatment information.

5. The hospital shall establish and enforce policies and procedures that require that all personnel providing direct care to

the patient identify themselves to the patient by name and title or function.

Authority: O.C.G.A. § 31-7-2.1.

111-8-40-.20 Discharge Planning and Transfers for Inpatients.

The hospital shall utilize an effective and on-going discharge planning process that identifies post-hospital needs of inpatients and arranges for appropriate resource referral and follow-up care.

(a) On admission, the nursing assessment shall identify patients who are likely to suffer adverse consequences upon discharge in the absence of adequate discharge planning.

(b) For those patients identified as needing a discharge plan, designated qualified staff shall complete an evaluation of post-hospital needs and shall develop a plan for meeting those needs. The discharge plan shall be revised as needed with changes in the patient's condition.

(c) The hospital shall provide education to patients, and their family members or interested persons as necessary or as requested by the patient, to prepare them for the patient's post-hospital care.

(d) The hospital shall arrange for the initial implementation of any discharge plan, including, as applicable, any transfer or referral of the patient to appropriate facilities, agencies, or outpatient services for follow-up or ancillary care. The hospital shall be responsible for the transfer of any necessary medical information to other facilities for the purpose of post-hospital care.

(e) The hospital shall regularly reassess the discharge planning process to ensure that it is responsive to patients' discharge needs.

(f) The hospital shall adopt and enforce a policy requiring annually during influenza season (inclusive of at least October 1st through March 1st) and prior to discharge, any inpatient 65 years of age or older shall be offered vaccinations for the influenza virus and pneumococcal disease unless contraindicated and contingent on availability.

1. The hospital policy may authorize such vaccinations to be administered per hospital medical staff approved standing order and protocol following an assessment for contraindications.

2. The hospital policy must also require the inpatient's medical record, where such vaccination is administered, to contain an assessment for contraindications, the date of such administration and patient response.

Authority: O.C.G.A. § 31-7-2.1.

111-8-40-.21 Nursing Services.

The hospital shall have an organized nursing service that provides twenty-four (24) hour nursing care to meet the needs of patients. Critical access hospitals are exempted from providing on-site twenty-four (24) hour nursing care when there are no hospitalized patients.

(a) **Organization of Nursing Services.** The hospital's nursing services shall be directed by a licensed registered nurse who shall be responsible for implementing a system for supervision and evaluation of nursing clinical activities.

1. The chief nurse executive shall establish and implement policies and procedures for nursing services based on generally accepted standards of practice including the evaluation of the effectiveness of the services in coordination with the hospital's quality management program.

2. The chief nurse executive shall be responsible for

ensuring that nursing personnel are oriented to nursing policies and procedures.

3. Nursing services shall have and follow a written plan for organization, administrative authority, delineation of responsibilities for patient care, and staff qualifications and competencies.

(i) The nursing service plan shall include the types and numbers of nursing personnel necessary to provide appropriate nursing care for each patient in the hospital.

(ii) Specialty areas shall specify nursing requirements for their areas that also define any special nursing competency requirements, staffing patterns based on patient acuity, and the required ratio of nurses to technical staff.

(iii) A system of patient assignment shall be defined which reflects a consideration of patient needs and nursing staff qualifications and competencies.

(b) **Delivery of Nursing Services.** Nursing services must be delivered in accordance with patients' needs and generally accepted standards of practice.

1. A license registered nurse must be on duty at all times to provide or supervise the provision of care. Critical access hospitals are permitted some flexibility in meeting this requirement as set forth in Rule 111-8-40-.38.

2. Within the first twelve (12) hours after admission, a basic nursing assessment shall be completed for each patient and a plan of care initiated.

3. The patient's condition shall be monitored by nursing staff on a schedule appropriate to the patient's needs.

4. Nursing staff shall be responsible for updating the patient's plan of care based on any changes in the patient's

condition.

5. Nursing staff administering drugs and biologicals shall act in accordance with the orders from the medical staff responsible for the patient's care, generally accepted standards of practice, and any federal and state laws pertaining to medication administration.

6. Nursing staff shall report medication administration errors and adverse drug reactions in accordance with established hospital policies.

7. Blood transfusions and other blood products shall be administered by licensed nursing staff or other qualified practitioners as authorized by law in accordance with established hospital policies, which shall include, at a minimum, the following:

(i) Obtaining and documenting appropriate patient consent to treatment and procedures, as required;

(ii) Responding to and reporting of transfusion reactions;

(iii) Monitoring patients appropriately; and

(iv) Designating personnel qualified to perform these procedures.

Authority: O.C.G.A. § 31-7-2.1.

111-8-40-.22 Pharmaceutical Services.

The hospital shall provide or have access to effective pharmaceutical services to meet the needs of its patients in accordance with generally accepted standards of practice and applicable laws and regulations.

(a) **Pharmacy Director.** All pharmaceutical services in the hospital shall be under the direction of a pharmacist licensed in

Georgia. The responsibilities of the director of pharmaceutical services shall include:

1. Developing, supervising, and coordinating all activities of the pharmaceutical service to be in compliance with state rules and regulations for hospital pharmacies including the evaluation of the effectiveness of the services in coordination with the hospital's quality management program; and

2. Developing and implementing an effective system that does the following:

(i) Minimizes drug errors and identifies potential drug interactions and adverse drug reactions;

(ii) Controls the availability and storage of drugs throughout the hospital;

(iii) Distributes and administers the drugs in compliance with generally accepted standards of practice;

(iv) Tracks the receipt and disposition of all scheduled drugs;

(v) Staffs pharmaceutical services to provide sufficient qualified personnel to respond to the pharmaceutical needs of the patient population being served, including twenty-four (24) hours per day, seven (7) days per week emergency coverage;

(vi) Labels and dispenses drugs, including a requirement that only licensed pharmacists or properly supervised licensed pharmacy interns are permitted to compound, label, and dispense drugs or biologicals;

(vii) Manages drug recalls;

(viii) Addresses the removal of drugs when a pharmacist is not available;

(ix) Compiles and reports data related to drug ordering;

dispensing and administration errors, and possible adverse drug reaction to the hospital's quality management program; and

(x) Reviews all activities and functions of the hospital's pharmaceutical services.

(b) **Management of Drugs.** The pharmacist shall be responsible for the management of drugs within the hospital.

1. The hospital's pharmaceutical services shall access, compile, and make available to medical and professional staff information relating to drug or food interactions, drug therapy, side effects, toxicology, dosage indicators, and routes of administration.

2. Loss and theft of controlled substances shall be reported to the pharmacy director, to the hospital administration, and to others as required by applicable laws and regulations.

3. All drugs and pharmaceuticals shall be stored in an area or on a cart which shall be locked when unattended to prevent access by unauthorized individuals.

4. Outdated, mislabeled, or otherwise unusable drugs and pharmaceuticals shall not be available for patient use.

5. Certain drugs and pharmaceuticals not specifically prescribed as to limitation of time or number of doses shall be automatically discontinued after a specified time pursuant to guidelines developed by the medical staff in conjunction with the pharmacy director.

6. Drug administration errors, adverse drug reactions, and drug incompatibilities shall be immediately reported in a timely manner to the attending physician and the pharmacist.

7. Drugs brought into the hospital by a patient may be administered to the patient only if the medications can be accurately identified, properly stored and secured, and ordered by

the attending physician for the patient's hospitalization. If the drugs cannot be administered to the patient, the drugs shall be returned to an adult member of the patient's immediate family or returned to the patient upon discharge unless otherwise prohibited by law.

Authority: O.C.G.A. §§ 16-4-77, 16-13-20 et seq. and 31-7-2.1.

111-8-40-.23 Food and Dietary Services.

The hospital shall have an organized food and dietary service that is directed and staffed by an adequate number of qualified personnel to meet the nutritional needs of hospital patients. All hospital food service areas and operations shall comply with current federal and state laws and rules concerning food service.

(a) **Organization of Food and Dietary Services.**

1. **Food Service Manager.** The hospital shall have a manager of food and dietary services who has training and experience in management of a food service system in a health care setting and receives on-going training. The responsibilities of the manager shall include:

(i) Overall coordination and integration of the therapeutic and administrative aspects of the service;

(ii) Development and implementation of policies and procedures concerning the scope and conduct of dietary services, including food preparation and delivery systems;

(iii) Orientation and training programs for dietary service personnel and other hospital personnel involved in food delivery on all applicable dietary services policies and procedures, including personal hygiene, safety, infection control requirements, and proper methods of waste disposal;

(iv) The implementation of a system to ensure that prescribed

diets are delivered to the correct inpatients;

(v) Maintenance of a staff of sufficient numbers of administrative and technical personnel competent in their assigned duties to carry out the dietary service program;

(vi) Procurement of food, paper, chemical, and other supplies sufficient to meet the anticipated food service needs of the hospital; and

(vii) Implementation of procedures to rotate all food items to ensure use in a timely manner.

2. **Dietitian.** Clinical supervision of the hospital's dietary service shall be provided by a dietitian on a full-time, part-time, or consultant basis, as determined by the needs of the hospital. If supervision by the dietitian is provided by a contractual arrangement or on a consultation basis, such services shall occur at least once per month for not less than eight hours. The dietitian shall be responsible for:

(i) Evaluation of inpatients' nutritional status and needs. If the admission screening identifies that an inpatient may be nutritionally at risk, the follow-up evaluation by the dietitian must be performed within twenty-four (24) hours of determination of the need for evaluation of the patient;

(ii) Review and approval of all menus, including menus for therapeutic or prescribed diets;

(iii) Participation in the development, revision, and review of policies and procedures for dietary services;

(iv) Guidance to the manager of dietary services and to the staff of the service on methods for maintaining nutritionally balanced meals that meet the needs of each patient and in maintaining sanitary dietary practices; and

(v) Appropriate documentation in the inpatients' medical

records of any evaluation of nutritional status or needs.

(b) **Physical Environment Requirements for Food Service Areas.** The hospital shall provide adequate space, equipment, and supplies for efficient, safe, and sanitary receiving, storage, refrigeration, preparation, and service of food. The physical environments for food service activities must meet the requirements of state regulations for food service.

(c) **Delivery of Dietary Services.** Dietary services shall be delivered in accordance with the nutritional needs of the hospital's patients.

1. There shall be a mechanism in place for the evaluation of nutritional needs for inpatients identified during admission as needing further assessment. The mechanism shall require that such evaluations be completed promptly, with modifications to patients' diets, if any, recorded in the patients' medical records within twenty-four (24) hours of notification of the need for the evaluation.

2. A current therapeutic diet manual, approved by the dietitian and medical staff, shall be readily available to all medical, nursing, and dietary service personnel.

3. Therapeutic diets shall be prescribed by the member of the medical staff responsible for the care of the inpatient.

4. A written order for the modified diet prescription as recorded in the inpatient's medical record shall be readily available to dietary service personnel throughout the duration of the order.

5. When clinically indicated, the dietary staff shall provide education for inpatients regarding their diets and nutritional needs. This training shall be documented in the inpatients' medical records.

6. Unless medically contraindicated, at least three (3) meals

a day shall be provided for inpatients, with no more than fifteen (15) hours elapsing between dinner and breakfast.

7. There shall be a system for providing means for inpatients outside the normal meal service hours, when necessary.

8. A system for meal requisition shall be in place and shall require a notation regarding the inpatients' food allergies, if any.

9. Snacks shall be available between meals and at night, as appropriate to each patient's needs and medical condition.

10. The dietary service shall follow policies and procedures approved by the medical staff for the management of possible food and drug interactions.

11. Pertinent observations and information related to special diets, the inpatients' food habits, and response to dietetic treatment or diet modifications shall be recorded in the inpatients' medical records.

Authority: O.C.G.A. § 31-7-2.1.

111-8-40-.24 Imaging and Therapeutic Radiology Services.

(1) **Imaging Services.** The hospital shall maintain or arrange for effective imaging services to meet the needs of patients. The radiological imaging services shall be provided by the hospital in accordance with the rules under Chapter 290-5-22 Rules and Regulations for X-rays, where applicable.

(a) **Organization and Staffing for Imaging Services**. The hospital shall have an organizational plan for imaging services that identifies the scope of the services provided and the qualifications of the individuals necessary for the performance of various aspects of imaging services and delineates the lines of authority

and accountability.

1. There shall be a qualified director of imaging services who is a member of the medical staff and a licensed doctor of medicine or osteopathy with knowledge and experience in imaging services to supervise the provision of imaging services on a full-time or part-time basis.

2. The director shall be responsible for all clinical aspects of the organization and delivery of imaging services, including the evaluation of the effectiveness of the services in coordination with the hospital's quality management program.

3. Basic radiological imaging services shall be available at all times, or there shall be an on-call procedure to provide access to qualified x-ray personnel within thirty (30) minutes.

4. The hospital shall have qualified staff performing imaging services.

(b) **Orders of Imaging Procedures.** No imaging procedures shall be performed without an order or referral from a licensed doctor of medicine or osteopathy, chiropractor, dentist, podiatrist, physician assistant or nurse with advanced training where such order is in conformity with an approved job description or nurse protocol, and as authorized under state law for such licensed healthcare professionals.

(c) Verbal/telephone orders for imaging services shall be given only to health care professionals licensed or certified by state law or authorized by medical staff rules and regulations and other hospital policy to receive those orders, in accordance with these rules, and shall be entered into the patient's medical record by those licensed, certified, or authorized health care professionals.

(2) **Reports of Imaging Interpretations.** Interpretation of imaging test results or procedures shall be made only by those medical staff designated as qualified to interpret those tests or

procedures. Interpretations must be signed and dated by the medical staff providing the interpretation.

(a) Reports of all imaging interpretations and consultations shall be included in the patient's medical record.

(b) The hospital shall have an effective procedure for notifying in a timely manner the patient's physician and responsible nursing staff of critical interpretations identified through imaging tests.

(c) Films, scans, and other images shall be retained by the hospital for at least five years after the date of the procedure unless the release of the original images is required for the care of the patient. When original images are released, documentation of the disposition of the original images shall be retained for the applicable five-year period. If the patient is a minor, the records shall be retained for at least five years past the age of majority.

(3) **Therapeutic Radiology Services.** Radiation oncology services, if provided, must be directed by a physician with training and experience in therapeutic radiology. The service must have a medical oncologist and hematologist available for consultation.

(a) Therapeutic radiology procedures shall be ordered by a licensed doctor of medicine or osteopathy and administered by persons trained and qualified for those procedures and as required under current state law and regulations.

(b) Reports of all imaging interpretations, consultations, and therapies shall be included in the patient's medical record.

(c) Radiation Safety. If the hospital is providing diagnostic or therapeutic radiological services, hospital policies and procedures shall be implemented to ensure that patients and hospital staff are not exposed to unnecessary or unsafe levels of radiation. All imaging staff and therapeutic radiology staff shall be trained in these policies and procedures.

(d) Medical Emergencies. The hospital shall have written protocols for managing medical emergencies in the imaging area and therapeutic radiology area.

(e) Infectious Disease. The hospital shall have written protocols for managing patients with infectious diseases and critical care patients in the imaging area, or wherever imaging services are provided, and in the therapeutic radiology area.

Authority: O.C.G.A. §§ 31-7-2.1 and 31-13-1 et seq.

111-8-40-.25 Laboratory Services.

The hospital shall maintain or arrange for clinical laboratory services to meet the needs of hospital patients.

(a) **Organization and Staffing for Clinical Laboratory Services.** The administration, performance, and operation of all laboratories used by the hospital, as well as any laboratory functions performed by the hospital, shall conform to the Rules and Regulations for Licensure of Clinical Laboratories, Chapter 111-8-10.

1. The hospital shall have an organizational plan for laboratory services that identifies the scope of the services provided and the qualifications of the individuals necessary for the performance of various aspects of clinical laboratory services and delineates the lines of authority and accountability.

2. There shall be a qualified director of clinical laboratory services who is a member of the medical staff and meets the requirements for a director set forth in the Rules and Regulations for Clinical Laboratories, Chapter 111-8-10.

3. The director shall be responsible for the administration of clinical laboratory services, including the evaluation of the effectiveness of the services in coordination with the hospital's quality management program.

(b) The hospital shall have emergency laboratory services available at all times.

(c) The hospital shall provide for medical staff a written description of all laboratory services available.

(d) Reports of laboratory procedures and results shall be included in the patient's medical record.

(e) The hospital shall have an effective procedure for notifying in a timely manner the patient's physician and responsible nursing staff of critical values from laboratory tests.

(f) The hospital shall require that the laboratory report any epidemiologically significant pathogens to the hospital's infection control program.

(g) **Tissue Pathology.** Hospitals which provide surgery services shall have or arrange for tissue pathology services through a licensed or certified clinical laboratory which has a system for:

1. Designation of those tissue specimens which require examination and for procedures for maintaining a tissue file; and

2. Directing pathology reports to the patient's medical record and for reporting unusual or abnormal results to the attending physician in a timely manner.

Authority: O.C.G.A. Ch. 31-22, Sec. 31-7-2.1.

111-8-40-.26 Respiratory/Pulmonary Services.

The hospital shall provide or arrange for effective services to meet the respiratory/ pulmonary needs of patients and shall define in writing the scope and complexity of the respiratory/pulmonary services offered by the facility.

(a) **Organization and Staffing of Respiratory/Pulmonary Services.**

1. The hospital shall have an organizational plan for respiratory/ pulmonary services that clearly defines the necessary staff for the services and the lines of authority and accountability.

2. **Director.** There shall be a qualified director of respiratory/pulmonary services who is a member of the medical staff and a licensed doctor of medicine or osteopathy with knowledge, experience, and capability to supervise the services on a full-time or part-time basis including the evaluation of the effectiveness of the services in coordination with the hospital's quality management program.

(i) The director shall be responsible for all clinical aspects of the organization and delivery of clinical respiratory care services, including the evaluation of the effectiveness of the services in coordination with the hospital's quality management program.

(ii) The director shall be responsible for the development, implementation, and periodic review of policies, procedures, and protocols for respiratory/pulmonary care, which shall reflect the scope of services offered, including at least:

(I) Routine inspection, cleaning, and maintenance procedures for respiratory equipment, as well as protocols for their assembly and operation;

(II) Adverse reaction protocols;

(III) Safety practices and interventions;

(IV) Staff participation in emergency situations at the facility;

(V) Infection control procedures;

(VI) Procedures for handling, storage, and dispensing of therapeutic gases;

(VII) Procedures for obtaining blood samples and analysis of samples, as applicable;

(VIII) Procedures for testing of pulmonary function, as applicable;

(IX) Procedures for therapeutic percussion and vibration and for broncho-pulmonary drainage, as applicable;

(X) Procedures for mechanical ventilation and oxygenation support and for administration of aerosol, humidification, and therapeutic gases, as applicable;

(XI) Policies for administration of medications;

(XII) A system for the reissuing and discontinuing of respiratory therapy orders; and

(XIII) Procedures for verbal/telephone orders taken by state-certified respiratory care professionals.

3. There shall be a sufficient number of qualified competent professionals and support personnel to respond to and meet the respiratory/ pulmonary care needs of the patients.

(b) **Delivery of Respiratory/Pulmonary Services.** Respiratory/ Pulmonary services shall be delivered in accordance with the needs of the patients.

1. Respiratory services shall be provided only in response to medical orders. Medical orders for services shall include the modality to be used, the type, frequency, and duration of treatment, and the type and dose of medications, including dilution ratios. Verbal/telephone orders for respiratory service shall be dated, timed, and given only to appropriately licensed or otherwise qualified individuals as determined by the medical staff in accordance with state law and these rules and shall be entered into the patient's medical record by those appropriately licensed or otherwise qualified individuals.

2. The hospital shall provide equipment and supplies sufficient to support the scope of the respiratory services offered.

3. All respiratory care services provided shall be documented in the patient's medical record, including the type of therapy, date and time of administration, effects of therapy, and any adverse reactions.

4. If blood gases or other clinical laboratory tests are performed by respiratory care staff, those staff shall have demonstrated competency in the administration of the tests as point-of-care technicians.

Authority: O.C.G.A. Ch. 31-22, Sec. 31-7-2.1.

111-8-40-.27 Organ, Tissue, and Eye Procurement and Transplantation.

The hospital shall participate, as appropriate, in the procurement of anatomical gifts.

(a) **Receipt of Donations.** The hospital shall receive donations of organs or tissues for the purposes of medical and dental education, research, advancement of medical or dental science, therapy, or transplantation only in accordance with the provisions of the "Georgia Anatomical Gift Act," O.C.G.A. Section 44-5-140, and the applicable rules of Chapter 111-8-5.

(b) **Voluntary Expression of Intent to Donate.** The hospital shall establish and implement policies and procedures for documenting requests by patients regarding their intentions for disposition of their bodies or organs and for seeing that these expressed intentions are honored upon death when possible.

(c) **Hospital Requests for Anatomical Gifts.** The hospital shall establish and implement policies and procedures for requesting anatomical gifts on or before the occurrence of death in the absence of a patient's expressed intentions.

1. Policies and procedures shall provide for a written agreement(s) with an organ bank or storage facility with the provisions specified in Rules for Anatomical Gifts, Chapter 111-8-5-.07, and provisions for the training of staff authorized to request the gifts, when applicable.

2. Where the hospital does not have the Organ Procurement Organization handle requests for anatomical gifts, the hospital shall designate staff authorized to make requests for anatomical gifts, and such staff shall be appropriately trained in the following areas:

(i) Psychological and emotional considerations when dealing with bereaved families;

(ii) Social, cultural, ethical, and religious factors affecting attitudes toward donations;

(iii) General medical concepts and issues in organ, tissue, and eye donations;

(iv) Procedures for declaring death and collecting and preserving organs, tissues, and/or other body parts and for how these procedures are to be explained to decedents' families;

(v) Procedures for notifying and involving banks or storage facilities; and

(vi) procedures for recording the outcomes of requests.

3. If the hospital engages in harvesting tissue and/or transplanting organs and tissues from living donors, the hospital shall develop a living donor organ/transplants policy that addresses the issues related to such donations.

(d) **Physicians Participating in the Removing or Transplanting of Organs or Tissues.** Where the medical staff participates in organ recovery, the hospital shall designate which medical staff members may not participate in the procedures for

removing and transplanting of organs and body parts in accordance with the Rules for Anatomical Gifts, Chapter 111-8-5-.08.

Authority: O.C.G.A. §§ 31-7-2.1 and 44-5-140.

111-8-40-.28 Surgical Services.

If the hospital provides surgical services, the services shall be provided in a manner which protects the health and safety of the patients and follows current accepted standards of medical and surgical practice. Personnel, equipment, policies and procedures, and the number of operating rooms shall be appropriate for the scope of services offered.

(a) **Organization of Surgical Services.** The hospital shall have an organizational plan which defines lines of authority, responsibility, and accountability within all operating room areas where surgical procedures are performed.

1. There shall be a current roster of surgical privileges granted each medical staff member available to nursing and scheduling staff in the surgical services area(s).

2. The hospital shall have bylaws, rules, or policies and procedures developed by the medical staff which require that within twenty-four (24) hours prior to surgery either a history and physical examination or an update of a previous history and physical is completed for every surgical patient. Where an update is used, the previous history and physical examination must not have occurred more than thirty (30) days prior to surgery.

3. Roles, responsibilities, and qualifications for any non-physician first and second assistants participating in surgery shall be defined by the hospital medical staff, including any limitations to their roles in patient care.

4. **Chief(s) of Surgery.** Physician member(s) of the medical

staff, who have been appropriately trained in the provision of surgical services, shall be designated by the medical staff to direct the hospital's surgical services, and shall be responsible for all clinical aspects of organization and delivery of the particular surgical services including the evaluation of the effectiveness of the services in coordination with the hospital's quality management program.

(i) The chief(s) of surgery shall be responsible for implementation of hospital policy related to medical staff utilizing the surgical suite.

(ii) In conjunction with the hospital's medical staff, the chief(s) of surgery shall implement procedures requiring an operative report for each surgery performed.

(I) The operative report shall describe techniques, findings, complications, tissues removed or altered, and the general condition of the patient during and following surgery.

(II) The full operative report shall be written or dictated immediately after surgery and signed or authenticated by the surgeon. Where the full operative report is not available to be placed immediately in the record, an operative/progress note by the surgeon must be entered into the medical record immediately.

5. **Nurse Manager.** A licensed registered nurse, who has been appropriately trained in the provision of surgical nursing services, shall manage the surgical suite(s) and shall be responsible for:

(i) Ensuring that a sufficient number of nursing personnel are on duty in the surgical suite to meet the needs and safety of the patients;

(ii) Ensuring that surgical technicians perform scrub functions only under the supervision of a licensed registered nurse who is immediately available to respond to emergencies;

(iii) Delineating the duties of scrub personnel and circulating registered nurses in the surgical suite;

(iv) Providing for orientation and on-going education and training of surgical personnel providing services within the surgical suite, to include at least equipment usage and inspections, infection control and safety in the surgical area, cardiopulmonary resuscitation, patient rights, and informed consent;

(v) Ensuring that patients are monitored and provided with nursing care from the time they enter the surgical suite to the time they exit the area;

(vi) Developing criteria for the use of equipment and supplies brought into the surgical suite from other areas; and

(vii) Ensuring that the operating room register is current and complete.

(b) **Infection Control in the Surgical Suite.** The hospital shall develop and implement infection control procedures specific to the surgical services areas, which include at least requirements for:

1. Surgical attire;

2. Surgical scrub procedures;

3. Housekeeping functions;

4. Cleaning, disinfecting, and sanitizing the area;

5. Appropriate maintenance of the heating, ventilation, and air conditioning systems for the surgical suite;

6. Packaging, sterilizing, and storage of equipment and supplies;

7. Waste disposal;

8. Traffic control patterns, including who may enter the operating room areas and under what circumstances; and

9. A surgical site surveillance system appropriate to the population served.

(c) **Minimum Equipment for the Surgical Suite.** The following emergency equipment shall be available and functional for the operating room(s) and for the post-anesthesia area, as appropriate:

1. A call system;

2. Cardiac monitors;

3. Resuscitation equipment;

4. A defibrillator;

5. Aspiration/suction equipment;

6. A traecheostomy kit;

7. A pulse oximeter; and

8. A end-tidal carbon dioxide monitor.

(d) **Post-Anesthesia Care Unit.**

1. The post-anesthesia care unit shall be located in an area of the hospital in close proximity to but physically separated from the operating room.

2. Policies and procedures for the post-anesthesia care unit shall include at a minimum the criteria for admission to and discharge from the unit.

3. If patients are not transferred to the post-anesthesia care

unit following surgery, provisions shall be made for monitoring the patient until it is determined that the patient is stable.

Authority: O.C.G.A. §§ 31-7-2.1 and 31-9-6.1.

111-8-40-.29 Anesthesia Services.

Any hospital offering surgical or obstetrical services shall have an organized anesthesia service which shall be responsible for all anesthesia delivered at the hospital. The anesthesia services will be provided in a manner which protects the health and safety of patients in accordance with generally accepted standards of practice.

(a) **Organization of Anesthesia Services.**

1. Anesthesia services shall be directed by a qualified physician member of the medical staff who is responsible for organizing the delivery of anesthesia services provided by the hospital in accordance with generally accepted standards of practice.

2. The anesthesia director shall be responsible for monitoring the quality and appropriateness of anesthesia services and for ensuring that identified problems are addressed through the quality management program.

3. The anesthesia director shall be responsible for establishing an orientation and continuing education program for anesthesia services staff that include, at a minimum, instruction in safety precautions, emergency patient management, equipment use and inspections, and infection control procedures in the surgical suite.

(b) **Anesthesia Service Delivery.**

1. Anesthesia shall be administered only by qualified members of the medical staff or qualified individuals who have

been granted clinical privileges to administer anesthesia in accordance with these rules and as permitted by state laws and regulations. Persons qualified to administer anesthesia may include:

(i) Anesthesiologists;

(ii) Physicians;

(iii) Dentists or oral surgeons possessing an active permit for administration of general anesthesia as issued by the State of Georgia;

(iv) Certified registered nurse anesthetists administering such anesthesia under the direction and responsibility of duly licensed physicians who are members of the medical staff; and

(v) Physician's assistants licensed by the State of Georgia with approved job descriptions as anesthesia assistants functioning under the direct supervision of anesthesiologists who are members of the medical staff and as otherwise authorized by applicable laws and regulations.

2. A pre-anesthesia patient evaluation shall be completed for each patient by a person qualified and granted privileges to administer anesthesia within a reasonable period of time preceding the surgery. The patient evaluation shall be updated immediately prior to induction. The pre-anesthesia evaluation must include review of heart and lung function, diagnostic data (laboratory, x-ray, etc., as applicable), medical and anesthesia history, notation of anesthesia risk, any potential anesthesia problems identified, and notation of patient's condition immediately prior to induction.

3. Checks of all anesthesia equipment shall be performed and documented immediately prior to each anesthesia administration.

4. A person qualified and granted privileges to administer

anesthesia shall be continuously present throughout the administration of all general anesthesia or major regional anesthesia and monitored anesthesia care.

5. During the administration of anesthesia, patients shall be monitored as appropriate for the nature of the anesthesia. Such monitoring shall include as appropriate:

(i) Heart and breath sounds, using a precordial or esophageal stethoscope;

(ii) Oxygenation levels;

(iii) Ventilation;

(iv) Circulatory function;

(v) The qualitative content of expired gases, if the patient has an endotracheal tube; and

(vi) The patient's temperature.

6. The intraoperative anesthesia record shall document all pertinent actions and events that occur during the induction, maintenance, and emergence from anesthesia.

7. The person qualified and granted privileges to administer anesthesia shall remain immediately available until the patient has been determined to be stable and is ready for discharge or transfer from the post-anesthesia care unit.

8. A person qualified and granted privileges to administer anesthesia shall complete the post-anesthesia evaluation for each patient receiving anesthesia, and it shall be included in the patient's medical record.

(i) The evaluation shall note at a minimum the presence or absence of anesthesia-related abnormalities or complications, the patient's level of consciousness and cardiopulmonary status, and

any follow-up care needed.

(ii) For outpatients, the post-anesthesia evaluation shall be performed prior to hospital discharge to check for anesthesia recovery in accordance with procedures and timelines established by the hospital's medical staff.

(c) **Anesthesia Safety Precautions.** Safety precautions related to the administration of anesthesia shall be clearly identified in written policies and procedures which are enforced and shall include at a minimum:

1. Routine maintenance and inspection of anesthesia equipment, recorded in a service record for each machine;

2. Emergency preparedness plans;

3. Life safety measures, including alarm systems for ventilators capable of detecting disconnection of any components, monitoring for scavenger gases, and a system for internal reporting of equipment malfunctions and unavailability;

4. Infection control procedures sufficient to adequately sterilize or appropriately disinfect all equipment components; and

5. Procedures for ensuring patient safety.

(d) **Conscious sedation.** The hospital shall develop and implement, with the assistance of the anesthesia services director, policies and procedures for the administration of conscious sedation, which shall be applicable hospital-wide. These policies and procedures shall be approved by appropriate members of the medical staff and shall include at least the following:

1. Designation of the licensed personnel authorized to administer conscious sedation and/or monitor the patient during conscious sedation;

2. Drugs approved for use in administering conscious

sedation;

3. Patient monitoring requirements; and

4. Criteria for discharge.

Authority: O.C.G.A. §§ 31-7-2.1, 43-22-21 and 43-26-11.1.

111-8-40-.30 Nuclear Medicine Services.

If the hospital provides nuclear medicine services, those services shall be organized and effective. The nuclear medicine services shall be provided in a manner consistent with applicable state laws and regulations and generally accepted standards of practice.

(a) Radioactive materials used in the provision of nuclear medicine services shall be prepared by personnel authorized as defined by state law to prepare radiopharmaceuticals and shall be labeled, used, transported, stored, and disposed of in a manner consistent with the "Georgia Radiation Control Act," O.C.G.A. Chapter 31-13 et seq., and applicable rules.

(b) If a clinical laboratory is utilized in the provision of nuclear medicine services, the laboratory shall be licensed to perform these services as required by the Rules and Regulations for Clinical Laboratories, Chapter 111-8-10.

(c) Nuclear medicine services shall be directed by a doctor of medicine or osteopathy who is a member of the medical staff qualified to perform and supervise those services. The director shall be responsible for the administration of nuclear medical services, including the evaluation of the effectiveness of the services in coordination with the hospital's quality management program.

(d) Nuclear medicine procedures shall be administered and/or supervised by licensed doctors of medicine or osteopathy

as authorized by state law.

Authority: O.C.G.A. §§ 31-7-2.1, 31-13-1 et seq. and 31-22-1 et seq.

111-8-40-.31 Emergency Services.

The hospital shall provide, within its capabilities, services to persons in need of emergency care.

(a) **Full-time Emergency Services.** If the hospital offers emergency care as an organized service and/or holds itself out to the public as offering emergency services, the service shall be included in the scope of services submitted with the application for the hospital permit and shall be offered twenty-four (24) hours per day.

1. **Organization.** Supervision and organization of emergency services shall be under the direction of a qualified member of the medical staff.

(i) The director shall be responsible for the development of policies and procedures related to emergency services and the review and update of policies as necessary. The policies and procedures shall be approved by appropriate members of the medical staff.

(ii) The director shall implement systems to assess the effectiveness of the emergency service and to address improvement issues through the hospital's quality management program.

(iii) Staffing assignments shall provide for sufficient nursing, medical, and technical staff to meet the anticipated needs of emergency patient care. There shall be available to emergency room staff procedures for accessing additional staff on an as-needed basis to meet unanticipated needs.

(iv) Patient care responsibilities for emergency services staff shall be specified by written policies and procedures, which shall include training and experience requirements appropriate to the assigned responsibilities and clearly defined lines of authority.

2. **Delivery of Services.** When the hospital provides emergency services, the services shall comply with the following:

(i) Policies and procedures for processing patients presenting for emergency care shall be in writing and shall include the procedures for initial patient assessment, prioritization for medical screening and treatment, and patient reassessment and monitoring.

(ii) There shall be a central log of all patients presenting for emergency care, with the presenting complaint and the level of acuity or triage documented. Entries in the log must be retrievable by the date and time the patient presents for treatment;

(iii) An emergency medical record shall be maintained for each patient which includes all assessment and treatment information about the patient from the time of presentation until the time of discharge or transfer;

(iv) Written protocols and standards of practice to guide emergency interventions by non-physician staff shall be available in the emergency services area;

(v) A licensed physician shall be available to cover basic emergency room services either on-site or by telephone. Where the licensed physician is providing such coverage by telephone, the physician must be able to arrive in the emergency room within thirty (30) minutes of the need for physician services having been determined;

(vi) The emergency services area shall have operable equipment and sufficient and appropriate supplies and medications to support emergency care for patients of all ages, including at least:

(I) An emergency call system;

(II) Oxygen;

(III) Manual breathing bags and masks;

(IV) Cardiac monitoring and defibrillator equipment;

(V) Laryngoscopes and endotracheal tubes;

(VI) Suction equipment; and

(VII) Emergency drugs and supplies as specified by the medical staff;

(vii) The hospital shall integrate functions of the emergency services with other services of the hospital to ensure appropriate patient care and treatment including those patients awaiting admission or transfer to another facility, placement in a hospital bed, or transfer to another facility;

(viii) Policies and procedures shall be developed and implemented for the appropriate transfer of emergency patients to other facilities or other areas of the hospital when appropriate;

(ix) The hospital shall have policies and procedures for the management of mass casualty situations which may require the coordination of the hospital's emergency services with other facilities, the local Emergency Management Agency (EMA), and local ambulance service providers;

(x) Emergency Services Where Maternity Services Are Customarily Offered. In addition to applicable federal laws regarding the treatment of persons requesting treatment for emergency medical conditions that are enforced by the federal government, state law requires any hospital which operates an emergency service to provide appropriate and necessary emergency services to any pregnant woman who is a resident of this state and who presents herself in active labor, to the hospital,

if those services are usually and customarily provided in that facility. Such services shall be provided within the scope of generally accepted practice based upon the information furnished the hospital by the pregnant woman, including such information as the pregnant woman reveals concerning her prenatal care, diet, allergies, previous births, general health information, and other such information as the pregnant woman may furnish the hospital. If, in the medical judgment of the physician responsible for the emergency service, the hospital must transfer the patient because the hospital is unable to provide appropriate treatment, the hospital shall provide appropriate treatment as set forth in O.C.G.A. § 31-8-42; and

(xi) Diversion Status — Inability to Deliver Emergency Services. The hospital shall develop and implement a diversion policy in consultation with the medical staff which describes the process of handling those times when the hospital must temporarily divert ambulances from transporting patients requiring emergency services to the hospital. The policy must include the following: when diversion is authorized to be called, who is authorized to call and discontinue diversion, efforts the hospital will make to minimize the usage of diversion, and how diversion will be monitored and evaluated. In connection with going on diversion status, the hospital shall:

(I) Notify the ambulance zoning system when it is temporarily unable to deliver emergency services and is declaring itself on diversion;

(II) Notify the ambulance zoning system when diversion status is no longer determined to be necessary; and

(III) Monitor and evaluate its usage of diversion status and make changes within its control to minimize the use of diversion status.

(b) **Hospitals Without Organized Emergency Services.** Hospitals not providing an organized emergency service shall have current policies and procedures and sufficient qualified staff

to provide for the appraisal and initial treatment of any patients or persons presenting with an emergency medical or psychiatric condition, within the capabilities of the hospital, and for referral of the patient for further treatment when appropriate.

Authority: O.C.G.A. §§ 31-7-2.1, 31-7-3.1, 31-8-42 and 31-11-82.

111-8-40-.32 Outpatient Services.

Outpatient services offered by the hospital, including but not limited to ambulatory care services and off-campus clinics, shall be integrated with other hospital services and systems and shall be provided in accordance with applicable rules in this Chapter for the specific service.

(a) **Organization of Outpatient Services.**

1. The hospital shall develop and implement policies and procedures to ensure that outpatient care provided meets the needs of patients in accordance with generally accepted standards of practice.

2. Each outpatient service shall be staffed with sufficient qualified personnel to promptly, safely, and effectively meet the care needs of patients. Staff providing care to outpatients shall meet the same qualification requirements as staff providing similar services to inpatients of the hospital.

3. The hospital shall assign responsibility for the periodic assessment of the quality and effectiveness of the outpatient services provided, and this assessment shall be a part of the hospital's quality management program.

(b) **Outpatient Service Delivery.**

1. Hospital services for outpatients shall be provided only on the order of a licensed physician, dentist, osteopath, physician's assistant, or advanced practice nurse as permitted by law in

accordance with the system of accountability established by the medical staff.

2. Outpatient services shall be provided in a manner which ensures the privacy of each patient and the confidentiality of the patient's disclosures. Private rooms or cubicles shall be provided for the use of outpatients and staff for consultation purposes, as appropriate to the needs of the service.

3. Hospitals shall provide waiting areas for outpatients with sufficient seating for the expected volume of patients.

4. Each outpatient shall have an outpatient record, which shall be maintained and stored in a manner to be available for subsequent outpatient or inpatient hospital visits.

Authority: O.C.G.A. § 31-7-2.1.

111-8-40-.33 Rehabilitation Services.

The hospital shall define the scope of rehabilitation services provided to patients. The hospital may offer limited or comprehensive rehabilitation services including such services as physical therapy, occupational therapy, audiology, speech-language pathology, or other services.

(a) **Organization of Limited Rehabilitation Services.** Where a hospital chooses to offer limited rehabilitation services, which are typically single or stand-alone therapy discipline(s), the rehabilitation service(s) shall be coordinated by an appropriately qualified individual assigned responsibility for the clinical aspects of organization and delivery of the rehabilitation service(s) provided by the hospital. The coordinator shall be responsible for monitoring the quality and appropriateness of rehabilitation services and for ensuring that identified problems are addressed through the quality management program.

(b) **Organization of Comprehensive Rehabilitation**

Services. Where a hospital chooses to offer a comprehensive rehabilitation service program which provides integrated and coordinated multidisciplinary therapy services as an organized inpatient service, the director must be a qualified member of the medical staff with appropriate training and experience.

(c) Professional and paraprofessional staff providing patient care shall meet licensing or registration requirements consistent with state law.

(d) Rehabilitation services shall be provided in accordance with orders from the licensed practitioner responsible for the patient's care. Orders for services shall be entered in the patient's medical record with the date of the order and shall be signed by the person giving the order. If rehabilitation services are provided by the hospital on an outpatient basis, the hospital shall specify how orders from outside sources will be managed.

(e) Following assessment, treatment services shall be provided according to a written treatment plan, which specifies the goals of treatment and the frequency and expected duration of services.

(f) There shall be a functional system for recording in the patient's medical record the patient's response to treatment and for communicating information regarding the patient's response or progress to the ordering licensed practitioner.

Authority: O.C.G.A. § 31-7-2.1.

111-8-40-.34 Maternal and Newborn Services.

(1) No later than 90 days after the effective date of these rules, if the hospital offers an organized service for the provision of care for expectant mothers and newborns, it shall clearly define the level of services provided according to the levels described in these rules (basic, intermediate, or intensive) and comply with the rules set forth in this section.

(a) The hospital shall establish and utilize admission criteria for the maternal and newborn services that reflect the level of services offered by the hospital.

(b) The hospital shall have established mechanisms, through written agreement and other arrangement, for transfers to or consultations with facilities providing services at the higher levels of care for those maternal and newborn patients who require such care. The agreements or arrangements shall ensure that there is collaboration between the sending and receiving hospital concerning the transfer of such patients prior to the actual need for transfer and shall include mechanisms for the communication of information regarding the outcome of each transfer and for periodic review of the agreements or arrangements.

(c) All hospitals offering obstetrical care shall have facilities, staff, and equipment necessary for delivery, management, and stabilization of expectant women who present at the hospital in active labor and for whom delivery is imminent, regardless of the level of care anticipated for the newborn. The hospital shall have in place a system for communication and consultation with a board certified obstetrician or maternal-fetal medicine specialist and a board certified neonatologist for situations where transport of high-risk patients prior to delivery is not feasible.

(d) The hospital shall establish a system for receipt of prenatal records for admissions to the maternal and newborn service other than emergency admissions to include the results of any routine laboratory tests as required by the hospital.

(e) The hospital shall have written plans and procedures for transfer of expectant mothers or newborns presenting at the hospital who exceed the criteria for admission, which shall include mechanisms for accessing transportation appropriate to the needs of the patient(s).

(f) The hospital shall include in the internal quality management program a systematic review of the admissions and transfers for maternal and newborn services, with comparison to

the established admission criteria, which shall prompt corrective action when indicated.

(g) With the exception of hospitals permitted as specialized children's hospitals, hospitals shall offer a level of services for maternal care comparable to the level of services offered for neonatal care.

(2) The hospital shall have sufficient staff, space, facilities, equipment, and supplies to support the range of maternal and infant services offered, according to generally accepted standards of practice.

(3) **Basic Maternal and Newborn Services.** All hospitals offering maternal and newborn services shall offer at least a basic level of those services. The basic level of maternal and newborn services shall provide comprehensive care for women with low-risk pregnancies, anticipated uncomplicated deliveries, and apparently normal developing fetuses with estimated gestation of thirty-six (36) weeks or greater and for newborns with anticipated birth weights of 2500 grams or greater. The maternal and newborn services of these hospitals shall meet the following minimum requirements:

(a) **Organization of Basic Maternal and Newborn Services.**

1. The director of obstetrical services shall be a board eligible or board certified obstetrician, or a board eligible or board certified family practitioner with obstetrical privileges, or shall be a credentialed member of the medical staff with obstetrical privileges with access to such board eligible or board certified specialists by consultation.

2. The director of newborn services shall be a member of the medical staff who is a board eligible or board certified pediatrician, or a board eligible or board certified family practitioner, or shall be a credentialed member of the medical staff with access to such specialists by consultation. The director of

newborn services shall be responsible for ensuring that medical care is provided for all newborns.

3. The perinatal nurse manager shall be a licensed registered nurse with education and demonstrated knowledge and experience in perinatal nursing;

(b) **Delivery of Basic Maternal and Newborn Services.**

1. **Staffing Plan.** The hospital shall follow a staffing plan that ensures the availability of appropriate numbers of qualified staff for the perinatal services offered, according to generally accepted standards of practice and state licensing regulations.

(i) **Staffing for the Labor and Delivery Area.** For the delivery of newborns, the hospital shall provide for at least the following:

(I) A birth attendant, who may be an obstetrician, a physician with obstetrical privileges, or a certified nurse midwife who has been granted clinical privileges in accordance with these rules, present at the hospital or immediately available by telephone and able to be on-site within thirty (30) minutes;

(II) A registered nurse present to assist with each delivery;

(III) An individual credentialed in neonatal resuscitation to be present in the delivery room for each delivery for the purpose of receiving the newborn;

(IV) For Cesarean deliveries, an additional physician or certified nurse midwife, a registered nurse, or a surgical assistant or technician, able and qualified to assist with a Cesarean section, on-site or able to arrive in sufficient time to accommodate the time limit for emergency Cesarean section of thirty (30) minutes from the physician's decision to operate to the initial incision; and

(V) Professional staff qualified to administer anesthesia, on-site or able to arrive in sufficient time to accommodate the time

limit for emergency Cesarean section of thirty (30) minutes from the physician's decision to operate to initial incision.

(ii) **Staffing for the Newborn Nursery.** The hospital shall provide for at least:

(I) A qualified registered nurse with experience or training in the care of newborns to supervise and be responsible for the quality of nursing care given to newborns, for nursing in-service programs in nursery issues, for assisting the director of the newborn nursery in carrying out his or her duties, and for the maintenance of the nursery records;

(II) A licensed nurse on duty in the nursery at all times in hospitals with a daily newborn nursery census greater than ten (10) newborns; and

(III) A staff member trained in newborn service provision present in the newborn nursery when it is occupied by any newborn.

2. The directors of obstetrical and newborn services shall develop and implement written policies, procedures, and guidelines for the services that reflect current standards of practice and address at least:

(i) Admission criteria for the services based on the level of service provided;

(ii) Guidelines and mechanisms for specialty consultations and transfer for high-risk patients whose needs exceed the range of services offered at the hospital;

(iii) The orientation program for maternal and newborn services staff;

(iv) Patient care requirements for mothers and newborns, including but not limited to nursing assessments, gestational age assessment, newborn assessments including Apgar scoring

immediately after delivery, assessment and management of nutritional needs including feedings for the newborn whether normal or gavage, umbilical and circumcision care, assessment of thermoregulation by the newborn, prevention of blindness, hypoglycemia, and hemorrhagic disease for the newborn, use of appropriate prophylaxes, patient monitoring needs, and assessment of educational needs of the mother;

(v) Procedures for a family-centered environment (rooming-in) as an option for each patient unless contraindicated by the medical condition of the mother or infant or unless the hospital does not have sufficient facilities to accommodate all such requests;

(vi) Room assignments and procedures for traffic control and security, including such security measures as are necessary to limit access to newborns by unauthorized persons and to prevent kidnapping of newborns;

(vii) Guidelines for the use of anesthetic agents for pain management and the requirements for the qualifications and responsibilities of persons who administer the agents and the required patient monitoring;

(viii) Guidelines for induction and augmentation of labor and for designation of qualified personnel who must be in attendance during these procedures;

(ix) Indicators and procedures for vaginal birth after Cesarean section (VBAC);

(x) Indicators and procedures for operative vaginal deliveries;

(xi) Staffing and procedural guidelines for management of obstetrical and newborn emergencies, including the availability of staff components to manage such emergencies twenty-four (24) hours per day;

(xii) Guidelines for the monitoring of newborns during the first twelve (12) hours after birth and until discharge;

(xiii) Procedures for infection control, including isolation procedures, visiting privileges, individualized infant hygiene care, and specific policies regarding the prevention and management of infectious diseases, including but not limited to Hepatitis B, Hepatitis C, Group B Streptococcal infections, tuberculosis, human immunodeficiency virus (HIV), and sexually transmitted diseases;

(xiv) Requirements for newborn screening tests for metabolic disorders and hemoglobinopathies and other screenings, as required by law.

(xv) Procedures for continuous and unquestionable identification of newborns;

(xvi) Procedures for completing birth and death certificates in accordance with Georgia's official vital records registration system; and

(xvii) Guidelines for discharge of mothers and newborns, including early discharge, and for assessment of education and other discharge needs.

(c) **Physical Environment for Maternal and Newborn Services.**

1. Obstetrical and newborn service areas shall be located, arranged, and utilized so as to provide for every reasonable protection from infection and from cross-infection. The physical arrangements shall separate the obstetric patients from other patients with the exception of non-infectious gynecological patients.

2. Rooms used for patients in labor shall be located with convenient access to the delivery room(s). If labor rooms also serve as birthing rooms, the rooms shall be equipped to handle

obstetric and neonatal emergencies.

3. Delivery suites shall be used for no purpose other than for the care of obstetrical patients. Each room shall have the necessary equipment and facilities for infection control and for the management of obstetric and neonatal emergencies. Delivery suites shall be designed to include an anesthesia supply and equipment storage room and a communication system to ensure that emergency backup personnel can be summoned when needed.

4. A newborn stabilization area shall be located within each delivery room or birthing room and shall be equipped with oxygen and suction outlets.

5. The newborn nursery shall have an air temperature maintained at 75-80 degrees Fahrenheit, with a relative humidity of thirty percent to sixty percent (30% - 60%).

6. Air from other areas of the hospital shall not be recirculated into the newborn nursery. Ventilation of the nursery suite(s) shall provide the equivalent admixture of a minimum of six (6) total air changes per hour.

7. Life-sustaining nursery equipment and lighting for the nursery areas shall be connected to outlets with an automatic transfer capability to emergency power.

8. Each labor room, delivery room, birthing room, and nursery station shall be equipped with sufficient power outlets to handle the equipment required for the provision of patient care without the use of extension cords, “cheater” plugs, or multiple outlet adapters, which are prohibited.

(d) **Clinical Laboratory, X-Ray, and Ultrasound Services.** Diagnostic support services such as laboratory, x-ray, and ultrasound, shall be available on an on-call basis, with the capability to perform studies as needed for maternal and newborn care; and

(e) **Records Requirements.**

1. The medical record for each maternity patient shall be maintained in accordance with Section 111-8-40-.18 of these rules, with the following additions:

(i) The medical record for each maternity patient shall contain a copy of the patient's prenatal records, submitted at or before the time of admission;

(ii) The admission data shall include the date and time of notification of the birth attendant, the condition on admission of the mother and fetus, labor and membrane status, presence of bleeding, if any, fetal activity level, and time and content of the most recent meal ingested; and

(iii) Labor and postpartum care notes shall be included.

2. The medical record for each newborn shall be cross-referenced with the mother's medical record and shall contain the following additional record information:

(i) Physical assessment of the newborn, including Apgar scores, presence or absence of three cord vessels, and vital signs;

(ii) Accommodation to extra uterine life including the ability to feed and description of maternal-newborn interaction;

(iii) Treatments and care provided to the newborn to include the specimens collected, newborn screening tests performed, and appropriate prophylaxes;

(iv) The infant's footprint and mother's fingerprint, or comparable positive newborn identification information; and

(v) Report of the physical examination of the newborn prior to discharge, performed by an appropriately credentialed physician, physician's assistant, nurse practitioner, or nurse

midwife.

3. The hospital shall maintain a register of births, in which is recorded the name of each patient admitted for delivery, the date of admission, date and time of birth, type of delivery, names of physicians or other birth attendants, assisting staff and anesthetists, the sex, weight, and gestational age of the infant, the location of the delivery, and the fetal outcome of the delivery.

4. The hospital shall maintain annual statistics regarding the number of births and number of infant deaths. Death statistics for infants shall include birth weights, gestational ages, race, sex, age at death, and cause of death.

(4) **Intermediate Maternal and Newborn Services.** The hospital offering intermediate maternal and newborn services shall offer comprehensive care for women with the potential or likelihood for only certain pre-defined high-risk complications and with anticipated delivery of a newborn at greater than thirty-two (32) weeks' gestation and birth weight greater than 1500 grams who are anticipated to have only such medical conditions which can be expected to resolve rapidly. The maternal and newborn service shall meet all of the requirements for provision of the basic services as described above in these rules, with the following additions or exceptions:

(a) **Organization of Intermediate Maternal and Newborn Services.**

1. The director of obstetric services shall be a member of the medical staff who is a board eligible or board certified obstetrician or board eligible or board certified maternal-fetal medicine specialist; provided, however, within five (5) years from the effective date of these rules, the director of obstetric services shall be a board certified obstetrician or board certified maternal-fetal medicine specialist.

2. The director of newborn services shall be a member of the medical staff who is board eligible or board certified

pediatrician or board eligible or board certified neonatologist; provided, however, within five (5) years from the effective date of these rules, the director of newborn services shall be a board certified pediatrician or board certified neonatologist.

3. A board eligible or board certified neonatologist shall be available to participate in care for the neonates.

4. The perinatal nurse manager shall be a licensed registered nurse with the training and demonstrated knowledge and experience in care of high-risk maternal care and moderately ill newborns.

5. When a neonate is on mechanical ventilation or when a high risk maternity patient is being managed, a respiratory therapist, certified lab technician/blood gas technician, and an x-ray technologist shall be on-site and available to the maternal and newborn services area on a twenty-four (24) hour basis.

6. If the facility offers care for newborns requiring parenteral support, a licensed dietitian and a licensed pharmacist with parenteral experience shall be on staff.

(b) **Delivery of Intermediate Maternal and Newborn Services.** Service delivery shall meet the requirements of the basic maternal and newborn services, with the following additions or exceptions:

1. The hospital shall provide care for expectant mothers and newborns requiring the basic level of maternal and newborn services, as well as for those requiring an intermediate level of care;

2. Portable x-ray and ultrasound equipment and services shall be available on a twenty-four (24) hour basis;

3. The intermediate level nursery shall provide care to neonates expected to require no more than short-term mechanical ventilation or parenteral support. Such support, if needed for more

than forty-eight (48) hours, shall be authorized daily by the consulting neonatologist, or the neonate shall be transferred to a facility with a higher (intensive) level of care; and

4. Written policies, procedures, protocols, and guidelines shall reflect the pre-defined level of care provided. Criteria for admission to and discharge from the intermediate level nursery shall be defined in the written policies and procedures.

(c) **Physical Environment for Intermediate Maternal and Newborn Services.** The physical environment shall meet the requirements of the basic maternal and newborn services, with the following additional requirements:

1. There shall be provided in the intermediate level nursery sufficient space between each patient station to allow for easy access for staff and visitors on three (3) sides of the patient bed and to allow for easy access with portable diagnostic and support equipment as may be required;

2. Each patient station in the intermediate level nursery shall have at least two (2) oxygen outlets, two (2) compressed air outlets, and two (2) suction outlets;

3. There shall be adequate lighting provided for patient care while avoiding extra illumination of adjacent neonates; and

4. The patient bed areas shall be designed to minimize the impact of noise on the infants.

(5) **Intensive Maternal and Newborn Services.** The hospital offering an intensive level of maternal and newborn services shall provide services for normal and high-risk maternal, fetal, and newborn conditions. The hospital providing the intensive level of services shall meet all requirements for basic and intermediate maternal and newborn services, with the following additions and/or exceptions:

(a) The director of intensive obstetric services shall be a

member of the medical staff who is a board certified obstetrician or board certified maternal-fetal medicine specialist;

(b) The director of intensive newborn services shall be a member of the medical staff who is a board certified pediatrician or board certified neonatologist;

(c) The hospital shall have on call, on a twenty-four (24) hour basis, a board certified obstetrician or maternal-fetal medicine specialist to provide on-site supervision and management of maternal patients;

(d) The hospital shall have available for consultation a maternal-fetal medicine specialist;

(e) The hospital shall have on call, on a twenty-four (24) hour basis, a board certified neonatologist to provide on-site supervision and management of neonates;

(f) The hospital shall provide pediatric subspecialties on staff or have a mechanism to provide consultation and care for pediatric subspecialties in a timely manner;

(g) The nursery manager of the intensive care nursery shall have demonstrated knowledge, training, and experience in neonatal intensive care nursing and shall have a dedicated assignment to the intensive care nursery;

(h) The hospital shall have on staff pharmacology personnel competent in perinatal pharmacology. Total parenteral nutrition shall be available; and

(i) The hospital shall have on staff a licensed physical therapist or occupational therapist and a licensed dietitian with training and experience in neonatal care.

Authority: O.C.G.A. § 31-7-2.1.

111-8-40-.35 Pediatric Services.

Any hospital providing care to infants and children shall have facilities, equipment, and policies and procedures specific to the provision of services for pediatric patients.

(a) Hospital policies shall define the ages of patients considered to be appropriate for pediatric services and the scope of services to be provided to them.

(b) Staff providing services to pediatric patients shall have experience and training in serving the pediatric population and shall have documented in-service training at least annually on age-specific care issues for the pediatric population served by the hospital.

(c) Protocols for screening and assessment of pediatric patients shall be approved by the medical staff and shall be individualized for the age and presenting signs and symptoms of the patient. In addition to the screening and assessment information required for all patients, the general screening and assessment protocol for pediatric patients shall include at a minimum:

1. Chronological age, weight, and length or height;

2. For infants and young children, a measurement of head circumference;

3. Immunization history;

4. A statement as to the developmental age and growth of the child as related to established norms; and

5. Family relationships, including expected family involvement during treatment.

(d) The hospital shall establish and implement policies and procedures to prohibit access to pediatric patients by unauthorized

persons and to prevent kidnapping or elopement of pediatric patients.

(e) The hospital shall provide space and equipment to allow for visitation of family members in the patient rooms and to allow for overnight stay of a parent or guardian where the parent or guardian's presence does not interfere with the course of treatment. The pediatric patient's medical record shall clearly indicate persons who are not permitted to visit the pediatric patient.

(f) Medical supplies and equipment including emergency equipment appropriate to the size and age of the pediatric patient shall be available in all areas of the hospital providing services to pediatric patients.

(g) The phone number for the Poison Control Center shall be available in a conspicuous place in the pediatric service area(s).

(h) Where pediatrics is provided as an organized service, there must be a qualified physician member of the medical staff with experience or training in pediatrics assigned responsibility for directing the clinical aspects of organization and delivery of all pediatric services provided by the hospital. The pediatric medical director shall be responsible for monitoring the quality and appropriateness of pediatric services in coordination with the hospital's quality management program and for ensuring that identified opportunities for improvement are addressed.

(i) Hospitals providing services to pediatric patients as an organized service shall have space, facilities, and appropriately sized equipment for providing those services apart from adult patient rooms and newborn units and shall provide for regular and routine cleaning of play equipment in the pediatric area according to protocols established for that purpose by the hospital's infection control program.

Authority: O.C.G.A. § 31-7-2.1.

111-8-40-.36 Dialysis Services

(1) If the hospital provides acute inpatient dialysis services or outpatient services either directly or through contract arrangements, the scope and organization of those services shall be defined.

(2) **Organization and Administration of Renal Dialysis Services.** The hospital shall have an organizational plan for dialysis services which clearly defines lines of authority, responsibility, and accountability and which includes provision for adequate staffing to provide dialysis care according to generally accepted standards of practice.

(a) **Medical Director.** The medical director for dialysis services shall be a physician member of the medical staff qualified to provide oversight to the specialized care required for dialysis patients and the medical director shall have at least one-year's experience in care for patients with end stage renal disease.

(b) **Nursing Services.** A registered nurse with demonstrated clinical competencies in providing dialysis services for patients shall be available during all dialysis treatments. Nursing staff and dialysis care technicians providing dialysis services shall have evidence of education, training, and demonstrated competencies in the provision of appropriate dialysis services and emergency care of patients receiving dialysis.

(c) **Policies and Procedures for Dialysis Services.** Where the hospital provides dialysis services directly to its patients, the hospital shall develop and implement policies and procedures that address the special needs of dialysis patients and shall include at least the following:

1. Maintenance of dialysis equipment;

2. Water treatment system safety;

3. Infection control;

4. Reuse of dialyzers and dialysis supplies, if applicable, and

5. Care of dialysis patients experiencing common complications of dialysis treatments.

(d) **Contracted Services.** Where the hospital provides dialysis services through a contract arrangement, the hospital must contract with a Georgia-licensed End Stage Renal Disease Facility. The contract must outline what specific services shall be provided and include who will be responsible for the maintenance of the dialysis equipment, the water treatment safety system, infection control, reuse of dialyzers and supplies, if applicable, the clinical qualification of staff to be provided, and the clinical supervision that will be provided to dialysis patients during the administration of dialysis treatments.

(3) **Appropriate Treatment.** The hospital shall provide dialysis services in accordance with accepted standards of care for the persons requiring dialysis services.

(4) **Quality Improvement.** The hospital shall ensure that problems identified during the on-going monitoring of the dialysis services are addressed in the hospital quality improvement program. Contracted services must participate in the hospital quality improvement program.

(5) **Outpatient Chronic Dialysis Services.** A hospital choosing to provide outpatient dialysis services directly as an integral part of the hospital to persons with end stage renal disease on a regularly recurring basis must meet the rules set forth in the Rules and Regulations for End Stage Renal Disease Facilities, Chapter 111-8-22, which are herein incorporated by reference, except for .03, .04, and .19.

Authority: O.C.G.A. § 31-7-2.1.

111-8-40-.37 Psychiatric and Substance Abuse Services.

(1) If the hospital provides psychiatric and/or substance abuse treatment services as an organized service, the scope of those services, including whether the services are provided for inpatients, outpatients, or both, shall be defined in the hospital's application for permit and meet the requirements set forth in this section and generally accepted standards of care.

(2) **Organization and Administration of Psychiatric and Substance Abuse Services.** The hospital shall have a plan for the service which clearly defines lines of authority, responsibility, and accountability and which includes provision for adequate staffing to provide patient care according to generally accepted standards of practice.

(a) **Director of Psychiatric and Substance Abuse Services.** The director of psychiatric and substance abuse services shall be a licensed physician member of the medical staff appropriately trained and qualified to supervise the provision of these services.

1. If the hospital offers substance abuse services only, the director shall be a licensed physician member of the medical staff certified or eligible for certification in addiction medicine by the American Society of Addiction Medicine or the American Osteopathic Academy of Addiction Medicine or a licensed physician member of the medical staff appropriately trained and qualified to supervise the service. If the director of the substance abuse services meets this certification requirement but is not board certified in psychiatry, the hospital must have a board eligible or board certified psychiatrist on staff to be utilized for psychiatric consultation as needed.

2. The director of the psychiatric and/or substance abuse services shall be responsible for all clinical aspects of the organization and delivery of services and for the evaluation of the effectiveness of the services in coordination with the hospital's

quality management program.

(b) **Staffing for Psychiatric and Substance Abuse Services.** The hospital shall provide sufficient clinical and support staff to assess and address the needs of psychiatric and substance abuse patients and to ensure the maintenance of a safe therapeutic environment for patients and staff.

1. **Nursing Manager/Director.** The nursing care for the psychiatric and/or substance abuse services shall be supervised by a licensed registered nurse with at least three (3) years of clinical psychiatric and/or substance abuse experience. Authorization from the Georgia Board of Nursing to practice as a Clinical Nurse Specialist, Psychiatric/Mental Health may substitute for two (2) years of the required clinical experience.

2. **Counseling Services.** Counseling services for the psychiatric and substance abuse services shall be supervised by a master's level clinician licensed in social work, marriage and family therapy, professional counseling, or a clinical nurse specialist, psychiatric mental health.

3. **Clinical Psychologist.** A licensed clinical psychologist shall be available to provide testing and treatment consultation for patients as needed.

4. **Child Psychiatrist.** If psychiatric services are provided for children, a board eligible or board certified child psychiatrist shall be on staff.

5. **Special Staffing Requirements for Inpatient Psychiatric or Substance Abuse Services.** Hospitals providing inpatient psychiatric and/or substance abuse care shall provide:

(i) A physician, with training and qualifications appropriate to the services offered, present in the hospital or available on call on a twenty-four (24) hour basis;

(ii) At least one registered nurse on duty at all times; and

(iii) Rehabilitative and therapeutic activity staff, trained and qualified to meet the needs of the patients as specified in the patients' individualized service plans.

(c) **Policies and Procedures for Psychiatric and Substance Abuse Services.** In addition to hospital policies and procedures otherwise required by these rules, the hospital providing psychiatric and/or substance abuse services shall develop and implement policies and procedures that address the special needs of the population served, to include at least:

1. Admission and discharge criteria and procedures, which comply with Georgia laws concerning involuntary admissions or treatment;

2. Safety and security precautions for the prevention of suicide, assault, and patient injury;

3. The handling of medical emergencies, including but not limited to suicide attempts, cardiac arrest, aspiration, or seizures;

4. Special procedures, such as electro convulsive therapy (ECT) and medical detoxification, as applicable; and

5. Procedures for the use of seclusion and restraint in accordance with O.C.G.A. Chapters 3 and 7 of Title 37 and these rules.

(3) **Patient's Rights in Psychiatric and Substance Abuse Services.**

(a) In addition to the rights afforded all patients at the hospital, the hospital shall ensure that patients served by the psychiatric and substance abuse services shall have the right to:

1. Receive treatment in the hospital using the least restrictive methods possible; and

2. Participate to the extent possible in the development,

implementation, and review of their individualized service plan.

(b) Any permissible restriction of patient rights by the hospital program shall be imposed only in order to protect the health and safety of the patient or others and shall be temporary. The nature, extent, and reason for the restriction shall be entered into the patient's medical record as a written order by a physician or licensed psychologist and reviewed for necessity as required by state law.

(4) **Patient Assessment and Treatment.**

(a) In addition to other assessment and treatment procedures otherwise required by these rules, psychiatric and substance abuse service programs at the hospital shall provide:

1. For inpatients:

(i) With the admission assessments performed within twenty-four (24) hours of admission, a psychiatric or substance abuse evaluation as indicated by the reason for admission; and

(ii) An individualized service plan, initiated within the first twelve (12) hours after admission and updated as needs are identified through assessments;

2. For outpatients:

(i) Within seven (7) days following the initiation of outpatient services, a complete assessment of patient needs, including an evaluation sufficient to identify significant medical conditions which may impact the course of treatment; and

(ii) Within ten (10) days following initiation of outpatient services, an individualized service plan developed and implemented to address needs identified;

3. Each patient's individualized service plan shall be developed from the patient's needs as identified through

psychological, medical, and social assessment and shall be an organized statement of the proposed treatment process which serves to guide the providers and patient through the duration of the service provision. The service plan shall reflect the following:

(i) The patient's participation, to the extent possible, in the development of the individualized service plan;

(ii) Measurable goals and/or objectives to be met toward the established discharge criteria; and

(iii) Regular review of the patient's progress toward goals and/or objectives in the individualized service plan, with modifications to the plan made in response to progress or lack of progress as reflected in progress notes recorded at each visit which document the patient's status and response to treatment;

4. At the time of development of the patient's treatment plan and with the participation of the patient, a discharge plan shall be developed for each inpatient or an aftercare plan for each outpatient. The discharge/aftercare plan shall be re-evaluated periodically during treatment to identify any need for revision; and

5. All medications administered or prescribed for psychiatric or substance abuse patients shall be solely for the purpose of providing effective treatment or habilitation as described in the individualized service plan and/or for protecting the safety of the patient or others and shall not be used for punishment or for the convenience of staff.

(b) If the hospital is not able to meet the patient needs as identified, including any acute medical or surgical needs, the hospital shall assist the patient in locating and accessing services to meet those needs, which may include transfer to another facility.

(5) **Physical Space and Design Requirements for Inpatient Psychiatric and Substance Abuse Services.** Hospitals providing inpatient psychiatric and substance abuse

services shall have:

(a) At least one seclusion area must be available to be used for the involuntary confinement of patients when necessary. The seclusion area shall be large enough to provide access to the patient from all sides of the bed or mattress and to accommodate emergency life-sustaining equipment, have a door that opens outward, and have provision for direct patient observations at all times by staff;

(b) A design conforming to the suicide prevention recommendations from the *Guidelines for Design and Construction of Hospital and Healthcare Facilities*, produced by the American Institute of Architects' Academy of Architecture for Health with the assistance of the U.S. Department of Health and Human Services, which is hereby adopted by reference;

(c) A day room that allows for social interaction, dining, and group therapy activities;

(d) Space for storage of patient's personal belongings and for securing valuables;

(e) A system for summoning help from within the immediate service area or other areas of the hospital in the event of an emergency.

Authority: O.C.G.A. § 31-7-2.1.

111-8-40-.38 Special Requirements for Critical Access Hospitals. Critical access hospitals (CAHs) shall be required to comply with the entirety of this chapter, as applicable to the scope of services offered, with the following exceptions and/or additions:

(a) Prior to application for a hospital permit, the hospital shall be approved for critical access hospital status by the Georgia Department of Community Health.

(b) The CAH shall be a member of a rural health network having at least one (1) additional hospital that furnishes acute care hospital services, which will serve as an affiliate hospital for the CAH. The CAH shall have current written agreement(s) with affiliate hospital(s) which include provisions for:

1. Patient referral and transfer between the facilities, with the use of emergency and non-emergency transportation;

2. Credentialing of medical and professional staff; and

3. Participation in quality management activities.

(c) The CAH's organization, scope, and availability of patient care services shall be defined and approved by the governing body, medical staff, and affiliate hospital. The CAH shall have:

1. Operational policies for the CAH shall be developed with participation from one (1) or more licensed physicians, one (1) or more healthcare practitioners if on the staff of the critical access hospital, and at least one (1) member of the affiliated hospital's staff who is not on the staff of the CAH;

2. Operational policies for the CAH which describe the patient care services the CAH will provide directly and those that will be provided through contract or other arrangement;

3. No more than twenty-five (25) inpatient beds or as currently defined in federal regulations. Of these beds, at least two (2), but no more than fifteen (15), shall be used for acute inpatients. If the CAH has approved swing bed services, a maximum of twenty-three (23) beds may be utilized for swing bed patients;

4. An average length of stay for patients of no more than ninety-six (96) hours or as currently defined in federal regulations;

5. A mechanism in place to ensure that emergency care is available twenty-four (24) hours per day. The CAH shall not be

required to remain open twenty-four (24) hours per day when it does not have inpatients.

(i) The CAH shall, in accordance with the local emergency response systems, establish procedures under which a physician is immediately available by telephone or radio contact, on a 24-hour per day basis, to receive emergency calls, provide information or treatment of emergency patients, and refer patients to the CAH or other appropriate location for treatment.

(ii) A physician or limited health care practitioner with training in emergency care shall be on-call and immediately available by telephone or radio contact and available to be on-site at the CAH within thirty (30) minutes.

(iii) The CAH shall have equipment, supplies, and medications available for treating emergencies, as are required of other organized hospital emergency services.

(iv) Staff assigned to provide emergency patient care shall have training in handling medical and non-medical emergencies; and

6. A registered nurse or licensed practical nurse shall be on duty whenever the critical access hospital has one (1) or more inpatients.

Authority: O.C.G.A. § 31-7-2.1.

111-8-40-.39 Physical Plant Design and Construction.

(1) **General.** The hospital shall be designed and constructed in accordance with the needs of the patients being served.

(a) The design and construction specifications for the hospital shall conform to those nationally accepted standards for hospital design and construction as set forth in the *Guidelines for Design and Construction of Hospital and Healthcare Facilities*,

published by the American Institute of Architects' Press, which has been accepted for use by the Department and which are current, as determined by the Department to be applicable, at either:

1. The time of construction of the hospital when the initial permit was obtained; or

2. The time of request for approval for renovation(s) or addition(s) to areas of the hospital which impact patient care.

(b) Compliance with standards acceptable to the Department shall be determined by a state architect designated by the Department to review hospital design and construction specifications.

1. All parts of the facility shall be subject to the architect's review, including new and existing buildings, additions, alterations, or renovations to existing structures, any mobile, transportable, or relocatable units, and any off-site structures intended to house hospital services or functions.

2. The hospital shall notify the Department prior to initiating new construction, modifications, or additions and shall submit plans for such new construction for review and approval by the state architect designated by the Department.

(c) The hospital shall have evidence of a satisfactory inspection of all buildings and structures, including any mobile units, by the local representative of the state fire marshal, the local fire and building authorities (where required by local ordinance), and the state architect.

(d) Designated space for the laundry, power plant, mechanical equipment, ambulance entrance, autopsy or morgue, loading dock, incinerator, garbage can cleaning, and storage areas for garbage and trash shall be constructed or arranged to avoid unreasonable noise, steam, odors, hazards to patients, and unsightliness relative to patient bedrooms, dining rooms, and lounge areas.

(e) Electrical, mechanical, and plumbing work and equipment shall be designed and installed in accordance with local and state ordinances.

(2) **Special Requirements for Mobile, Transportable, and Relocatable Units.** If the hospital utilizes, by ownership or contract, mobile, relocatable, or transportable units for the provision of hospital services, the units shall meet the following requirements:

(a) If the unit is used to provide routine ancillary services for hospital inpatients or to provide services for the hospital emergency room, there shall be a covered or enclosed walkway from the hospital to the unit to ensure patient safety from the outside elements;

(b) The unit shall be located so as to prevent diesel or exhaust fumes from the tractor or unit generator from entering the fresh air intake of either the unit or the facility;

(c) The unit shall have means of preventing unit movement, either by blocking the wheels or use of pad anchors;

(d) The hospital shall provide waiting areas for the unit and, in close proximity to the unit, patient and staff toilet facilities for use by the staff providing services from the unit and for use by the patients accessing the services in the unit;

(e) Each unit shall be accessible to wheelchair and stretcher bound patients;

(f) The hospital shall provide access to hand washing facilities for staff in the unit, as appropriate to the services provided in the unit and sufficient to allow compliance with the hospital's infection control program;

(g) The hospital shall have a plan for the handling of emergencies that may occur in the unit. The unit shall be connected to the hospital communication system for access to

emergency response services;

(h) Waste lines to the unit shall be designed and constructed to discharge into an approved sewage system. The hospital shall ensure that back-flow prevention is installed at the point of water connection on the unit;

(i) If stairs are used to access the unit, they shall have stable handrails; and

(j) The hospital shall ensure that approaches to the unit have adequate lighting for safe negotiation at all hours of operation.

(3) **Emergency Lighting and Power.** The hospital shall have access to emergency lighting and electrical power meeting the following requirements:

(a) Functioning automatic emergency lighting equipment in all corridors in nursing units and in each operating room, delivery room, emergency room, exit, elevator, and stairway; and

(b) A functioning emergency electrical system. The emergency electrical system shall be so controlled that after interruption of the normal electric power supply, the generator is brought to full voltage and frequency and connected within ten (10) seconds through one or more primary automatic transfer switches to all emergency lighting; all alarms; blood banks; nurses' call; equipment necessary for maintaining telephone service; pump for central suction system; and receptacles in operating rooms and delivery rooms, patient corridors, patient rooms, recovery rooms, intensive care nursing areas, and nurseries. All other lighting and equipment required to be connected to the emergency system shall either be connected through the above-described primary automatic transfer switching or shall be subsequently connected through other automatic or manual transfer switching. Receptacles connected to the emergency system shall be distinctively marked for identification. Storage-battery-powered lights, provided to augment the

emergency lighting during the interim of transfer switching immediately following an interruption of the normal service supply, shall not be used as a substitute for the requirement of a generator. Where fuel is normally stored on the site, the storage capacity shall be sufficient for twenty-four (24) hour operation. Where fuel is normally piped underground to the site from a utility distribution system, storage facilities on the site will not be required.

Authority: O.C.G.A. § 31-7-2.1.

111-8-40-.40 Requests for Waiver or Variance.

A hospital may request a waiver or variance of a specific rule by application on forms provided by the Department. A waiver or variance may be granted in accordance with the following considerations:

(a) The Department may grant or deny the request for waiver or variance at its discretion. If the waiver or variance is granted, the Department may establish conditions which must be met by the hospital in order to operate under the waiver or variance. Waivers or variances may be granted with consideration of the following:

1. **Variance.** A variance may be granted by the Department upon a showing by the applicant that the particular rule or regulation that is the subject of the variance request should not be applied as written because strict application would cause undue hardship. The applicant must also show that adequate standards exist for affording protection for the health, safety, and care of patients, and these existing standards would be met in lieu of the exact requirements of the rule or regulation.

2. **Waiver.** The Department may dispense altogether with the enforcement of a rule or regulation by granting a waiver upon a showing by the applicant that the purpose of the rule or regulation is met through equivalent standards affording

equivalent protection for the health, safety, and care of the patients.

3. **Experimental Waiver or Variance.**

The Department may grant a waiver or variance to allow experimentation and demonstration of new and innovative approaches to delivery of services upon a showing by the applicant that the intended protections afforded by the rule or regulation in question are met and the innovative approach has the potential to improve service delivery;

(b) Waivers and variances granted by the Department shall be for a time certain, as determined by the Department; and

(c) Waivers and variances granted to a facility shall be recorded and shall be available to interested parties upon request.

Authority: O.C.G.A. § 31-2-7.

111-8-40-.41 Enforcement of Rules and Regulations.

A hospital that fails to comply with these rules and regulations shall be subject to sanctions and/or permit revocation as provided by law. The enforcement and administration of these rules and regulations shall be as prescribed in the Rules and Regulations for General Licensing and Enforcement Requirements, Chapter 111-8-25, pursuant to O.C.G.A. § 31-2-8.

Authority: O.C.G.A. § 31-2-8.

111-8-40-.42 Severability of These Rules.

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. The remaining rules or portions of rules 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 of these rules.

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