# RULES OF DEPARTMENT OF COMMUNITY HEALTH HEALTHCARE FACILITY REGULATION DIVISION

# REVISE CHAPTER 111-8-40 RULES AND REGULATIONS FOR HOSPITALS

#### SYNOPSIS OF PROPOSED RULE CHANGES

**STATEMENT OF PURPOSE:** The Department of Community Health proposes to revise the Rules and Regulations for Hospitals, Chapter 111-8-40, to identify and define rural free standing emergency departments. Changes have been made to identify the services that a rural free standing emergency department may provide. In addition, changes have been made to identify special requirements applicable to rural free standing emergency departments. These changes are being proposed pursuant to the authority granted the Department of Community Health in O.C.G.A. §§ 31-2-5 and 31-2-7.

#### MAIN FEATURES OF THE PROPOSED RULES:

111-8-40-.02 has been edited to add a new subsection (h) to define rural free standing emergency departments. Any hospital may downgrade its existing scope of services to operate as a rural free standing emergency department provided that the hospital is currently licensed by the Department of Community Health as a hospital or was previously licensed by the Department of Community Health as a hospital and such license expired within the previous 12 months. The hospital must be located in a rural county and no more than 35 miles from a licensed general hospital. The rural free standing emergency department must be open 7 days a week, 24 hours a day, and provide non-elective emergency treatment and procedures for periods continuing less than 24 hours. Optional services that may be provided by the rural free standing emergency department include: elective, out-patient surgical treatment and procedures for periods continuing less than 24 hours and basic obstetrics and gynecology treatment and procedures for periods continuing less than 24 hours.

111-8-40-.02(h) has been renumbered as (i).

111-8-40-.02(i) has been renumbered as (j).

111-8-40-.02(j) has been renumbered as (k).

111-8-40-.02(k) has been renumbered as (l).

111-8-40-.02(I) has been renumbered as (m).

111-8-40-.02(m) has been renumbered as (n).

111-8-40-.02(n) has been renumbered as (o).

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111-8-40-.02(o) has been renumbered as (p).
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111-8-40-.02(p) has been renumbered as (q).

111-8-40-.02(q) has been renumbered as (r).

111-8-40-.02(r) has been renumbered as (s).

111-8-40-.02(s) has been renumbered as (t).

111-8-40-.02(t) has been renumbered as (u).

111-8-40-.02(u) has been renumbered as (v).

111-8-40-.02(v) has been renumbered as (w).

111-8-40-.03(c)(1) has been edited to add a new subsection (iii) which defines rural free standing emergency department as a third classification of a hospital for licensing purposes.

111-8-40-.39 has been edited to define the special requirements applicable to rural free standing emergency departments. Special requirements include: reasonable efforts to secure a written agreement with general hospitals located within 35 miles of the rural free standing emergency department to facilitate patient referral and transfer; the governing body to approve the rural free standing emergency department's organization, scope and availability of patient care services; operational policies to include definition of services to be provided by the rural free standing emergency department or through contract; and that rural free standing emergency department's that would not otherwise be subject to the federal Emergency Medical Treatment & Labor Act must provide each patient, regardless of the individual's ability to pay, an appropriate medical screening, examination, stabilization if possible and, if necessary or requested by the patient, transfer to another facility that has the capability of stabilizing the patient. In addition, the rural free standing emergency department must comply with the entirety of the chapter as applicable to the services to be provided by the rural free standing emergency department.

111-8-40-.39 has been renumbered as 111-8-40-.40.

111-8-40-.40 has been renumbered as 111-8-40-.41.

111-8-40-.41 has been renumbered as 111-8-40-.42.

111-8-40-.42 has been renumbered as 111-8-40-.43.

#### 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) Rural Free Standing Emergency Department means any hospital that downgrades its existing scope of services to meet all of the following conditions:
  - (i) <u>is currently licensed by the Department as a hospital or was previously licensed by the Department as a hospital and such license expired within the previous 12 months;</u>
  - (ii) is located in a rural county as defined by O.C.G.A. § 31-6-2(32);
  - (iii) is located no more than 35 miles from a licensed general hospital;
  - (iv) is open 7 days a week, 24 hours a day;
  - (v) <u>provides non-elective emergency treatment and procedures for periods</u> continuing less than 24 hours;
  - (vi) <u>may provide elective, out-patient surgical treatment and procedures for periods</u> continuing less than 24 hours;

- (vii) may provide basic obstetrics and gynecology treatment and procedures for periods continuing less than 24 hours; and
- (viii) <u>is classified by the department, as provided for in this chapter, as a Rural Free Standing Emergency Department.</u>

Rural Free Standing Emergency Departments may provide elective endoscopy or other elective treatment and procedures which are not performed in an operating room environment.

- (hi) 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.
- (ii) 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.
- (jk) 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.
- (kl) 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.
- (Im) 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.
- (mn) 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.
- (<u>no</u>) *Permit* means the authorization granted by the Department to a hospital governing body to operate the hospital's authorized services.
- (ep) 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.
- (pg) *Physician* means any person who is licensed to practice medicine in this state by the Georgia Composite State Board of Medical Examiners.
- (er) *Practitioner* means any individual engaged in the practice of the profession for which they are licensed, certified, or otherwise qualified or authorized to practice.

- (FS) 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.
- (st) Rules and regulations means the set of rules formally adopted internally by a specified hospital body to provide guidance for internal functions or practices.
- (tu) Seclusion means the confinement of a person to a room or an area where the person is prevented from leaving.
- (<u>uv</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.
- (<u>vw</u>) 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; er
- (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: or

#### (iii) Classification as a Rural Free Standing Emergency Department.

- 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 reopening. 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-.39 Special Requirements for Rural Free Standing Emergency Departments.
  Rural Free Standing Emergency Departments shall be required to comply with the entirety of this chapter, as applicable to the scope of services offered by the Rural Free Standing Emergency Department, with the following exceptions and/or additions:
- (a) The Rural Free Standing Emergency Department shall make all reasonable efforts to secure written agreement(s) with hospital(s) within 35 miles which include provisions for patient referral and transfer between the facilities, with the use of emergency and non-emergency transportation.
- (b) The Rural Free Standing Emergency Department's organization, scope, and availability of patient care services shall be defined and approved by the governing body.
- (c) The Rural Free Standing Emergency Department shall have operational policies developed with participation from one (1) or more licensed physicians. The operational policies must describe the patient care services the Rural Free Standing Emergency Department will provide directly and those that will be provided through contract or other arrangement.
- (d) A Rural Freestanding Emergency Department that is not otherwise subject to the federal Emergency Medical Treatment & Labor Act, 42 U.S.C. 1395dd shall provide to each patient, without regard to the individual's ability to pay, an appropriate medical screening examination to determine whether an emergency medical condition exists, and if so, shall provide stabilizing treatment within its capability. If the Rural Freestanding Emergency Department is unable to

stabilize the patient within its capability, or if the patient requests, it shall implement a transfer of the patient to another facility that has the capability of stabilizing the patient.

Authority: O.C.G.A. § 31-7-2.1.

## 111-8-40-.3940 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-.4041 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-.4142 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-.4243 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.