2019 Crosswalk on
Georgia Rules and Regulations for Hospitals and Medicare Conditions of Participation

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Tag #	Georgia Final Rules	Medicare Conditions of Participation* * Please note that the regulations, statutes, or interpretive guidance may not always be quoted in full in this Crosswalk. For the complete regulation, statute, or interpretive guidance, please reference the citation provided in this Crosswalk.
0100	**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. **History:** Original Rule entitled "Title and Purpose" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.	**42 C.F.R. § 482.1 Basis and scope.** (a) Statutory basis. (1) Section 1861 of the Social Security Act provides that— (i) Hospitals participating in Medicare must meet certain specified requirements; and (ii) The Secretary may impose additional requirements if they are found necessary in the interest of the health and safety of the individuals who are furnished services in hospitals. (2) Section 1861(f) of the [Social Security] Act provides that an institution participating in Medicare as a psychiatric hospital must meet certain specified requirements imposed on hospitals under section 1861(e), must be primarily engaged in providing, by or under the supervision of a physician, psychiatric services for the diagnosis and treatment of mentally ill persons, must maintain clinical records and other records that the Secretary finds necessary, and must meet staffing requirements that the Secretary finds necessary to carry out an active program of treatment for individuals who are furnished services in the hospital. A distinct part of an institution can participate as a psychiatric hospital if the institution meets the specified 1861(e) requirements and is primarily engaged in providing psychiatric services, and if the distinct part meets the records and staffing requirements that the Secretary finds necessary. (3) Sections 1861(k) and 1902(a)(30) of the Act provide that hospitals participating in Medicare and Medicaid must have a utilization review plan that meets specified requirements. (4) Section 1883 of the Act sets forth the requirements for hospitals that provide long term care under an agreement with the Secretary. (5) Section 1905(a) of the Act provides that "medical assistance" (Medicaid) payments may be applied to various hospital services. Regulations interpreting those provisions specify that hospitals receiving payment under Medicaid must meet the requirements for participation in Medicare (except in the case of medical supervision of nurse-midwife services. See §§440.10 and 440.165 of this chapter.). (b) Scope. Except as provided in subpart A of part 488, the provisions of this part serve as the basis of determining whether a hospital qualifies for a provider agreement under Medicare and Medicaid.
0200	**111-8-40-.02 Definitions** Unless a context otherwise requires, these identified terms mean the following when used in these rules:	

0201	(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.	
0202	(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.	
0203	(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.	
0204	(d) *Department* means the Department of Community Health of the State of Georgia.	
0205	(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.	
0206	(f) *Hospital* means any building, facility, or place in which are provided two (2) or more beds 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.	**42 U.S.C. § 1395x(e)** A hospital is an institution primarily engaged in providing, by or under the supervision of physicians, inpatient diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons, or (B) rehabilitation services for the rehabilitation of injured, disabled, or sick persons The term "hospital" does not include a critical access hospital. For the complete definition, please see: https://www.ssa.gov/OP_Home/ssact/title18/1861.htm
0207	(g) *Inpatient* means a person admitted to a hospital for an intended length of stay of twenty- four (24) hours or longer.	
0208	(h) *Rural Free Standing Emergency Department* means any hospital that downgrades its existing scope of services to meet all of the following conditions:	
	(i) 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;	
	(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) provides non-elective emergency treatment and procedures for periods continuing less than 24 hours;	
	(vi) may provide elective, out-patient surgical treatment and procedures for periods continuing less than 24 hours;	
	(vii) may provide basic obstetrics and gynecology treatment and procedures for periods continuing less than 24 hours; and	
	(viii) is classified by the department, as provided for in this chapter, as a Rural Free Standing Emergency Department.	

	Rural Free Standing Emergency Departments may provide elective endoscopy or other elective treatment and procedures which are not performed in an operating room environment	
0209	(i) *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.	
0210	(j) *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.	
0211	(k) *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.	
0212	(l) *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.	
0213	(m) *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.	
0214	(n) *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.	
0215	(o) *Permit* means the authorization granted by the Department to a hospital governing body to operate the hospital's authorized services.	**42 C.F.R. § 489.3 Definitions.** Provider agreement means an agreement between CMS and one of the providers specified in §489.2(b) to provide services to Medicare beneficiaries and to comply with the requirements of section 1866 of the Act. See also, Ctrs.for Medicare & Medicaid Servs., *Medicare General Information, Eligibility, and Entitlement*, Chapter 5 (2018), https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/ge101c05.pdf.
0216	(p) *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.	**42 C.F.R. § 482.13(e)(1)(i)** A restraint is— (A) Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely; or (B) A drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition. (C) A restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine

		physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort).
0217	(q) *Physician* means any person who is licensed to practice medicine in this state by the Georgia Composite State Board of Medical Examiners.	**42 C.F.R. § 405.400 Definitions.** Physician means a doctor of medicine; doctor of osteopathy; doctor of dental surgery or of dental medicine; doctor of podiatric medicine; or doctor of optometry who is legally authorized to practice medicine, osteopathy, dental surgery, dental medicine, podiatric medicine, or optometry by the State in which he performs such function and who is acting within the scope of his license when he performs such functions. **42 U.S.C. § 1395x(r)** The term "physician," when used in connection with the performance of any function or action, means (1) A doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action (including a physician within the meaning of section 1101(a)(7)), (2) A doctor of dental surgery or of dental medicine who is legally authorized to practice dentistry by the State in which he performs such function and who is acting within the scope of his license when he performs such functions, (3) A doctor of podiatric medicine for the purposes of subsections (k), (m), (p)(1), and (s) of this section and sections 1814(a), 1832(a)(2)(F)(ii), and 1835 but only with respect to functions which he is legally authorized to perform as such by the State in which he performs them, (4) A doctor of optometry, but only for purposes of subsection (p)(1) with respect to the provision of items or services described in subsection (s) which he is legally authorized to perform as a doctor of optometry by the State in which he performs them, or (5) A chiropractor who is licensed as such by the State (or in a State which does not license chiropractors as such, is legally authorized to perform the services of a chiropractor in the jurisdiction in which he performs such services), and who meets uniform minimum standards promulgated by the Secretary, but only for the purpose of sections 1861(s)(1) and 1861(s)(2)(A) and only with respect to treatment by means of manual manipulation of the spine (to correct a subluxation) which he is legally authorized to perform by the State or jurisdiction in which such treatment is provided. For the purposes of section 1862(a)(4) and subject to the limitations and conditions provided in the previous sentence, such term includes a doctor of one of the arts, specified in such previous sentence, legally authorized to practice such art in the country in which the inpatient hospital services (referred to in such section 1862(a)(4)) are furnished.
0218	(r) *Practitioner* means any individual engaged in the practice of the profession for which they are licensed, certified, or otherwise qualified or authorized to practice.	**42 C.F.R. § 405.400 Definitions.** Practitioner means a physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, clinical psychologist, clinical social worker, registered dietitian or nutrition professional, who is currently legally authorized to practice in that capacity by each State in which he or she furnishes services to patients or clients.

0219	(s) *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.	
0220	(t) *Rules and regulations* means the set of rules formally adopted internally by a specified hospital body to provide guidance for internal functions or practices.	
0221	(u) *Seclusion* means the confinement of a person to a room or an area where the person is prevented from leaving.	**42 C.F.R. § 482.13(e)(1)(ii)** Seclusion is the involuntary confinement of a patient alone in a room or an area and the patient is physically prevented from leaving. Seclusion may only be used for the management of violent or self-destructive behavior.
0222	(v) *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.	
0223	(w) 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. **History:** Original Rule entitled "Definitions" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.	
0300	**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.	**42 C.F.R. § 482.11 Compliance with Federal, State and local laws.** (a) The hospital must be in compliance with applicable Federal laws related to the health and safety of patients. (b) The hospital must be— (1) Licensed; or (2) Approved as meeting standards for licensing established by the agency of the State or locality responsible for licensing hospitals. (c) The hospital must assure that personnel are licensed or meet other applicable standards that are required by State or local laws.
0301	(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.	Please see Ctrs.for Medicare & Medicaid Servs., *State Operations Manual:* Chapter 2 58 *(2016)*, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107c02.pdf
0302	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.	Please see Section 2004 of the CMS State Operations Manual that addresses Provider-Based Determinations and required criteria. Ctrs.for Medicare & Medicaid Servs., *State Operations Manual*: Chapter 2 28 (2018), https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf.
0303	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.	
0304	(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.	

0305	(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.	
0306	1. The classification shall be one of the following:	
0307	(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;	
0308	(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	
0309	(iii) Classification as a Rural Free Standing Emergency Department.	
0310	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.	
0311	(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.	
0312	(e) The permit issued to the hospital shall be prominently displayed in a public area of the hospital at all times.	
0313	(f) A permit is not transferable from one governing body to another nor from one hospital location to another.	**42 C.F.R. § 489.18 Change of ownership or leasing: Effect on provider agreement.** (a) What constitutes change of ownership—(1) Partnership. In the case of a partnership, the removal, addition, or substitution of a partner, unless the partners expressly agree otherwise, as permitted by applicable State law, constitutes change of ownership. (2) Unincorporated sole proprietorship. Transfer of title and property to another party constitutes change of ownership. (3) Corporation. The merger of the provider corporation into another corporation, or the consolidation of two or more corporations, resulting in the creation of a new corporation constitutes change of ownership. Transfer of corporate stock or the merger of another corporation into the provider corporation does not constitute change of ownership. (4) Leasing. The lease of all or part of a provider facility constitutes change of ownership of the leased portion. (b) Notice to CMS. A provider who is contemplating or negotiating a change of ownership must notify CMS.

		(c) Assignment of agreement. When there is a change of ownership as specified in paragraph (a) of this section, the existing provider agreement will automatically be assigned to the new owner. (d) Conditions that apply to assigned agreements. An assigned agreement is subject to all applicable statutes and regulations and to the terms and conditions under which it was originally issued including, but not limited to, the following: (1) Any existing plan of correction. (2) Compliance with applicable health and safety standards. (3) Compliance with the ownership and financial interest disclosure requirements of part 420, subpart C, of this chapter. (4) Compliance with civil rights requirements set forth in 45 CFR parts 80, 84, and 90. (e) Effect of leasing. The provider agreement will be assigned to the lessee only to the extent of the leased portion of the facility.
0314	(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.	
0315	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.	
0316	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.	
0317	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.	
0318	(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.	
0319	(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.	
0320	(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.	
0321	(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. **History:** Original Rule entitled "Hospital Permit Requirement" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.	Provider agreements require the providers to comply with regulations. Therefore, new provider agreements are not made when regulations change. An agreement with a hospital is not time limited and has no fixed expiration date. The agreement remains in effect until such time as there is a voluntary termination, or involuntary termination, or a change of ownership. Ctrs.for Medicare & Medicaid Servs., *State Operations Manual*: Chapter 5 (2018), https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/ge101c05.pdf
0400	**111-8-40-.04 Facilities Exempt from These Rules** The following classes of hospitals are exempt from these rules:	
0401	(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	
0402	(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. **History:** Original Rule entitled "Facilities Exempt from These Rules" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.	
0500	**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.	
0501	(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:	
0502	1. A listing of the services provided:	
0503	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;	
0504	3. A list of the locations of any services offered by the hospital on separate premises; and	
0505	4. A copy of the Certificate of Need (CON) from the Department.	
0506	(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.	
0507	(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:	
0508	1. A listing of the service(s) to be provided; and	
0509	2. A copy of the required Certificate of Need (CON) from the Department, if applicable.	
0510	(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. **History:** Original Rule entitled "Application for a Permit" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.	When an organization having a provider agreement undergoes a change of ownership, the agreement is automatically assigned to the new owner. A participating provider which plans to change ownership should give advance notice of its intention so that necessary action can be taken in the event the newly-owned institution does not wish to participate in the Medicare program or does not want to accept assignment of the previous owners provider number. Ctrs.for Medicare & Medicaid Servs., *State Operations Manual*: Chapter 2 (2018), https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107c02.pdf
0600	**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.	
0601	(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:	
0602	1. The hospital has failed to demonstrate compliance with these rules and regulations;	
0603	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;	
0604	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	
0605	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.	
0606	**(b) Sanction of a Permit.**	
0607	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:	**42 C.F.R. § 489.53(a) Basis for termination of agreement.** CMS may terminate the agreement with any provider if CMS finds that any of the following failings is attributable to that provider, and may, in addition to the applicable requirements in

		this chapter governing the termination of agreements with suppliers, terminate the agreement with any supplier to which the failings in paragraphs (a)(2), (13) and (18) of this section are attributable: (1) It is not complying with the provisions of title XVIII and the applicable regulations of this chapter or with the provisions of the agreement. (2) The provider or supplier places restrictions on the persons it will accept for treatment and it fails either to exempt Medicare beneficiaries from those restrictions or to apply them to Medicare beneficiaries the same as to all other persons seeking care. (3) It no longer meets the appropriate conditions of participation or requirements (for SNFs and NFs) set forth elsewhere in this chapter. In the case of an RNHCI no longer meets the conditions for coverage, conditions of participation and requirements set forth elsewhere in this chapter. (4) It fails to furnish information that CMS finds necessary for a determination as to whether payments are or were due under Medicare and the amounts due. (5) It refuses to permit examination of its fiscal or other records by, or on behalf of CMS, as necessary for verification of information furnished as a basis for payment under Medicare. (6) It failed to furnish information on business transactions as required in §420.205 of this chapter. (7) It failed at the time the agreement was entered into or renewed to disclose information on convicted individuals as required in §420.204 of this chapter. (8) It failed to furnish ownership information as required in §420.206 of this chapter. (9) It failed to comply with civil rights requirements set forth in 45 CFR parts 80, 84, and 90. (10) In the case of a hospital or a critical access hospital as defined in section 1861(mm)(1) of the Act that has reason to believe it may have received an individual transferred by another hospital in violation of §489.24(d), the hospital failed to report the incident to CMS or the State survey agency. (11) In the case of a hospital requested to furnish inpatient services to CHAMPUS or CHAMPVA beneficiaries or to veterans, it failed to comply with §489.25 or §489.26, respectively. (12) It failed to furnish the notice of discharge rights as required by §489.27. (13) The provider or supplier refuses to permit copying of any records or other information by, or on behalf of, CMS, as necessary to determine or verify compliance with participation requirements. (14) The hospital knowingly and willfully fails to accept, on a repeated basis, an amount that approximates the Medicare rate established under the inpatient hospital prospective payment system, minus any enrollee deductibles or copayments, as payment in full from a fee-for-service FEHB plan for inpatient hospital services provided to a retired Federal enrollee of a fee-for-service FEHB plan, age 65 or older, who does not have Medicare Part A benefits.

		(15) It had its enrollment in the Medicare program revoked in accordance to §424.535 of this chapter. (16) It has failed to pay a revisit user fee when and if assessed. (17) In the case of an HHA, it failed to correct any deficiencies within the required time frame.
0608	(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;	
0609	(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;	**42 C.F.R. § 489.53(a)(18)** The provider or supplier fails to grant immediate access upon a reasonable request to a state survey agency or other authorized entity for the purpose of determining, in accordance with §488.3, whether the provider or supplier meets the applicable requirements, conditions of participation, conditions for coverage, or conditions for certification.
0610	(iii) Failed to comply with the licensing requirements of this state; or	
0611	(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.	
0612	2. Such sanctions may include any one or more of the following:	
0613	(i) Administration of a public reprimand;	
0614	(ii) Suspension of the permit;	
0615	(iii) Prohibition of persons in management or control;	
0616	(iv) Imposition of civil penalties as provided by law; and	
0617	(v) Revocation of the permit.	
0618	(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. **History:** Original Rule entitled "Permit Denial and Sanctions" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.	
0700	**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.	
0701	(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:	
0702	1. A copy of the certificate of occupancy;	
0703	2. Verification of building safety and fire safety from local and state authorities; and	
0704	3. Evidence of appropriate approvals by the state architect.	

0705	(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.	
0706	(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.	
0707	(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.	
0708	(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.	Section 1865(a)(1) of the Social Security Act (the Act) permits providers and suppliers "accredited" by an approved national accreditation organization (AO) to be exempt from routine surveys by State survey agencies to determine compliance with Medicare conditions. Accreditation by an AO is voluntary and is not required for Medicare certification or participation in the Medicare Program. A provider's or supplier's ability to bill Medicare for covered services is not impacted if it chooses to discontinue accreditation from a CMS-approved AO or change AOs. Section 1865(a)(1) of the Act provides that if the Secretary finds that accreditation of a provider entity by a national accreditation body demonstrates that all applicable conditions are met or exceeded, the Secretary may deem those requirements to be met by the provider or supplier. Ctrs.for Medicare & Medicaid Servs., *Accreditation of Medicare Certified Providers & Suppliers* (2017), https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Accreditation-of-Medicare-Certified-Providers-and-Suppliers.html.
0709	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.	
0710	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:	
0711	(i) A validation study of the accreditation process is necessary;	
0712	(ii) There has been a complaint alleging a rule violation which the Department determines requires investigation;	

0713	(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	
0714	(iv) There are additions to the services previously offered by the hospital which the Department determines requires an on-site visit.	
0715	**(2) Required Reports to the Department.**	
0716	(a) **Patient Incidents Requiring Report.**	
0717	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:	
0718	(i) Any unanticipated patient death not related to the natural course of the patient's illness or underlying condition;	**42 C.F.R. § 482.13(g) Standard: Death reporting requirements.** Hospitals must report deaths associated with the use of seclusion or restraint. (1) With the exception of deaths described under paragraph (g)(2) of this section, the hospital must report the following information to CMS by telephone, facsimile, or electronically, as determined by CMS, no later than the close of business on the next business day following knowledge of the patient's death: (i) Each death that occurs while a patient is in restraint or seclusion. (ii) Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion. (iii) Each death known to the hospital that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death, regardless of the type(s) of restraint used on the patient during this time. "Reasonable to assume" in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing or asphyxiation. (2) When no seclusion has been used and when the only restraints used on the patient are those applied exclusively to the patient's wrist(s), and which are composed solely of soft, non-rigid, cloth-like materials, the hospital staff must record in an internal log or other system, the following information: (i) Any death that occurs while a patient is in such restraints. (ii) Any death that occurs within 24 hours after a patient has been removed from such restraints. (3) The staff must document in the patient's medical record the date and time the death was: (i) Reported to CMS for deaths described in paragraph (g)(1) of this section; or (ii) Recorded in the internal log or other system for deaths described in paragraph (g)(2) of this section. (4) For deaths described in paragraph (g)(2) of this section, entries into the log or other system must be documented as follows: (i) Each entry must be made not later than seven days after the date of death of the patient.

		(ii) Each entry must document the patient's name, date of birth, date of death, name of attending physician or other licensed independent practitioner who is responsible for the care of the patient as specified under §482.12(c), medical record number, and primary diagnosis(es). (iii) The information must be made available in either written or electronic form to CMS immediately upon request.
0719	(ii) Any rape which occurs in a hospital;	
0720	(iii) Any surgery on the wrong patient or the wrong body part of the patient; and	
0721	(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:	
0722	(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;	
0723	(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;	
0724	(III) Serious injury to a patient resulting from the malfunction or intentional or accidental misuse of patient care equipment;	
0725	(IV) Discharge of an infant to the wrong family;	
0726	(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	
0727	(VI) Any assault on a patient, which results in an injury that requires treatment.	
0728	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:	
0729	(i) The name of the hospital;	
0730	(ii) The date of the incident and the date the hospital became aware that a reportable incident may have occurred;	
0731	(iii) The medical record number of any affected patient(s);	
0732	(iv) The type of reportable incident suspected, with a brief description of the incident; and	
0733	(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.	

0734	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:	**42 C.F.R. § 482.21(c)(2)** Performance improvement activities must track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospital.
0735	(i) An explanation of the circumstances surrounding the incident, including the results of a root cause analysis or other systematic analysis;	
0736	(ii) Any findings or conclusions associated with the review; and	
0737	(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.	**42 C.F.R. § 482.21(c)(3)** The hospital must take actions aimed at performance improvement and, after implementing those actions, the hospital must measure its success, and track performance to ensure that improvements are sustained.
0738	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	
0739	(b) **Other Events/Incidents Requiring Report.**	
0740	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:	
0741	(i) A labor strike, walk-out, or sick-out;	
0742	(ii) An external disaster or other community emergency situation; and	
0743	(iii) An interruption of services vital to the continued safe operation of the facility, such as telephone, electricity, gas, or water services.	
0744	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:	
0745	(i) The name of the hospital;	
0746	(ii) The date of the event, or the anticipated date of the event, and the anticipated duration, if known;	
0747	(iii) The anticipated effect on patient care services, including any need for relocation of patients; and	
0748	(iv) Any immediate plans the hospital had made regarding patient management during the event.	
0749	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. **History:** Original Rule entitled "Hospital Inspections and Required Reports to the Department" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.	
0800	**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. **History:** Original Rule entitled "Hospital Ownership" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.	
0900	**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.	**42 C.F.R. § 482.12 Condition of participation: Governing body.** There must be an effective governing body that is legally responsible for the conduct of the hospital. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body.
0901	(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.	**42 C.F.R. § 482.12(d) Standard: Institutional plan and budget.** The institution must have an overall institutional plan that meets the following conditions: (1) The plan must include an annual operating budget that is prepared according to generally accepted accounting principles. (2) The budget must include all anticipated income and expenses. This provision does not require that the budget identify item by item the components of each anticipated income or expense. (3) The plan must provide for capital expenditures for at least a 3-year period, including the year in which the operating budget specified in paragraph (d)(2) of this section is applicable. (4) The plan must include and identify in detail the objective of, and the anticipated sources of financing for, each anticipated capital expenditure in excess of $600,000 (or a lesser amount that is established, in accordance with section 1122(g)(1) of the Act, by the State in which the hospital is located) that relates to any of the following: (i) Acquisition of land; (ii)Improvement of land, buildings, and equipment; or (iii) The replacement, modernization, and expansion of buildings and equipment. (5) The plan must be submitted for review to the planning agency designated in accordance with section 1122(b) of the Act, or if an agency is not designated, to the appropriate health planning agency in the State. (See part 100 of this title.) A capital expenditure is not subject to section 1122 review if 75 percent of the health care facility's patients who are expected to use the service for which the capital expenditure is made are individuals enrolled in a health maintenance organization

		(HMO) or competitive medical plan (CMP) that meets the requirements of section 1876(b) of the Act, and if the Department determines that the capital expenditure is for services and facilities that are needed by the HMO or CMP in order to operate efficiently and economically and that are not otherwise readily accessible to the HMO or CMP because— (i) The facilities do not provide common services at the same site; (ii) The facilities are not available under a contract of reasonable duration; (iii) Full and equal medical staff privileges in the facilities are not available; (iv) Arrangements with these facilities are not administratively feasible; or (v) The purchase of these services is more costly than if the HMO or CMP provided the services directly. (6) The plan must be reviewed and updated annually. (7) The plan must be prepared— (i) Under the direction of the governing body; and (ii) By a committee consisting of representatives of the governing body, the administrative staff, and the medical staff of the institution.
0902	(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:	**42 C.F.R. § 482.12(a) Standard: Medical staff.** The governing body must: (1) Determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff; (2) Appoint members of the medical staff after considering the recommendations of the existing members of the medical staff;
0903	1. That every inpatient is under the care of a qualified member of the medical staff;	**42 C.F.R. § 482.12(c) Standard: Care of patients.** In accordance with hospital policy, the governing body must ensure that the following requirements are met: (1) Every Medicare patient is under the care of: (i) A doctor of medicine or osteopathy (this provision is not to be construed to limit the authority of a doctor of medicine or osteopathy to delegate tasks to other qualified health care personnel to the extent recognized under State law or a State's regulatory mechanism; (ii) A doctor of dental surgery or dental medicine who is legally authorized to practice dentistry by the State and who is acting within the scope of his or her license; (iii) A doctor of podiatric medicine, but only with respect to functions which he or she is legally authorized by the State to perform; (iv) A doctor of optometry who is legally authorized to practice optometry by the State in which he or she practices; or (v) A chiropractor who is licensed by the State or legally authorized to perform the services of a chiropractor, but only with respect to treatment by means of manual manipulation of the spine to correct a sublaxation demonstrated by x-ray to exist; and (vi) A clinical psychologist as defined in Sec. 410.71 of this chapter, but only with respect to clinical psychologist services as defined in Sec. 410.71 of this chapter and only to the extent permitted by State law. (2) Patients are admitted to the hospital only on the recommendation of a licensed practitioner permitted by the State to admit patients to a hospital. If a Medicare

		patient is admitted by a practitioner not specified in paragraph (c)(1) of this section, that patient is under the care of a doctor of medicine or osteopathy. (3) A doctor of medicine or osteopathy is on duty or on call at all times. (4) A doctor of medicine or osteopathy is responsible for the care of each Medicare patient with respect to any medical or psychiatric problem that— (i) Is present on admission or develops during hospitalization; and (ii) Is not specifically within the scope of practice of a doctor of dental surgery, dental medicine, podiatric medicine, or optometry; a chiropractor; or clinical psychologist, as that scope is-- (A) Defined by the medical staff; (B) Permitted by State law; and (C) Limited, under paragraph (c)(1)(v) of this section, with respect to chiropractors.
0904	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	**42 C.F.R. § 482.12(a) Standard: Medical staff.** The governing body must: (3) Assure that the medical staff has bylaws. (4) Approve medical staff bylaws and other medical staff rules and regulations. **42 C.F.R. § 482.22 Condition of participation: Medical staff.** The hospital must have an organized medical staff that operates under bylaws approved by the governing body, and which is responsible for the quality of medical care provided to patients by the hospital. **42 C.F.R. § 482.22(b) Standard: Medical staff organization and accountability.** The medical staff must be well organized and accountable to the governing body for the quality of the medical care provided to the patients. (1) The medical staff must be organized in a manner approved by the governing body. (2) If the medical staff has an executive committee, a majority of the members of the committee must be doctors of medicine or osteopathy. (3) The responsibility for organization and conduct of the medical staff must be assigned only to one of the following: (i) An individual doctor of medicine or osteopathy. (ii) A doctor of dental surgery or dental medicine, when permitted by State law of the State in which the hospital is located. (iii) A doctor of podiatric medicine, when permitted by State law of the State in which the hospital is located. (4) If a hospital is part of a hospital system consisting of multiple separately certified hospitals and the system elects to have a unified and integrated medical staff for its member hospitals, after determining that such a decision is in accordance with all applicable State and local laws, each separately certified hospital must demonstrate that: (i) The medical staff members of each separately certified hospital in the system (that is, all medical staff members who hold specific privileges to practice at that hospital) have voted by majority, in accordance with medical staff bylaws, either

		to accept a unified and integrated medical staff structure or to opt out of such a structure and to maintain a separate and distinct medical staff for their respective hospital; (ii) The unified and integrated medical staff has bylaws, rules, and requirements that describe its processes for self-governance, appointment, credentialing, privileging, and oversight, as well as its peer review policies and due process rights guarantees, and which include a process for the members of the medical staff of each separately certified hospital (that is, all medical staff members who hold specific privileges to practice at that hospital) to be advised of their rights to opt out of the unified and integrated medical staff structure after a majority vote by the members to maintain a separate and distinct medical staff for their hospital; (iii) The unified and integrated medical staff is established in a manner that takes into account each member hospital's unique circumstances and any significant differences in patient populations and services offered in each hospital; and (iv) The unified and integrated medical staff establishes and implements policies and procedures to ensure that the needs and concerns expressed by members of the medical staff, at each of its separately certified hospitals, regardless of practice or location, are given due consideration, and that the unified and integrated medical staff has mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed. **42 C.F.R. § 482.22(c) Standard: Medical staff bylaws.** The medical staff must adopt and enforce bylaws to carry out its responsibilities. The bylaws must: (1) Be approved by the governing body. (2) Include a statement of the duties and privileges of each category of medical staff. (e.g., active, courtesy, etc.) (3) Describe the organization of the medical staff.
0905	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.	**42 C.F.R. § 482.12(a)(5)** The governing body must ensure that the medical staff is accountable to the governing body for the quality of care provided to patients.
0906	(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.	**42 C.F.R. § 482.12(f)(2)** If emergency services are not provided at the hospital, the governing body must assure that the medical staff has written policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate.
0907	(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:	**42 C.F.R. § 482.12(b) Standard: Chief executive officer.** The governing body must appoint a chief executive officer who is responsible for managing the hospital.
0908	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;	
0909	2. Ensure that patients receive the same quality of care throughout the hospital; and	**42 C.F.R. § 482.21(e)(1)-(5) Standard: Executive responsibilities.** The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and

		administrative officials are responsible and accountable for ensuring the following: (1) That an ongoing program for quality improvement [is defined, implemented, and maintained.] [That an ongoing program for] patient safety, including the reduction of medical errors, [is defined, implemented, and maintained.] (2) That the hospital-wide quality assessment and performance improvement efforts address priorities for improved quality of care, and that all improvement actions are evaluated. [That the hospital-wide quality assessment and performance improvement efforts address priorities for improved] and patient safety [and that all improvement actions are evaluated.] (3) That clear expectations for safety are established. (4) That adequate resources are allocated for measuring, assessing, improving, and sustaining the hospital's performance and [that adequate resources are allocated for] reducing risk to patients. (5) That the determination of the number of distinct improvement projects is conducted annually
0910	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.	
0911	(e) The hospital shall advise the Department immediately and in writing of a change in the designation of the administrator or chief executive officer.	
0912	(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.	**42 C.F.R. § 482.12(e) Standard. Contracted services.** The governing body must be responsible for services furnished in the hospital whether or not they are furnished under contracts. The governing body must ensure that a contractor of services (including one for shared services and joint ventures) furnishes services that permit the hospital to comply with all applicable conditions of participation and standards for the contracted services. (1) The governing body must ensure that the services performed under a contract are provided in a safe and effective manner. (2) The hospital must maintain a list of all contracted services, including the scope and nature of the services provided.
0913	(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. **History:** Original Rule entitled "Governing Body and Hospital Administration" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.	**42 C.F.R. § 482.11(a**) The hospital must be in compliance with applicable Federal laws related to the health and safety of patients.
1000	**111-8-40-.10 Hospital-Patient Communications** The hospital shall develop, implement, and enforce policies and procedures to ensure that each patient is:	
1001	(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;	**42 C.F.R. § 482.13 Condition of participation: Patient's rights**. A hospital must protect and promote each patient's rights. (a) Standard: Notice of rights—(1) A hospital must inform each patient, or when appropriate, the patient's representative (as allowed under State law), of the

		patient's rights, in advance of furnishing or discontinuing patient care whenever possible. (2) The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance. The hospital's governing body must approve and be responsible for the effective operation of the grievance process and must review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee. The grievance process must include a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control Peer Review Organization. At a minimum: (i) The hospital must establish a clearly explained procedure for the submission of a patient's written or verbal grievance to the hospital. (ii) The grievance process must specify time frames for review of the grievance and the provision of a response. (iii) In its resolution of the grievance, the hospital must provide the patient with written notice of its decision that contains the name of the hospital contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.
1002	(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;	**42 C.F.R. § 482.51(b)(2)** A properly executed informed consent form for the operation must be in the patient's chart before surgery, except in emergencies. **42 C.F.R. § 482.13(b)(2)** The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate. **42 C.F.R. § 482.24(c)(4)** All records must document the following, as appropriate:...(v) properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law, if applicable, to require written patient consent.
1003	(c) Afforded the right to refuse medical and surgical treatment to the extent permitted by law;	**42 C.F.R. § 482.13(b) Standard: Exercise of rights.** (1) The patient has the right to participate in the development and implementation of his or her plan of care. (2) The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.
1004	(d) Have advance directives honored in accordance with the law and afforded the opportunity to issue advance directives if admitted on inpatient status;	**42 C.F.R. § 482.13(b)(3)** The patient has the right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these directives, in accordance with Sec. 489.100 of this part

		(Definition), Sec. 489.102 of this part (Requirements for providers), and Sec. 489.104 of this part (Effective dates).
1005	(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;	
1006	(f) Provided an itemized statement of all charges for which the patient or third-party payer is being billed; and	
1007	(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. **History:** Original Rule entitled "Hospital-Patient Communications" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.	**42 C.F.R. § 482.13(b)(4)** The patient has the right to have a family member or representative of his or her choice and his or her own physician notified promptly of his or her admission to the hospital. **42 C.F.R. § 482.13(h) Standard: Patient visitation rights.** A hospital must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights and the reasons for the clinical restriction or limitation. A hospital must meet the following requirements: (1) Inform each patient (or support person, where appropriate) of his or her visitation rights, including any clinical restriction or limitation on such rights, when he or she is informed of his or her other rights under this section. (2) Inform each patient (or support person, where appropriate) of the right, subject to his or her consent, to receive the visitors whom he or she designates, including, but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend, and his or her right to withdraw or deny such consent at any time. (3) Not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability. (4) Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.
1100	**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.	**42 C.F.R. § 482.22** The hospital must have an organized medical staff that operates under bylaws approved by the governing body, and which is responsible for the quality of medical care provided to patients by the hospital. **42 C.F.R. § 482.22(b)(1)** The medical staff must be organized in a manner approved by the governing body.
1101	(a) **Organization of the Medical Staff.** The medical staff shall be organized and may operate through defined committees as appropriate.	**42 C.F.R. § 482.22(b) Standard: Medical staff organization and accountability.** The medical staff must be well organized and accountable to the governing body for the quality of the medical care provided to patients. (2) If the medical staff has an executive committee, a majority of the members of the committee must be doctors of medicine or osteopathy. (3) The responsibility for organization and conduct of the medical staff must be assigned only to an individual doctor of medicine or osteopathy or, when

		permitted by State law of the state in which the hospital is located, a doctor of dental surgery or dental medicine.
1102	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.	**42 C.F.R. § 482.12(c) Standard: Care of patients.** In accordance with hospital policy, the governing body must ensure that the following requirements are met: (1) Every Medicare patient is under the care of: (i) A doctor of medicine or osteopathy. (This provision is not to be construed to limit the authority of a doctor of medicine or osteopathy to delegate tasks to other qualified health care personnel to the extent recognized under State law or a State's regulatory mechanism.); (ii) A doctor of dental surgery or dental medicine who is legally authorized to practice dentistry by the State and who is acting within the scope of his or her license; (iii) A doctor of podiatric medicine, but only with respect to functions which he or she is legally authorized by the State to perform; (iv) A doctor of optometry who is legally authorized to practice optometry by the State in which he or she practices; (v) A chiropractor who is licensed by the State or legally authorized to perform the services of a chiropractor, but only with respect to treatment by means of manual manipulation of the spine to correct a subluxation demonstrated by x-ray to exist; and (vi) A clinical psychologist as defined in §410.71 of this chapter, but only with respect to clinical psychologist services as defined in §410.71 of this chapter and only to the extent permitted by State law. (2) Patients are admitted to the hospital only on the recommendation of a licensed practitioner permitted by the State to admit patients to a hospital. If a Medicare patient is admitted by a practitioner not specified in paragraph (c)(1) of this section, the patient is under the care of a doctor of medicine or osteopathy. **42 C.F.R. § 482.22(a) Standard: Eligibility and process for appointment to medical staff.** The medical staff must be composed of doctors of medicine or osteopathy. In accordance with State law, including scope-of-practice laws, the medical staff may also include other categories of physicians (as listed at §482.12(c)(1)) and non-physician practitioners who are determined to be eligible for appointment by the governing body.
1103	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:	**42 C.F.R. § 482.12(a) Standard: Medical staff.** The governing body must… (6) Ensure the criteria for selection are individual character, competence, training, experience, and judgment; and (7) Ensure that under no circumstances is the accordance of staff membership or professional privileges in the hospital dependent solely upon certification, fellowship, or membership in a specialty body or society. (8) Ensure that, when telemedicine services are furnished to the hospital's patients through an agreement with a distant-site hospital, the agreement is written and that it specifies that it is the responsibility of the governing body of the distant-site hospital to meet the requirements in paragraphs (a)(1) through (a)(7) of this

		section with regard to the distant-site hospital's physicians and practitioners providing telemedicine services. The governing body of the hospital whose patients are receiving the telemedicine services may, in accordance with Sec. 482.22(a)(3) of this part, grant privileges based on its medical staff recommendations that rely on information provided by the distant-site hospital. (9) Ensure that when telemedicine services are furnished to the hospital's patients through an agreement with a distant-site telemedicine entity, the written agreement specifies that the distant-site telemedicine entity is a contractor of services to the hospital and as such, in accordance with §482.12(e), furnishes the contracted services in a manner that permits the hospital to comply with all applicable conditions of participation for the contracted services, including, but not limited to, the requirements in paragraphs (a)(1) through (a)(7) of this section with regard to the distant-site telemedicine entity's physicians and practitioners providing telemedicine services. The governing body of the hospital whose patients are receiving the telemedicine services may, in accordance with §482.22(a)(4) of this part, grant privileges to physicians and practitioners employed by the distant-site telemedicine entity based on such hospital's medical staff recommendations; such staff recommendations may rely on information provided by the distant-site telemedicine entity. (10) Consult directly with the individual assigned the responsibility for the organization and conduct of the hospital's medical staff, or his or her designee. At a minimum, this direct consultation must occur periodically throughout the fiscal or calendar year and include discussion of matters related to the quality of medical care provided to patients of the hospital. For a multi-hospital system using a single governing body, the single multi-hospital system governing body must consult directly with the individual responsible for the organized medical staff (or his or her designee) of each hospital within its system in addition to the other requirements of this paragraph (a). **42 C.F.R. § 482.22(c) Standard: Medical staff bylaws.** The medical staff must adopt and enforce bylaws to carry out is responsibilities. The bylaws must: (4) Describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body.
1104	(i) Valid and current Georgia license to practice the respective profession;	**42 C.F.R. § 482.22(a) Standard: Eligibility and process for appointment to medical staff.** (2) The medical staff must examine the credentials of all eligible candidates for medical staff membership and make recommendations to the governing body on the appointment of the candidates in accordance with State law, including scope-of-practice laws, and the medical staff bylaws, rules, and regulations. A candidate who has been recommended by the medical staff and who has been appointed by the governing body is subject to all medical staff bylaws, rules, and regulations, in addition to the requirements contained in this section. (3) When telemedicine services are furnished to the hospital's patients through an agreement with a distant-site hospital, the governing body of the hospital whose

		patients are receiving the telemedicine services may choose, in lieu of the requirements in paragraphs (a)(1) and (a)(2) of this section, to have its medical staff rely upon the credentialing and privileging decisions made by the distant-site hospital when making recommendations on privileges for the individual distant-site physicians and practitioners providing such services, if the hospital's governing body ensures, through its written agreement with the distant-site hospital, that all of the following provisions are met: (i) The distant-site hospital providing the telemedicine services is a Medicare-participating hospital. (ii) The individual distant-site physician or practitioner is privileged at the distant-site hospital providing the telemedicine services, which provides a current list of the distant-site physician's or practitioner's privileges at the distant-site hospital. (iii) The individual distant-site physician or practitioner holds a license issued or recognized by the State in which the hospital whose patients are receiving the telemedicine services is located. (iv) With respect to a distant-site physician or practitioner, who holds current privileges at the hospital whose patients are receiving the telemedicine services, the hospital has evidence of an internal review of the distant-site physician's or practitioner's performance of these privileges and sends the distant-site hospital such performance information for use in the periodic appraisal of the distant-site physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the hospital's patients and all complaints the hospital has received about the distant-site physician or practitioner. (4) When telemedicine services are furnished to the hospital's patients through an agreement with a distant-site telemedicine entity, the governing body of the hospital whose patients are receiving the telemedicine services may choose, in lieu of the requirements in paragraphs (a)(1) and (a)(2) of this section, to have its medical staff rely upon the credentialing and privileging decisions made by the distant-site telemedicine entity when making recommendations on privileges for the individual distant-site physicians and practitioners providing such services, if the hospital's governing body ensures, through its written agreement with the distant-site telemedicine entity, that the distant-site telemedicine entity furnishes services that, in accordance with §482.12(e), permit the hospital to comply with all applicable conditions of participation for the contracted services. The hospital's governing body must also ensure, through its written agreement with the distant-site telemedicine entity, that all of the following provisions are met: (i) The distant-site telemedicine entity's medical staff credentialing and privileging process and standards at least meet the standards at §482.12(a)(1) through (a)(7) and §482.22(a)(1) through (a)(2). (ii) The individual distant-site physician or practitioner is privileged at the distant-site telemedicine entity providing the telemedicine services, which provides the hospital with a current list of the distant-site physician's or practitioner's privileges at the distant-site telemedicine entity.

		(iii) The individual distant-site physician or practitioner holds a license issued or recognized by the State in which the hospital whose patients are receiving such telemedicine services is located. (iv) With respect to a distant-site physician or practitioner, who holds current privileges at the hospital whose patients are receiving the telemedicine services, the hospital has evidence of an internal review of the distant-site physician's or practitioner's performance of these privileges and sends the distant-site telemedicine entity such performance information for use in the periodic appraisal of the distant-site physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the hospital's patients, and all complaints the hospital has received about the distant-site physician or practitioner.
1105	(ii) Confirmed educational qualifications for the position of appointment;	
1106	(iii) References for practice and performance background;	
1107	(iv) Current health and mental status sufficient to perform medical and professional duties;	
1108	(v) Current Drug Enforcement Agency registration; if applicable;	
1109	(vi) Evidence of inquiry through relevant practitioner databases, such as databases maintained by licensing boards and the National Practitioner Data Bank; and	
1110	(vii) Congruity of the qualifications and/or training requirements with the privilege requested.	
1112	3. The medical staff shall evaluate at least biennially the credentials and professional performance of any individual granted clinical privileges for consideration for reappointment.	**42 C.F.R. § 482.22(a)(1)** The medical staff must periodically conduct appraisals of its members.
1113	4. The medical staff shall establish a system for the approval of temporary or emergency staff privileges when needed.	
1114	(b) **Medical Staff Accountability.** The medical staff shall be accountable to the governing body for the quality of medical care provided to all patients.	**42 C.F.R. § 482.12(a)** The governing body must: (5) Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients. **42 C.F.R. § 482.22(a) Standard: Eligibility and process for appointment to medical staff.** The medical staff must be composed of doctors of medicine or osteopathy. In accordance with State law, including scope-of-practice laws, the medical staff may also include other categories of physicians (as listed at §482.12(c)(1)) and non-physician practitioners who are determined to be eligible for appointment by the governing body. **42 C.F.R. § 482.22(b) Standard: Medical staff organization and accountability.** The medical staff must be well organized and accountable to the governing body for the quality of the medical care provided to the patients.
1115	1. The medical staff shall require that all individuals granted clinical privileges comply with generally accepted standards of practice.	

1116	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.	
1117	3. The medical staff shall establish effective systems of accountability for any hospital services ordered by physicians and other practitioners.	**42 C.F.R. § 482.22(b) Standard: Medical staff organization and accountability.** The medical staff must be well organized and accountable to the governing body for the quality of the medical care provided to the patients. **42 C.F.R. § 482.30(b) Standard: Composition of utilization review committee.** A UR committee consisting of two or more practitioners must carry out the UR function. At least two of the members of the committee must be doctors of medicine or osteopathy. The other members may be any of the other types of practitioners specified in §482.12(c)(1). (1) Except as specified in paragraphs (b)(2) and (3) of this section, the UR committee must be one of the following: (i) A staff committee of the institution; (ii) A group outside the institution-- (A) Established by the local medical society and some or all of the hospitals in the locality; or (B) Established in a manner approved by CMS. (2) If, because of the small size of the institution, it is impracticable to have a properly functioning staff committee, the UR committee must be established as specified in paragraph (b)(1)(ii) of this section. (3) The committee or group's reviews may not be conducted by any individual who-- (i) Has a direct financial interest (for example, an ownership interest) in that hospital; or (ii) Was professionally involved in the care of the patient whose case is being reviewed. **42 C.F.R. § 482.30(f) Standard: Review of professional services.** The committee must review professional services provided, to determine medical necessity and to promote the most efficient use of available health facilities and services.
1118	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.	
1119	(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	**42 C.F.R. § 482.22(b) Standard: Medical staff organization and accountability.** The medical staff must be well organized and accountable to the governing body for the quality of the medical care provided to the patients. (1) The medical staff must be organized in a manner approved by the governing body.

	rules and regulations shall become effective when approved by the governing body and shall include at a minimum:	**42 C.F.R. § 482.22(c) Standard: Medical staff bylaws.** The medical staff must adopt and enforce bylaws to carry out its responsibilities. The bylaws must: (1) Be approved by the governing body. (2) Include a statement of the duties and privileges of each category of medical staff (e.g., active, courtesy, etc.).
1120	1. A mechanism for participation of medical staff in policy decisions related to patient care in all areas of the hospital;	
1121	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;	**42 C.F.R. § 482.22(c)** The medical staff must adopt and enforce bylaws to carry out its responsibilities. The bylaws must: (3) Describe the organization of the medical staff.
1122	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;	**42 C.F.R. § 482.22(c)** The medical staff must adopt and enforce bylaws to carry out its responsibilities. The bylaws must: (4) Describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body. (6) Include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges. For distant-site physicians and practitioners requesting privileges to furnish telemedicine services under an agreement with the hospital, the criteria for determining privileges and the procedure for applying the criteria are also subject to the requirements in §482.12(a)(8) and (a)(9), and §482.22(a)(3) and (a)(4).
1123	4. Criteria and procedures for recommending the privileges to be granted to individual physicians, dentists, or podiatrists;	**42 C.F.R. § 482.22(c)** The medical staff must adopt and enforce bylaws to carry out its responsibilities. The bylaws must: (4) Describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body.
1124	5. A requirement that members of the medical staff comply with ethical and professional standards;	
1125	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;	
1126	7. A mechanism for ensuring physician response to inpatient emergencies twenty-four (24) hours per day;	**42 C.F.R. § 482.12(c)** In accordance with hospital policy, the governing body must ensure that the following requirements are met: (3) A doctor of medicine or osteopathy is on duty or on call at all times.
1127	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;	
1128	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;	

1129	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.	**42 C.F.R. § 482.22(c)** The medical staff must adopt and enforce bylaws to carry out its responsibilities. The bylaws must: (5) Include a requirement that— (i) A medical history and physical examination be completed and documented for each patient no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. The medical history and physical examination must be completed and documented by a physician (as defined in section 1861(r) of the Act), an oromaxillofacial surgeon, or other qualified individual in accordance with State law and hospital policy. (ii) An updated examination of the patient, including any changes in the patient's condition, be completed and documented within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, when the medical history and physical examination are completed within 30 days before admission or registration. The updated examination of the patient, including any changes in the patient's condition, must be completed and documented by a physician (as defined in section 1861(r) of the Act), an oromaxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy.
1130	11. Establishment of procedures for the choice and control of all drugs in the hospital;	
1131	12. The requirements for the completion of medical records;	
1132	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;	**42 C.F.R. § 482.23(c)(3)** With the exception of influenza and pneumococcal vaccines, which may be administered per physician-approved hospital policy after an assessment of contraindications, orders for drugs and biologicals must be documented and signed by a practitioner who is authorized to write orders in accordance with State law and hospital policy, and who is responsible for the care of the patient as specified under § 482.23(c). (i) If verbal orders are used, they are to be used infrequently. (ii) When verbal orders are used, they must only be accepted by persons who are authorized to do so by hospital policy and procedures consistent with Federal and State law. (iii) Orders for drugs and biologicals may be documented and signed by other practitioners not specified under 482.12(c) only if such practitioners are acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff by laws, rules, and regulations.
1133	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	
1134	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.	
1135	(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:	

1136	1. Criteria for when an autopsy shall be sought and a requirement that the attending physician be notified when an autopsy is performed; and	**42 C.F.R. § 482.22(d) Standard: Autopsies.** The medical staff should attempt to secure autopsies in all cases of unusual deaths and of medical-legal and educational interest. The mechanism for documenting permission to perform an autopsy must be defined. There must be a system for notifying the medical staff, and specifically the attending practitioner, when an autopsy is being performed.
1137	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. **History:** Original Rule entitled "Medical Staff" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.	**42 C.F.R. § 482.12(c) Standard: Care of patients.** In accordance with hospital policy, the governing body must ensure that the following requirements are met: (4) A doctor of medicine or osteopathy is responsible for the care of each Medicare patient with respect to any medical or psychiatric problem that— (i) is present on admission or develops during hospitalization; and (ii) is not specifically within the scope of practice of a doctor of dental surgery, dental medicine, podiatric medicine, or optometry; a chiropractor; or clinical psychologist, as that scope is— (A) defined by the medical staff; (B) permitted by state law; and (C) limited, under paragraph (c)(1) (v) of this section with respect to chiropractors.
1200	**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.	
1201	(a) The hospital shall establish and implement human resources policies and procedures to include at least:	
1202	1. Procedures for selecting qualified personnel;	
1203	2. A system for documenting the current licensure and/or certification status for those personnel whose positions or functions require such licensure or certification;	**42 C.F.R. § 482.11(c)** The hospital must assure that personnel are licensed or meet other applicable standards that are required by State or local laws. **42 C.F.R. § 482.23(b)(2)** The nursing service must have a procedure to ensure that hospital nursing personnel for whom licensure is required have valid and current licensure.
1204	3. A system for assessing competency of all personnel providing health care services, on a time schedule defined by hospital policy; and	
1205	4. Policies and procedures regarding the hospital-approved method for identification of personnel to patients, other staff, and visitors.	
1206	(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.	
1207	(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	**42 C.F.R. § 482.42(a) Standard: Organization and policies.** …The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel.

	with hospital administration, medical staff, occupational health, and infection control/safety staff.	
1208	(d) **Personnel Training Programs.** The hospital shall have and implement a planned program of training for personnel to include at least:	
1209	1. Hospital policies and procedures;	
1210	2. Fire safety, hazardous materials handling and disposal, and disaster preparedness;	
1211	3. Policies and procedures for maintaining patients' medical records;	
1212	4. The infection control program and procedures; and	
1213	5. The updating of job-specific skills or knowledge.	**42 C.F.R. § 482.13(f) Standard: Restraint or seclusion: Staff training requirements.** The patient has the right to safe implementation of restraint or seclusion by trained staff. (1) Training intervals. Staff must be trained and able to demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a patient in restraint or seclusion— (i) Before performing any of the actions specified in this paragraph; (ii) As part of orientation; and (iii) Subsequently on a periodic basis consistent with hospital policy. (2) Training content. The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following: (i) Techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require the use of a restraint or seclusion. (ii) The use of nonphysical intervention skills. (iii) Choosing the least restrictive intervention based on an individualized assessment of the patient's medical, or behavioral status or condition. (iv) The safe application and use of all types of restraint or seclusion used in the hospital, including training in how to recognize and respond to signs of physical and psychological distress (for example, positional asphyxia); (v) Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary. (vi) Monitoring the physical and psychological well-being of the patient who is restrained or secluded, including but not limited to, respiratory and circulatory status, skin integrity, vital signs, and any special requirements specified by hospital policy associated with the 1-hour face-to-face evaluation. (vii) The use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including required periodic recertification. (3) Trainer requirements. Individuals providing staff training must be qualified as evidenced by education, training, and experience in techniques used to address patients' behaviors. (4) Training documentation. The hospital must document in the staff personnel records that the training and demonstration of competency were successfully completed.

1214	(e) Personnel records shall be maintained for each employee of the hospital and shall contain, at a minimum:	
1215	1. The employment application or resume;	
1216	2. Dates of hire and position changes since hiring;	
1217	3. The job or position description(s) for the employee;	
1218	4. All evaluations of performance or competencies for the employee since the date of hire or at least the last five (5) years;	
1219	5. Credible evidence of current registration, licensure, or certification as required for that position by state law;	
1220	6. Evidence of completion of in-service training as required by hospital policy; and	**42 C.F.R. § 482.13(f) Standard: Restraint or seclusion: Staff training requirements.** The patient has the right to safe implementation of restraint or seclusion by trained staff. (1) Training intervals. Staff must be trained and able to demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a patient in restraint or seclusion— (i) Before performing any of the actions specified in this paragraph; (ii) As part of orientation; and (iii) Subsequently on a periodic basis consistent with hospital policy. (2) Training content. The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following: (i) Techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require the use of a restraint or seclusion. (ii) The use of nonphysical intervention skills. (iii) Choosing the least restrictive intervention based on an individualized assessment of the patient's medical, or behavioral status or condition. (iv) The safe application and use of all types of restraint or seclusion used in the hospital, including training in how to recognize and respond to signs of physical and psychological distress (for example, positional asphyxia); (v) Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary. (vi) Monitoring the physical and psychological well-being of the patient who is restrained or secluded, including but not limited to, respiratory and circulatory status, skin integrity, vital signs, and any special requirements specified by hospital policy associated with the 1-hour face-to-face evaluation. (vii) The use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including required periodic recertification. (3) Trainer requirements. Individuals providing staff training must be qualified as evidenced by education, training, and experience in techniques used to address patients' behaviors. (4) Training documentation. The hospital must document in the staff personnel records that the training and demonstration of competency were successfully completed.

		Please note that there may be additional staff training requirements for specific services.
1221	7. Evidence of completion of any requirements of the occupational health program at the hospital. Authority: O.C.G.A. § 31-7-2.1. **History:** Original Rule entitled "Human Resources Management" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.	
1300	**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.	**42 C.F.R. § 482.21 Condition of participation: Quality assessment and performance improvement program.** The hospital must develop, implement, and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program. The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS. **42 C.F.R. § 482.30 Condition of participation: Utilization review.** The hospital must have in effect a utilization review (UR) plan that provides for review of services furnished by the institution and by members of the medical staff to patients entitled to benefits under the Medicare and Medicaid programs. **42 C.F.R. § 482.30(a) Standard: Applicability.** The provisions of this section apply except in either of the following circumstances: (1) A Utilization and Quality Control Quality Improvement Organization (QIO) has assumed binding review for the hospital. (2) CMS has determined that the UR procedures established by the State under title XIX of the Act are superior to the procedures required in this section, and has required hospitals in that State to meet the UR plan requirements under §§456.50 through 456.245 of this chapter.
1301	(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.	**42 C.F.R. § 482.21(a) Standard: Program scope.** (1) The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will improve health outcomes and identify and reduce medical errors. **42 C.F.R. § 482.30(b) Standard: Composition of utilization review committee.** A UR committee consisting of two or more practitioners must carry out the UR function. At least two of the members of the committee must be doctors of medicine or osteopathy. The other members may be any of the other types of practitioners specified in §482.12(c)(1). (1) Except as specified in paragraphs (b)(2) and (3) of this section, the UR committee must be one of the following: (i) A staff committee of the institution; (ii) A group outside the institution—

		(A) Established by the local medical society and some or all of the hospitals in the locality; or (B) Established in a manner approved by CMS. (2) If, because of the small size of the institution, it is impracticable to have a properly functioning staff committee, the UR committee must be established as specified in paragraph (b)(1)(ii) of this section. (3) The committee or group's reviews may not be conducted by any individual who— (i) Has a direct financial interest (for example, an ownership interest) in that hospital; or (ii) Was professionally involved in the care of the patient whose case is being reviewed.
1302	(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:	**42 C.F.R. § 482.21(a)(2)** The hospital must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital service and operations.
1303	1. Operative procedures and other invasive and non-invasive procedures that place patients at risk;	
1304	2. Nosocomial infection rates;	
1305	3. Patient mortality;	
1306	4. Medication use;	
1307	5. Patient injuries, such as, but not limited to, those related to falls and restraint use;	
1308	6. Errors in procedures or practices which could compromise patient safety ("near-miss" events);	
1309	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;	
1310	8. Significant adverse drug reactions (as identified by the hospital);	
1311	9. Adverse events or patterns of adverse events during anesthesia;	
1312	10. Equipment malfunctions, for equipment used for patient care; and	
1313	11. Reportable patient incidents as required under Rule 111-8-40- .07.	**42 C.F.R. § 482.21(c)(2)** Performance improvement activities must track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospital.
1314	(c) The quality management program shall utilize a defined methodology for implementation, including at least mechanisms and methodology for:	**42 C.F.R. § 482.21(b) Standard: Program data.** (1) The program must incorporate quality indicator data including patient care data, and other relevant data, for example, information submitted to, or received from, the hospital's Quality Improvement Organization. (2) The hospital must use the data collected to— (i) Monitor the effectiveness and safety of services and quality of care; and (ii) Identify opportunities for improvement and changes that will lead to improvement.

1315	1. Performance measurement including consideration of scope of services;	
1316	2. Monitoring, evaluating, and assessing accountability;	**42 C.F.R. § 482.30(c) Standard: Scope and frequency of review.** (1) The UR plan must provide for review for Medicare and Medicaid patients with respect to the medical necessity of— (i) Admissions to the institution; (ii) The duration of stays; and (iii) Professional services furnished including drugs and biologicals. (2) Review of admissions may be performed before, at, or after hospital admission. (3) Except as specified in paragraph (e) of this section, reviews may be conducted on a sample basis. (4) Hospitals that are paid for inpatient hospital services under the prospective payment system set forth in Part 412 of this chapter must conduct review of duration of stays and review of professional services as follows: (i) For duration of stays, these hospitals need review only cases that they reasonably assume to be outlier cases based on extended length of stay, as described in §412.80(a)(1)(i) of this chapter; and (ii) For professional services, these hospitals need review only cases that they reasonably assume to be outlier cases based on extraordinarily high costs, as described in §412.80(a)(1)(ii) of this chapter.
1317	3. Setting priorities;	**42 C.F.R. § 482.21(c) Standard: Program activities**. (1) The hospital must set priorities for its performance improvement activities that— (i) Focus on high-risk, high-volume, or problem-prone areas; (ii) Consider the incidence, prevalence, and severity of problems in those areas; and (iii) Affect health outcomes, patient safety and quality of care.
1318	4. Root cause analyses, as appropriate, of problems identified;	
1319	5. Process improvement;	
1320	6. Identification of expected outcomes;	
1321	7. Reporting mechanisms; and	
1322	8. Authority for problem resolution.	
1323	(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.	**42 C.F.R. § 482.21(b)(3)** The frequency and detail of data collection must be specified by the hospital's governing body. **42 C.F.R. § 482.21(c)(3)** The hospital must take actions aimed at performance improvement and, after implementing those actions, the hospital must measure its success, and track performance to ensure that improvements are sustained.
1324	(e) The hospital shall take and document action to address opportunities for improvement identified through the quality management program.	**42 C.F.R. § 482.21(d) Standard: Performance improvement projects.** As part of its quality assessment and performance improvement program, the hospital must conduct performance improvement projects. (1) The number and scope of distinct improvement projects conducted annually must be proportional to the scope and complexity of the hospital's services and operations.

		(2) A hospital may, as one of its projects, develop and implement an information technology system explicitly designed to improve patient safety and quality of care. This project, in its initial stage of development, does not need to demonstrate measurable improvement in indicators related to health outcomes. (3) The hospital must document what quality improvement projects are being conducted, the reasons for conducting these projects, and the measurable progress achieved on these projects. (4) A hospital is not required to participate in a QIO cooperative project, but its own projects are required to be of comparable effort.
1325	(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. **History:** Original Rule entitled "Quality Management" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.	**42 C.F.R. § 482.21(e) Standard: Executive responsibilities.** The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following: (1) That an ongoing program for quality improvement and patient safety, including the reduction of medical errors, is defined, implemented, and maintained. (2) That the hospital-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety; and that all improvement actions are evaluated. (3) That clear expectations for safety are established. (4) That adequate resources are allocated for measuring, assessing, improving, and sustaining the hospital's performance and reducing risk to patients. (5) That the determination of the number of distinct improvement projects is conducted annually.
1400	**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.	**42 C.F.R. § 482.41 Condition of participation: Physical environment.** The hospital must be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment and for special hospital services appropriate to the needs of the community. (a) Standard: Buildings. The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients are assured. (1) There must be emergency power and lighting in at least the operating, recovery, intensive care, and emergency rooms, and stairwells. In all other areas not serviced by the emergency supply source, battery lamps and flashlights must be available. (2) There must be facilities for emergency gas and water supply. (d) Standard: Facilities. The hospital must maintain adequate facilities for its services. (1) Diagnostic and therapeutic facilities must be located for the safety of patients. (2) Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality. (3) The extent and complexity of facilities must be determined by the services offered.

		(4) There must be proper ventilation, light, and temperature controls in pharmaceutical, food preparation, and other appropriate areas.
1401	(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;	**42 C.F.R. § 482.41(b) Standard: Life safety from fire.** (1) Except as otherwise provided in this section— (i) The hospital must meet the applicable provisions and must proceed in accordance with the Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4.) Outpatient surgical departments must meet the provisions applicable to Ambulatory Health Care Occupancies, regardless of the number of patients served. (ii) Notwithstanding paragraph (b)(1)(i) of this section, corridor doors and doors to rooms containing flammable or combustible materials must be provided with positive latching hardware. Roller latches are prohibited on such doors. (2) In consideration of a recommendation by the State survey agency or Accrediting Organization or at the discretion of the Secretary, may waive, for periods deemed appropriate, specific provisions of the Life Safety Code, which would result in unreasonable hardship upon a hospital, but only if the waiver will not adversely affect the health and safety of the patients. (3) The provisions of the Life Safety Code do not apply in a State where CMS finds that a fire and safety code imposed by State law adequately protects patients in hospitals. (4) The hospital must have procedures for the proper routine storage and prompt disposal of trash. (5) The hospital must have written fire control plans that contain provisions for prompt reporting of fires; extinguishing fires; protection of patients, personnel and guests; evacuation; and cooperation with fire fighting authorities. (6) The hospital must maintain written evidence of regular inspection and approval by State or local fire control agencies. (7) A hospital may install alcohol-based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects against inappropriate access; (8) When a sprinkler system is shut down for more than 10 hours, the hospital must: (i) Evacuate the building or portion of the building affected by the system outage until the system is back in service, or (ii) Establish a fire watch until the system is back in service. (9) Buildings must have an outside window or outside door in every sleeping room, and for any building constructed after July 5, 2016 the sill height must not exceed 36 inches above the floor. Windows in atrium walls are considered outside windows for the purposes of this requirement. (i) The sill height requirement does not apply to newborn nurseries and rooms intended for occupancy for less than 24 hours. (ii) The sill height in special nursing care areas of new occupancies must not exceed 60 inches.

1402	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;	
1403	3. A program to inspect, monitor, and maintain biomedical equipment, electrical equipment, and emergency power generators;	**42 C.F.R. § 482.41(d)(2)** Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.
1404	4. A program for the monitoring and maintenance of electrical safety;	
1405	5. Security procedures for controlling access to sensitive areas, as defined by the hospital, for patients, employees, and visitors;	
1406	6. Procedures for the safe management of medical gases;	
1407	7. A system for patients or staff to summon assistance, when needed, from patient rooms, bathrooms, and treatment areas;	
1408	8. Policies regarding smoking which apply to employees, patients, and visitors; and	
1409	9. Procedures for storage and disposal of biohazardous medical waste in accordance with applicable laws.	
1410	(b) **Cleanliness and Sanitation.** The hospital shall maintain an environment that is clean and in good repair, through a program that establishes and maintains:	
1411	1. Standardized daily, interim, and terminal cleaning routines for all areas;	**42 C.F.R. § 482.41(b)(4)** The hospital must have procedures for the proper routine storage and prompt disposal of trash.
1412	2. Facilities for convenient and effective hand washing throughout the hospital;	**42 C.F.R. § 482.41(b)(7)** A hospital may install alcohol-based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects against inappropriate access;
1413	3. Systems for management of linens, including collection, sorting, transport, and washing of soiled linens, and storage and distribution of clean linens;	
1414	(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;	
1415	(ii) Clean and soiled linens shall be transported in separate containers or carts;	
1416	(iii) The laundering process for soiled linens shall be sufficient to remove organic soil and render the linen incapable of causing human illness; and	
1417	(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;	
1418	4. Standards regarding the use of hospital disinfectants;	
1419	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	**42 C.F.R. § 482.41(b)(4)** The hospital must have procedures for the proper routine storage and prompt disposal of trash.
1420	6. Procedures for the prevention of infestation by insects, rodents, or other vermin or vectors.	
1421	(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	**42 C.F.R. § 482.41(d)(4)** There must be proper ventilation, light, and temperature controls in pharmaceutical, food preparation, and other appropriate areas.

	maintain such systems to function at least minimally to the design standards current at the time of approved facility construction or renovation.	
1422	(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. **History:** Original Rule entitled "Physical Environment" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.	**42 C.F.R. § 482.41(d)(3)** The extent and complexity of facilities must be determined by the services offered.
1500	**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.	
1501	(a) The disaster preparedness plan shall include at a minimum plans for the following emergency situations:	
1502	1. Local and widespread weather emergencies or natural disasters, such as tornadoes, hurricanes, earthquakes, ice or snowstorms, or floods;	
1503	2. Manmade disasters such as acts of terrorism and hazardous materials spills;	
1504	3. Unanticipated interruption of service of utilities, including water, gas, or electricity, either within the facility or within a local or widespread area;	
1505	4. Loss of heat or air conditioning;	
1506	5. Fire, explosion, or other physical damage to the hospital; and	
1507	6. Pandemics or other situations where the community's need for services exceeds the availability of beds and services regularly offered by the hospital.	
1508	(b) There shall be plans to ensure sufficient staffing and supplies to maintain safe patient care during the emergency situation.	
1509	(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.	
1510	(d) The hospital shall document participation of all areas of the hospital in quarterly fire drills.	**42 C.F.R. § 482.41(b)(5)** The hospital must have written fire control plans that contain provisions for prompt reporting of fires; extinguishing fires; protection of patients, personnel and guests; evacuation; and cooperation with fire fighting authorities.
1511	(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.	
1512	(f) The plan shall include the notification to the Department of the emergency situation as required by these rules.	
1513	(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.	
1514	(h) The hospital's disaster preparedness plan shall be made available to the Department for inspection upon request.	
1515	(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. **History:** Original Rule entitled "Disaster Preparedness" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.	
1600	**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.	**42 C.F.R. § 482.42 Condition of participation: Infection control.** The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.
1601	(a) The hospital shall designate qualified infection control staff to coordinate the infection control program.	**42 C.F.R. § 482.42(a) Standard: Organization and policies.** A person or persons must be designated as infection control officer or officers to develop and implement policies governing control of infections and communicable diseases. The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infections, and communicable diseases of patients and personnel.
1602	(b) The administrative and medical staff of the hospital, as well as staff from appropriate organized services, shall participate in the infection control program.	
1603	(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.	**42 C.F.R. § 482.42(a)** …The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel.
1604	(d) The surveillance plan shall require collection of sufficient baseline data on the incidence of nosocomial infections in order that outbreaks can be identified.	**42 C.F.R. § 482.42(a)** …The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel.
1605	(e) The infection control methodologies for effective investigation and control of outbreaks, once identified, shall include at least:	
1606	1. The availability of microbiology laboratory capacity to detect and investigate outbreaks;	
1607	2. A system for obtaining appropriate clinical specimens for culture;	
1608	3. Access to necessary information in order to investigate infectious outbreaks; and	
1609	4. Administrative, physician, and nursing support to direct hospital changes to achieve immediate control of outbreaks and for implementation of corrective actions.	**42 C.F.R. § 482.42(b) Standard: Responsibilities of chief executive officer, medical staff, and director of nursing services.** The chief executive officer, the medical staff, and the director of nursing services must: (1) Ensure that the hospital-wide quality assessment and performance improvement (QAPI) programs address problems identified by the infection control officer or officers; and (2) Be responsible for the implementation of successful corrective action plans in affected problem areas.

1610	(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:	**42 C.F.R. § 482.42(a)** The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel.
1611	1. The approved hospital isolation system;	
1612	2. The approved procedures for handling and disposing of hazardous waste products;	
1613	3. The standards for approved cleaning, disinfection, and sterilization of all areas of the hospital;	
1614	4. The standards for hand washing and hand antisepsis; and	
1615	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.	
1616	(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:	**42 C.F.R. § 482.42(b)** The chief executive officer, the medical staff, and the director of nursing must: (1) Ensure that the hospital-wide quality assessment and performance improvement (QAPI) program and training programs address problems identified by the infection control officer or officers; and (2) Be responsible for the implementation of successful corrective action plans in affected problem areas**.**
1617	1. An orientation plan;	
1618	2. A plan for on-going training on isolation precautions, aseptic practices, and prevention of blood and body fluid exposure; and	
1619	3. Provision of specially designed training programs that result from outcome and process surveillance data.	
1620	(h) The hospital shall designate which departments are responsible for the reporting of communicable diseases as required by law.	**42 C.F.R. § 482.42(b)** The chief executive officer, the medical staff, and the director of nursing must— (1) Ensure that the hospital-wide quality assessment and performance improvement programs address problems identified by the infection control officer or officers) Ensure that the hospital-wide quality assessment and performance improvement (QAPI) program and training programs address problems identified by the infection control officer or officers; and (2) Be responsible for the implementation of successful corrective action plans in affected problem areas**.**
1621	(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. **History:** Original Rule entitled "Infection Control" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.	**42 C.F.R. § 482.42(b)** The chief executive officer, the medical staff, and the director of nursing must— (1) Ensure that the hospital-wide quality assessment and performance improvement (QAPI) program and training programs address problems identified by the infection control officer or officers; and (2) Be responsible for the implementation of successful corrective action plans in affected problem areas**.**
1700	**111-8-40-.17 Sterile Processing Services**	**42 C.F.R. § 482.42** The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be

	Each hospital shall designate a sterile processing service area designated for the decontamination, cleaning, sterilizing of reusable equipment, instruments, and supplies.	an active program for the prevention, control, and investigation of infections and communicable diseases.
1701	(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:	
1702	1. Decontamination and cleaning of instruments and other items and description of reprocessing protocols for contaminated patient equipment;	
1703	2. Disinfecting and/or sterilizing equipment and other items;	
1704	3. Monitoring of the systems used for sterilization;	
1705	4. Procedures for ensuring the sterility of packaged instruments and supplies;	
1706	5. Recall of items; and	
1707	6. Mechanisms for protection of workers from exposure to blood and other potentially infectious materials and environmental hazards.	
1708	(b) The sterile processing service shall be staffed by qualified personnel. Authority: O.C.G.A. § 31-7-2.1. **History:** Original Rule entitled "Sterile Processing Services" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.	
1800	**111-8-40-.18 Medical Records**	**42 C.F.R. § 482.24 Condition of participation: Medical record services.** The hospital must have a medical record service that has administrative responsibility for medical records. A medical record must be maintained for every individual evaluated or treated in the hospital.
1801	(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.	**42 C.F.R. § 482.24(a) Standard: Organization and staffing.** The organization of the medical record service must be appropriate to the scope and complexity of the services performed. The hospital must employ adequate personnel to ensure prompt completion, filing, and retrieval of records.
1802	(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.	
1803	(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.	**42 C.F.R. § 482.24(c) Standard: Content of record.** The medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services. (1) All patient medical record entries must be legible, complete, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided, consistent with hospital policies and procedures. (2) All orders, including verbal orders, must be dated, timed, and authenticated promptly by the ordering practitioner or by another practitioner who is responsible for the care of the patient only if such practitioner is acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules and regulations. (3) Hospitals may use pre-printed and electronic standing orders, order sets, and protocols for patient orders only if the hospital:

		(i) Establishes that such orders and protocols have been reviewed and approved by the medical staff and the hospital's nursing and pharmacy leadership; (ii) Demonstrates that such orders and protocols are consistent with nationally recognized and evidence-based guidelines; (iii) Ensures that the periodic and regular review of such orders and protocols is conducted by the medical staff and the hospital's nursing and pharmacy leadership to determine the continuing usefulness and safety of the orders and protocols; and (iv) Ensures that such orders and protocols are dated, timed, and authenticated promptly in the patient's medical record by the ordering practitioner or by another practitioner responsible for the care of the patient only if such a practitioner is acting in accordance with State law, including scope-of-practice laws, hospital policies and medical staff bylaws, rules, and regulations. (4) All records must document the following, as appropriate: (i) Evidence of— (A) A medical history and physical examination completed and documented no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. The medical history and physical examination must be placed in the patient's medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. (B) An updated examination of the patient, including any changes in the patient's condition, when the medical history and physical examination are completed within 30 days before admission or registration. Documentation of the updated examination must be placed in the patient's medical record after admission or registration, but prior to surgery or a procedure requiring anesthesia services.
1804	(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.	**42 C.F.R. § 482.24(b)(3)** The hospital must have a procedure for ensuring the confidentiality of patient records. Information from or copies of records may be released only to authorized individuals and the hospital must ensure that unauthorized individuals cannot gain access to or alter patient records. Original medical records must be released by the hospital only in accordance with Federal or State laws, court orders, or subpoenas. **42 C.F.R. § 482.13(d)(1)** The patient has the right to the confidentiality of his or her clinical records.
1805	(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.	**42 C.F.R. § 482.13(d)(2)** The patient has the right to access information contained in his or her clinical records within a reasonable time frame. The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its recordkeeping system permits.
1806	(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.	
1807	(f) Patients' medical records shall be coded and indexed in a manner that allows for timely retrieval by diagnosis or procedure when necessary.	**42 C.F.R. § 482.24 Condition of participation: Medical record services.** (a) Standard: Organizing and staffing. The organization of the medical record service must be appropriate to the scope and complexity of the service performed. The hospital must employ adequate personnel to ensure prompt completion, filing, and retrieval of records. (b) Standard: Form and retention of record. The hospital must maintain a medical record for each inpatient and outpatient. Medical records must be accurately written, promptly completed, properly filed and retained, and accessible. The hospital must use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries… (2) The hospital must have a system of coding and indexing medical records. The system must allow for timely retrieval by diagnosis and procedure, in order to support medical care evaluation studies.
1808	(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.	**42 C.F.R. § 482.24 Condition of participation: Medical record services.** (a) Standard: Organization and staffing. The organization of the medical record service must be appropriate to the scope and complexity of the service performed. The hospital must employ adequate personnel to ensure prompt completion, filing, and retrieval of records. (b) Standard: Form and retention of record. The hospital must maintain a medical record for each inpatient and outpatient. Medical records must be accurately written, promptly completed, properly filed and retained, and accessible. The hospital must use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries… (c)(4) All records must document the following, as appropriate: …(viii) Final diagnosis with completion of medical records within 30 days following discharge.
1809	(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.	**42 C.F.R. § 482.24(b)(1)** Medical records must be retained in their original or legally reproduced form for a period of at least 5 years. **42 C.F.R. § 482.26(d) Standard: Records.** Records of radiologic services must be maintained…. (2) The hospital must maintain the following for at least five years: (i) copies of reports and printouts (ii) Films, scans, and other image records, as appropriate. **42 C.F.R. § 482.53(d)(1)** the hospital must maintain copies of nuclear medicine reports for at least five years.
1810	(i) Medical records shall be secured in such a manner as to provide protection from damage or unauthorized access.	**42 C.F.R. § 482.24(b)(3)** The hospital must have a procedure for ensuring the confidentiality of patient records. Information from or copies of records may be released only to authorized individuals and the hospital must ensure that

		unauthorized individuals cannot gain access to or alter patient records. Original medical records must be released by the hospital only in accordance with Federal or State laws, court orders, or subpoenas.
1811	(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.	**42 C.F.R. § 482.24(c) Standard: Content of record.** The medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services.
1812	(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.	**42 C.F.R. § 482.24(c)(1)** All patient medical record entries must be legible, complete, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided, consistent with hospital policies and procedures. (2) All orders, including verbal orders, must be dated, timed, and authenticated promptly by the ordering practitioner or by another practitioner who is responsible for the care of the patient only if such a practitioner is acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules and regulations. (3) Hospitals may use pre-printed and electronic standing orders, order sets, and protocols for patient orders only if the hospital: (i) Establishes that such orders and protocols have been reviewed and approved by the medical staff and the hospital's nursing and pharmacy leadership; (ii) Demonstrates that such orders and protocols are consistent with nationally recognized and evidence-based guidelines; (iii) Ensures that the periodic and regular review of such orders and protocols is conducted by the medical staff and the hospital's nursing and pharmacy leadership to determine the continuing usefulness and safety of the orders and protocols; and (iv) Ensures that such orders and protocols are dated, timed, and authenticated promptly in the patient's medical record by the ordering practitioner or by another practitioner responsible for the care of the patient only if such a practitioner is acting in accordance with State law, including scope-of-practice laws, hospital policies and medical staff bylaws, rules, and regulations. (4) All records must document the following, as appropriate: (i) Evidence of— (A) A medical history and physical examination completed and documented no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. The medical history and physical examination must be placed in the patient's medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. (B) An updated examination of the patient, including any changes in the patient's condition, when the medical history and physical examination are completed within 30 days before admission or registration. Documentation of the updated examination must be placed in the patient's medical record within 24 hours after

		admission or registration, but prior to surgery or a procedure requiring anesthesia services. **42 C.F.R. § 482.53(d) Standard: Records.** The hospital must maintain signed and dated reports of nuclear medicine interpretations, consultations and procedures…. (2) The practitioner approved by the medical staff to interpret diagnostic procedures must sign and date the interpretation of these tests.
1813	(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.	**42 C.F.R. § 482.24(c) Standard: Content of record.** The medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services. (1) All patient medical record entries must be legible, complete, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided, consistent with hospital policies and procedures. (2) All orders, including verbal orders, must be dated, timed, and authenticated promptly by the ordering practitioner or by another practitioner who is responsible for the care of the patient only if such a practitioner is acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules and regulations. (3) Hospitals may use pre-printed and electronic standing orders, order sets, and protocols for patient orders only if the hospital: (i) Establishes that such orders and protocols have been reviewed and approved by the medical staff and the hospital's nursing and pharmacy leadership; (ii) Demonstrates that such orders and protocols are consistent with nationally recognized and evidence-based guidelines; (iii) Ensures that the periodic and regular review of such orders and protocols is conducted by the medical staff and the hospital's nursing and pharmacy leadership to determine the continuing usefulness and safety of the orders and protocols; and (iv) Ensures that such orders and protocols are dated, timed, and authenticated promptly in the patient's medical record by the ordering practitioner or by another practitioner responsible for the care of the patient only if such a practitioner is acting in accordance with State law, including scope-of-practice laws, hospital policies and medical staff bylaws, rules, and regulations.
1814	(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.	**42 C.F.R. § 482.23(c)(3)** With the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved hospital policy after an assessment of contraindications, orders for drugs and biologicals must be documented and signed by a practitioner who is authorized to write orders by hospital policy and in accordance with State law, and who is responsible for the care of the patient as specified under § 482.12(c). (i) If verbal orders are used, they are to be used infrequently.

		(ii) When verbal orders are used, they must only be accepted by persons who are authorized to do so by hospital policy and procedures consistent with Federal and State law. (iii) Orders for drugs and biologicals may be documented and signed by other practitioners not specified under 482.12(c) only if such practitioners are acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff by laws, rules, and regulations.
1815	(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."	
1816	(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.	**42 C.F.R. § 482.23(c)(3)** With the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved hospital policy after an assessment of contraindications, orders for drugs and biologicals must be documented and signed by a practitioner who is authorized to write orders by hospital policy and in accordance with State law, and who is responsible for the care of the patient as specified under § 482.12(c). (i) If verbal orders are used, they are to be used infrequently. (ii) When verbal orders are used, they must only be accepted by persons who are authorized to do so by hospital policy and procedures consistent with Federal and State law. (iii) Orders for drugs and biologicals may be documented and signed by other practitioners not specified under 482.12(c) only if such practitioners are acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff by laws, rules, and regulations.
1817	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.	
1818	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.	
1819	(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.	
1820	(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.	
1821	(a) **Inpatient Records.** Medical records for inpatients shall contain at least the following:	

1822	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;	**42 C.F.R. § 482.24(b) Standard: Form and retention of records.** The hospital must maintain a medical record for each inpatient and outpatient. Medical records must be accurately written, promptly completed, properly filed and retained, and accessible. The hospital must use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries.
1823	2. The date and time of the patient's admission;	
1824	3. The admitting diagnosis and clinical symptoms;	**42 C.F.R. § 482.24(c)(4)** All records must document the following, as appropriate: (ii) Admitting diagnosis.
1825	4. The name of the attending physician;	
1826	5. Any patient allergies;	
1827	6. Documentation regarding advanced directives;	
1828	7. The report from the history and physical examination;	**42 C.F.R. § 482.24(c)(4)** All records must document the following, as appropriate: (i) Evidence of— (A) A medical history and physical examination completed and documented no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. The medical history and physical examination must be placed in the patient's medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. (B) An updated examination of the patient, including any changes in the patient's condition, when the medical history and physical examination are completed within 30 days before admission or registration. Documentation of the updated examination must be placed in the patient's medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.
1829	8. The report of the nursing assessment performed after admission;	**42 C.F.R. § 482.24(c)(4)** All records must document the following, as appropriate: (vi) All practitioners' orders, nursing notes, reports of treatment, medication records, radiology and laboratory reports, and vital signs and other information necessary to monitor the patient's condition.
1830	9. Laboratory, radiological, electrocardiogram, and other diagnostic assessment data or reports as indicated;	**42 C.F.R. § 482.24(c)(4)** All records must document the following, as appropriate: (vi) All practitioners' orders, nursing notes, reports of treatment, medication records, radiology and laboratory reports, and vital signs and other information necessary to monitor the patient's condition. **42 C.F.R. § 482.53(d) Standard: Records.** The hospital must maintain signed and dated reports of nuclear medicine interpretations, consultations and procedures.
1831	10. Reports from any consultations;	**42 C.F.R. § 482.24(c)(4)** All records must document the following, as appropriate:

		(iii) Results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient. **42 C.F.R. § 482.53(d) Standard: Records.** The hospital must maintain signed and dated reports of nuclear medicine interpretations, consultations and procedures.
1832	11. The patient's plan of care;	**42 C.F.R. § 482.24(c)(4)** All records must document the following, as appropriate: (vi) All practitioners' orders, nursing notes, reports of treatment, medication records, radiology and laboratory reports, and vital signs and other information necessary to monitor the patient's condition.
1833	12. Physician's orders or orders from another practitioner authorized by law to give medical or treatment orders;	**42 C.F.R. § 482.24(c)(4)** All records must document the following, as appropriate: (vi) All practitioners' orders, nursing notes, reports of treatment, medication records, radiology and laboratory reports, and vital signs and other information necessary to monitor the patient's condition.
1834	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;	**42 C.F.R. § 482.24(c)(4)** All records must document the following, as appropriate: (iv) Documentation of complications, hospital acquired infections, and unfavorable reactions to drugs and anesthesia. (vi) All practitioners' orders, nursing notes, reports of treatment, medication records, radiology and laboratory reports, and vital signs and other information necessary to monitor the patient's condition.
1835	14. Data, or summary data where appropriate, from routine or special monitoring;	
1836	15. Medication, anesthesia, surgical, and treatment records;	**42 C.F.R. § 482.24(c)(4)** All records must document the following, as appropriate: (vi) All practitioners' orders, nursing notes, reports of treatment, medication records, radiology and laboratory reports, and vital signs and other information necessary to monitor the patient's condition. **42 C.F.R. § 482.51(b)(6)** An operative report describing techniques, findings, and tissues removed or altered must be written or dictated immediately following surgery and signed by the surgeon.
1837	16. Documentation that the patient has been offered the opportunity to consent to procedures for which consent is required by law;	**42 C.F.R. § 482.24(c)(4)** All records must document the following, as appropriate: (v) Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law, if applicable, to require written patient consent.
1838	17. Date and time of discharge;	**42 C.F.R. § 482.24(c)(4)** All records must document the following, as appropriate: (vii) Discharge summary with outcome of hospitalization, disposition of case and provisions for follow-up care.
1839	18. Description of condition, final diagnosis, and disposition on discharge or transfer;	**42 C.F.R. § 482.24(c)(4)** All records must document the following, as appropriate:

		(vii) Discharge summary with outcome of hospitalization, disposition of case and provisions for follow-up care. (viii) Final diagnosis with completion of medical records within 30 days following discharge.
1840	19. Discharge summary with a summary of the hospitalization and results of treatment; and	**42 C.F.R. § 482.24(c)(4)** All records must document the following, as appropriate: (vii) Discharge summary with outcome of hospitalization, disposition of case and provisions for follow-up care. **42 C.F.R. § 482.43(b)(6) Standard: Discharge planning evaluations.** The hospital must include the discharge planning evaluation in the patient's medical record for use in establishing an appropriate discharge plan and must discuss the results of the evaluation with the patient or individual acting on his or her behalf.
1841	20. If applicable, the report of autopsy results.	
1842	(b) **Outpatient Records.** Medical reports for outpatients shall contain at least the following:	
1843	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;	
1844	2. Diagnosis of the patient's condition;	
1845	3. The name of the physician ordering treatment or procedures;	
1846	4. Patient allergies;	
1847	5. Physician's orders or orders from another practitioner authorized by law to give medical or treatment orders as applicable;	
1848	6. Documentation that the patient has been offered the opportunity to consent to procedures for which consent is required by law;	
1849	7. Reports from any diagnostic testing; and	
1850	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. **History:** Original Rule entitled "Medical Records" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.	
1900	**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.	**42 C.F.R. § 482.12(c)(2)** Patients are admitted to the hospital only on the recommendation of a licensed practitioner permitted by the State to admit patients to a hospital. If a Medicare patient is admitted by a practitioner not specified in paragraph (c)(1) of this section, that patient is under the care of a doctor of medicine or osteopathy.
1901	(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.	

1902	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.	**42 C.F.R. § 482.22(c) Standard: Medical staff bylaws.** The medical staff must adopt and enforce bylaws to carry out its responsibilities. The bylaws must: (5) Include a requirement that— (i) A medical history and physical examination be completed and documented for each patient no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. The medical history and physical examination must be completed and documented by a physician (as defined in section 1861(r) of the Act), an oromaxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy. (ii) An updated examination of the patient, including any changes in the patient's condition, be completed and documented within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, when the medical history and physical examination are completed within 30 days before admission or registration. The updated examination of the patient, including any changes in the patient's condition, must be completed and documented by a physician (as defined in section 1861(r) of the Act), an oromaxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy.
1903	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:	
1904	(i) Screening and referral for further assessment of patient needs related to social, nutritional, and functional status; and	**42 C.F.R. § 482.24(c)(4)** All records must document the following, as appropriate: (vi) All practitioners' orders, nursing notes, reports of treatment, medication records, radiology and laboratory reports, and vital signs and other information necessary to monitor the patient's condition.
1905	(ii) Screening of educational and potential post-hospitalization needs.	
1906	3. Inquiry as to the status of any advance directives for the patient shall be made at the time of admission.	**42 C.F.R. § 482.13(b)(3)** The patient has the right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these directives, in accordance with §489.100 of this part (Definition), §489.102 of this part (Requirements for providers), and §489.104 of this part (Effective dates).
1907	(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.	
1908	(ii) If the patient does not have anadvance directive in place, admissions procedures shall require that designated hospital personnel will offer information regarding advance directives according to hospital policy and timelines.	**42 C.F.R. § 482.13** (b)(4) The patient has the right to have a family member or representative of his or her choice and his or her own physician notified promptly of his or her admission to the hospital… (h) Standard: Patient visitation rights. A hospital must have

		written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights and the reasons for the clinical restriction or limitation. A hospital must meet the following requirements: (1) Inform each patient (or support person, where appropriate) of his or her visitation rights, including any clinical restriction or limitation on such rights, when he or she is informed of his or her other rights under this section. (2) Inform each patient (or support person, where appropriate) of the right, subject to his or her consent, to receive the visitors whom he or she designates, including, but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend, and his or her right to withdraw or deny such consent at any time. (3) Not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability. (4) Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.
1909	(b) **Patient's Plan of Care.**	
1910	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.	**42 C.F.R. § 482.23(b)(4)** The hospital must ensure that the nursing staff develops and keeps current a nursing care plan for each patient. The nursing care plan may be part of an interdisciplinary care plan.
1911	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.	
1912	(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:	
1913	1. During and following an invasive procedure;	
1914	2. Following a change in the patient's condition or level of care;	
1915	3. During and following the administration of blood and blood products;	
1916	4. Following any adverse drug reaction or allergic reaction; and	
1917	5. During and following any use of physical restraints or seclusion.	**42 C.F.R. § 482.13(e)(10)** The condition of the patient who is restrained or secluded must be monitored by a physician, other licensed independent practitioner or trained staff that have completed the training criteria specified in paragraph (f) of this section at an interval determined by hospital policy.
1918	(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.	**42 C.F.R. § 482.13(b) Standard: Exercise of rights.** (1) The patient has the right to participate in the development and implementation of his or her plan of care. (2) The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate…

		(4) The patient has the right to have a family member or representative of his or her choice and his or her own physician notified promptly of his or her admission to the hospital.
1919	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.	**42 C.F.R. § 482.13(e) Standard: Restraint or seclusion.** All patients have the right to be free from physical or mental abuse, and corporal punishment. All patients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time. (1) Definitions. (i) A restraint is— (A) Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely; or (B) A drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition. (C) A restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort). (ii) Seclusion is the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. Seclusion may only be used for the management of violent or self-destructive behavior. (2) Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient a staff member or others from harm. (3) The type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient, a staff member, or others from harm. (4) The use of restraint or seclusion must be— (i) In accordance with a written modification to the patient's plan of care; and (ii) Implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by hospital policy in accordance with State law. (5) The use of restraint or seclusion must be in accordance with the order of a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under § 482.12(c) and authorized to order restraint or seclusion by hospital policy in accordance with State law. (6) Orders for the use of restraint or seclusion must never be written as a standing order or on an as needed basis (PRN). (7) The attending physician must be consulted as soon as possible if the attending physician did not order the restraint or seclusion.

		(8) Unless superseded by State law that is more restrictive— (i) Each order for restraint or seclusion used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others may only be renewed in accordance with the following limits for up to a total of 24 hours: (A) 4 hours for adults 18 years of age or older; (B) 2 hours for children and adolescents 9 to 17 years of age; or (C) 1 hour for children under 9 years of age; and (ii) After 24 hours, before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior, a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under § 482.12(c) of this part and authorized to order restraint or seclusion by hospital policy in accordance with State law must see and assess the patient. (iii) Each order for restraint used to ensure the physical safety of the nonviolent or non-self-destructive patient may be renewed as authorized by hospital policy. (9) Restraint or seclusion must be discontinued at the earliest possible time, regardless of the length of time identified in the order. (10) The condition of the patient who is restrained or secluded must be monitored by a physician, other licensed independent practitioner or trained staff that have completed the training criteria specified in paragraph (f) of this section at an interval determined by hospital policy. (11) Physician and other licensed independent practitioner training requirements must be specified in hospital policy. At a minimum, physicians and other licensed independent practitioners authorized to order restraint or seclusion by hospital policy in accordance with State law must have a working knowledge of hospital policy regarding the use of restraint or seclusion. (12) When restraint or seclusion is used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient must be seen face-to-face within 1 hour after the initiation of the intervention— (i) By a— (A) Physician or other licensed independent practitioner; or (B) Registered nurse or physician assistant who has been trained in accordance with the requirements specified in paragraph (f) of this section. (ii) To evaluate— (A) The patient's immediate situation; (B) The patient's reaction to the intervention; (C) The patient's medical and behavioral condition; and (D) The need to continue or terminate the restraint or seclusion. (13) States are free to have requirements by statute or regulation that are more restrictive than those contained in paragraph (e)(12)(i) of this section. (14) If the face-to-face evaluation specified in paragraph (e)(12) of this section is conducted by a trained registered nurse or physician assistant, the trained

		registered nurse or physician assistant must consult the attending physician or other licensed independent practitioner who is responsible for the care of the patient as specified under § 482.12(c) as soon as possible after the completion of the 1-hour face-to-face evaluation. (15) All requirements specified under this paragraph are applicable to the simultaneous use of restraint and seclusion. Simultaneous restraint and seclusion use is only permitted if the patient is continually monitored— (i) Face-to-face by an assigned, trained staff member; or (ii) By trained staff using both video and audio equipment. This monitoring must be in close proximity to the patient. (16) When restraint or seclusion is used, there must be documentation in the patient's medical record of the following: (i) The 1-hour face-to-face medical and behavioral evaluation if restraint or seclusion is used to manage violent or self-destructive behavior; (ii) A description of the patient's behavior and the intervention used; (iii) Alternatives or other less restrictive interventions attempted (as applicable); (iv) The patient's condition or symptom(s) that warranted the use of the restraint or seclusion; and (v) The patient's response to the intervention(s) used, including the rationale for continued use of the intervention.
1920	3. Patients shall receive care in a manner free from all forms of abuse or neglect.	**42 C.F.R. § 482.13(c) Standard: Privacy and safety.** (2) The patient has the right to receive care in a safe setting. (3) The patient has the right to be free from all forms of abuse or harassment.
1921	4. Patients shall receive treatment in an environment that respects their personal privacy, both of their physical person and their treatment information.	**42 C.F.R. § 482.13(c) Standard: Privacy and safety.** (1) The patient has the right to personal privacy.
1922	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. **History:** Original Rule entitled "Patient Assessment and Treatment" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.	
2000	**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.	**42 C.F.R. § 482.43 Condition of participation: Discharge planning.** The hospital must have in effect a discharge planning process that applies to all patients. The hospital's policies and procedures must be specified in writing.
2001	(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.	**42 C.F.R. § 482.43(a) Standard: Identification of patients in need of discharge planning.** The hospital must identify at an early stage of hospitalization all patients who are likely to suffer adverse health consequences upon discharge if there is no adequate discharge planning.
2002	(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.	**42 C.F.R. § 482.43(b) Standard: Discharge planning evaluation.** (1) The hospital must provide a discharge planning evaluation to the patients identified in paragraph (a) of this section, and to other patients upon the patient's request, the request of a person acting on the patient's behalf, or the request of the physician. (2) A registered nurse, social worker, or other appropriately qualified personnel must develop, or supervise the development of, the evaluation.

		(3) The discharge planning evaluation must include an evaluation of the likelihood of a patient needing post-hospital services and of the availability of the services. **42 C.F.R. § 482.43(c) Standard: Discharge plan.** (1) A registered nurse, social worker, or other appropriately qualified personnel must develop or supervise the development of a discharge plan if the discharge planning evaluation indicates a need for a discharge plan. (2) In the absence of a finding by a hospital that a patient needs a discharge plan, the patient's physician may request a discharge plan. In such a case, the hospital must develop a discharge plan for the patient.
2003	(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.	**42 C.F.R. § 482.43(c)(5)** As needed, the patient and family members or interested persons must be counseled to prepare them for post-hospital care.
2004	(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.	**42 C.F.R. § 482.43(b) Standard: Discharge planning evaluation.** (3) The discharge planning evaluation must include an evaluation of the likelihood of a patient needing post-hospital services and of the availability of the services. (4) The discharge planning evaluation must include an evaluation of the likelihood of a patient's capacity for self-care or of the possibility of the patient being cared for in the environment from which he or she entered the hospital… (5) The hospital personnel must complete the evaluation on a timely basis so that appropriate arrangements for post-hospital care are made before discharge, and to avoid unnecessary delays in discharge… **42 C.F.R. § 482.43(c) Standard: Discharge plan.** (3) The hospital must arrange for the initial implementation of the patient's discharge plan… (6) The hospital must include in the discharge plan a list of HHAs or SNFs that are available to the patient, that are participating in the Medicare program, and that serve the geographic area (as defined by the HHA) in which the patient resides, or in the case of a SNF, in the geographic area requested by the patient. HHAs must request to be listed by the hospital as available. (i) This list must only be presented to patients for whom home health care or post-hospital extended care services are indicated and appropriate as determined by the discharge planning evaluation. (ii) For patients enrolled in managed care organizations, the hospital must indicate the availability of home health and post-hospital extended care services through individuals and entities that have a contract with the managed care organizations. (iii) The hospital must document in the patient's medical record that the list was presented to the patient or to the individual acting on the patient's behalf. (7) The hospital, as part of the discharge planning process, must inform the patient or the patient's family of their freedom to choose among participating Medicare providers of post-hospital care services and must, when possible, respect patient and family preferences when they are expressed. The hospital must not specify or otherwise limit the qualified providers that are available to the patient.

		(8) The discharge plan must identify any HHA or SNF to which the patient is referred in which the hospital has a disclosable financial interest, as specified by the Secretary, and any HHA or SNF that has a disclosable financial interest in a hospital under Medicare. Financial interests that are disclosable under Medicare are determined in accordance with the provisions of Part 420, Subpart C, of this chapter. **42 C.F.R. § 482.43(d) Standard: Transfer or referral.** The hospital must transfer or refer patients, along with the necessary medical information, to appropriate facilities, agencies, or outpatient services, as needed, for follow-up or ancillary care. **42 C.F.R. § 482.30(d) Standard: Determination regarding admissions or continued stays.** (1) The determination that an admission or continued stay is not medically necessary— (i) May be made by one member of the UR committee if the practitioner or practitioners responsible for the care of the patient, as specified of §482.12(c), concur with the determination or fail to present their views when afforded the opportunity; and (ii) Must be made by at least two members of the UR committee in all other cases. (2) Before making a determination that an admission or continued stay is not medically necessary, the UR committee must consult the practitioner or practitioners responsible for the care of the patient, as specified in §482.12(c), and afford the practitioner or practitioners the opportunity to present their views. (3) If the committee decides that admission to or continued stay in the hospital is not medically necessary, written notification must be given, no later than 2 days after the determination, to the hospital, the patient, and the practitioner or practitioners responsible for the care of the patient, as specified in §482.12(c); **42 C.F.R. § 482.30(e) Standard: Extended stay review.** (1) In hospitals that are not paid under the prospective payment system, the UR committee must make a periodic review, as specified in the UR plan, or each current inpatient receiving hospital services during a continuous period of extended duration. The scheduling of the periodic reviews may— (i) Be the same for all cases; or (ii) Differ for different classes of cases. (2) In hospitals paid under the prospective payment system, the UR committee must review all cases reasonably assumed by the hospital to be outlier cases because the extended length of stay exceeds the threshold criteria for the diagnosis, as described in §412.80(a)(1)(i). The hospital is not required to review an extended stay that does not exceed the outlier threshold for the diagnosis. (3) The UR committee must make the periodic review no later than 7 days after the day required in the UR plan.

2005	(e) The hospital shall regularly reassess the discharge planning process to ensure that it is responsive to patients' discharge needs.	**42 C.F.R. § 482.43(c)(4)** The hospital must reassess the patient's discharge plan if there are factors that may affect continuing care needs or the appropriateness of the discharge plan. **42 C.F.R. § 482.43(e) Standard: Reassessment.** The hospital must reassess its discharge planning process on an on-going basis. The reassessment must include a review of discharge plans to ensure that they are responsive to 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. **History:** Original Rule entitled "Discharge Planning and Transfers for Inpatients" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.	
2100	**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.	**42 C.F.R. § 482.23 Condition of participation: Nursing services.** The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse….(b)(1) The hospital must provide 24-hour nursing services furnished or supervised by a registered nurse, and have a licensed practical nurse or a registered nurse on duty at all times, except for rural hospitals that have in effect a 24-hour nursing waiver granted under §488.54(c) of this chapter.
2101	(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.	**42 C.F.R. § 482.23 Condition of participation: Nursing services.** The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse.
2102	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.	**42 C.F.R. § 482.23(a) Standard: Organization.** The hospital must have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care. The director of the nursing service must be a licensed registered nurse. He or she is responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital.
2103	2. The chief nurse executive shall be responsible for ensuring that nursing personnel are oriented to nursing policies and procedures.	
2104	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.	**42 C.F.R. § 482.23(a) Standard: Organization.** The hospital must have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care. The director of the nursing service must be a licensed registered nurse. He or she is responsible for the operation of the service,

		including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital.
2105	(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.	**42 C.F.R. § 482.23(b) Standard: Staffing and delivery of care.** The nursing service must have adequate numbers of licensed registered nurses, licensed practical (vocational) nurses, and other personnel to provide nursing care to all patients as needed. There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for bedside care of any patient… (6) Non-employee licensed nurses who are working in the hospital must adhere to the policies and procedures of the hospital. The director of nursing service must provide for the adequate supervision and evaluation of the clinical activities of non-employee nursing personnel which occur within the responsibility of the nursing services.
2106	(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.	
2107	(iii) A system of patient assignment shall be defined which reflects a consideration of patient needs and nursing staff qualifications and competencies.	**42 C.F.R. § 482.23(b)(5)** A registered nurse must assign the nursing care of each patient to other nursing personnel in accordance with the patient's needs and the specialized qualifications and competence of the nursing staff available.
2108	(b) **Delivery of Nursing Services.** Nursing services must be delivered in accordance with patients' needs and generally accepted standards of practice.	
2109	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.	**42 C.F.R. § 482.23(b)** The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse. (1) The hospital must provide 24-hour nursing services furnished or supervised by a registered nurse, and have a licensed practical nurse or registered nurse on duty at all times, except for rural hospitals that have in effect a 24-hour nursing waiver granted under Sec. 488.54 of this chapter. (3) A registered nurse must supervise and evaluate the nursing care for each patient.
2110	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.	**42 C.F.R. § 482.23(b)(4)** The hospital must ensure that the nursing staff develops and keeps current a nursing care plan for each patient. The nursing care plan may be part of an interdisciplinary care plan. **42 C.F.R. § 482.24(c)(4)** All records must document the following, as appropriate: (vi) All practitioners' orders, nursing notes, reports of treatment, medication records, radiology and laboratory reports, and vital signs and other information necessary to monitor the patient's condition.
2111	3. The patient's condition shall be monitored by nursing staff on a schedule appropriate to the patient's needs.	**42 C.F.R. § 482.23(b)(5)** A registered nurse must assign the nursing care of each patient to other nursing personnel in accordance with the patient's needs and the specialized qualifications and competence of the nursing staff available.

2112	4. Nursing staff shall be responsible for updating the patient's plan of care based on any changes in the patient's condition.	**42 C.F.R. § 482.23(b)(4)** The hospital must ensure that the nursing staff develops and keeps current a nursing care plan for each patient. The nursing care plan may be part of an interdisciplinary care plan. **42 C.F.R. § 482.24(c)(4)** All records must document the following, as appropriate: (vi) All practitioners' orders, nursing notes, reports of treatment, medication records, radiology and laboratory reports, and vital signs and other information necessary to monitor the patient's condition.
2113	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.	**42 C.F.R. § 482.23(c) Standard: Preparation and administration of drugs.** (1) Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under §482.12(c), and accepted standards of practice. (i) Drugs and biologicals may be prepared and administered on the orders of other practitioners not specified under § 482.12(c) only if such practitioners are acting in accordance with State law, including scope-of practice laws, hospital policies, and medical staff bylaws, rules, and regulations. (ii) Drugs and biologicals may be prepared and administered on the orders contained within pre-printed and electronic standing orders, order sets, and protocols for patient orders only if such orders meet the requirements of § 482.24(c)(3). (2) All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures. (3) With the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved hospital policy after an assessment of contraindications, orders for drugs and biologicals must be documented and signed by a practitioner who is authorized to write orders in accordance with State law and hospital policy, and who is responsible for the care of the patient as specified under § 482.12(c). (i) If verbal orders are used, they are to be used infrequently. (ii) When verbal orders are used, they must only be accepted by persons who are authorized to do so by hospital policy and procedures consistent with Federal and State law. (iii) Orders for drugs and biologicals may be documented and signed by other practitioners not specified under § 482.12(c) only if such practitioners are acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations. (4) Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures. (5) There must be a hospital procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.

		(6) The hospital may allow a patient (or his or her caregiver/support person where appropriate) to self-administer both hospital-issued medications and the patient's own medications brought into the hospital, as defined and specified in the hospital's policies and procedures. (i) If the hospital allows a patient to self-administer specific hospital-issued medications, then the hospital must have policies and procedures in place to: (A) Ensure that a practitioner responsible for the care of the patient has issued an order, consistent with hospital policy, permitting self-administration. (B) Assess the capacity of the patient (or the patient's caregiver/support person where appropriate) to self-administer the specified medication(s). (C) Instruct the patient (or the patient's caregiver/support person where appropriate) in the safe and accurate administration of the specified medication(s). (D) Address the security of the medication(s) for each patient. (E) Document the administration of each medication, as reported by the patient (or the patient's caregiver/ support person where appropriate), in the patient's medical record. (ii) If the hospital allows a patient to self-administer his or her own specific medications brought into the hospital, then the hospital must have policies and procedures in place to: (A) Ensure that a practitioner responsible for the care of the patient has issued an order, consistent with hospital policy, permitting self-administration of medications the patient brought into the hospital. (B) Assess the capacity of the patient (or the patient's caregiver/support person where appropriate) to self-administer the specified medication(s), and also determine if the patient (or the patient's caregiver/support person where appropriate) needs instruction in the safe and accurate administration of the specified medication(s). (C) Identify the specified medication(s) and visually evaluate the medication(s) for integrity. (D) Address the security of the medication(s) for each patient. (E) Document the administration of each medication, as reported by the patient (or the patient's caregiver/support person where appropriate), in the patient's medical record.
2114	6. Nursing staff shall report medication administration errors and adverse drug reactions in accordance with established hospital policies.	**42 C.F.R. § 482.21(c)(2)** Performance improvement activities must track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospital.
2115	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:	**42 C.F.R. § 482.23(c) Standard: Preparation and administration of drugs.** (4) Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures… (5) There must be a hospital procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.
2116	(i) Obtaining and documenting appropriate patient consent to treatment and procedures, as required;	**42 C.F.R. § 482.13(b) Standard: Exercise of rights.** (1) The patient has the right to participate in the development and implementation of his or her plan of care.

		(2) The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.
2117	(ii) Responding to and reporting of transfusion reactions;	**42 C.F.R. § 482.23(c)(5)** There must be a hospital procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.
2118	(iii) Monitoring patients appropriately; and	
2119	(iv) Designating personnel qualified to perform these procedures. Authority: O.C.G.A. § 31-7-2.1. **History:** Original Rule entitled "Nursing Services" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.	
2200	**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.	**42 C.F.R. § 482.25 Condition of participation: Pharmaceutical services.** The hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service. (a) Standard: Pharmacy management and administration. The pharmacy or drug storage area must be administered in accordance with accepted professional principles.
2201	(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:	**42 C.F.R. § 482.25(a)(1)** A full-time, part-time, or consulting pharmacist must be responsible for developing, supervising, and coordinating all the activities of the pharmacy services.
2202	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	
2203	2. Developing and implementing an effective system that does the following:	
2204	(i) Minimizes drug errors and identifies potential drug interactions and adverse drug reactions;	
2205	(ii) Controls the availability and storage of drugs throughout the hospital;	
2206	(iii) Distributes and administers the drugs in compliance with generally accepted standards of practice;	**42 C.F.R. § 482.25(a) Standard: Pharmacy management and administration.** The pharmacy or drug storage area must be administered in accordance with accepted professional principles.
2207	(iv) Tracks the receipt and disposition of all scheduled drugs;	**42 C.F.R. § 482.25(a)(3)** Current and accurate records must be kept on the receipt and disposition of all scheduled drugs.
2208	(v) Staffs pharmaceutical services to provide sufficient qualified personnel to respond to the pharmaceutical needs of the patient population being served,	**42 C.F.R. § 482.25(a)(2)** The pharmaceutical services must have an adequate number of personnel to ensure quality pharmaceutical services, including emergency services.

	including twenty-four (24) hours per day, seven (7) days per week emergency coverage;	
2209	(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;	**42 C.F.R. § 482.25(b) Standard: Delivery of services.** In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law. (1) All compounding, packaging, and dispensing of drugs and biologicals must be under the supervision of a pharmacist and performed consistent with State and Federal laws.
2210	(vii) Manages drug recalls;	**42 C.F.R. § 482.25(b)(3)** Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use.
2211	(viii) Addresses the removal of drugs when a pharmacist is not available;	**42 C.F.R. § 482.25(b)(4)** When a pharmacist is not available, drugs and biologicals must be removed from the pharmacy or storage area only by personnel designated in the policies of the medical staff and pharmaceutical service, in accordance with Federal and State law.
2212	(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	**42 C.F.R. § 482.25(b)(6)** Drug administration errors, adverse drug reactions, and incompatibilities must be immediately reported to the attending physician and, if appropriate, to the hospital's quality assessment and performance improvement program.
2213	(x) Reviews all activities and functions of the hospital's pharmaceutical services.	
2214	(b) **Management of Drugs.** The pharmacist shall be responsible for the management of drugs within the hospital.	**42 C.F.R. § 482.25(b)(9)** A formulary system must be established by the medical staff to assure quality pharmaceuticals at reasonable costs
2215	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.	**42 C.F.R. § 482.25(b)(8)** Information relating to drug interactions and information on drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration must be available to the professional staff.
2216	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.	**42 C.F.R. § 482.25(b)(7)** Abuses and losses of controlled substances must be reported, in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.
2217	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.	**42 C.F.R. § 482.25(b)(2)(i)** All drugs and biologicals must be kept in a secure area, and locked when appropriate. (ii) Drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 must be kept locked within a secure area. (iii) Only authorized personnel may have access to locked areas.
2218	4. Outdated, mislabeled, or otherwise unusable drugs and pharmaceuticals shall not be available for patient use.	**42 C.F.R. § 482.25(b)(3)** Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use.
2219	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.	**42 C.F.R. § 482.25(b)(5)** Drugs and biologicals not specifically prescribed as to time or number of doses must automatically be stopped after a reasonable time that is pre-determined by the medical staff.

2220	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.	**42 C.F.R. § 482.25(b)(6)** Drug administration errors, adverse drug reactions, and incompatibilities must be immediately reported to the attending physician and, if appropriate, to the hospital's quality assessment and performance improvement program.
2221	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. **History:** Original Rule entitled "Pharmaceutical Services" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.	
2300	**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.	**42 C.F.R. § 482.28 Condition of participation: Food and dietetic services.** The hospital must have organized dietary services that are directed and staffed by adequate qualified personnel. However, a hospital that has a contract with an outside food management company may be found to meet this Condition of Participation if the company has a dietitian who serves the hospital on a full-time, part-time, consultant basis, and if the company maintains at least the minimum standards specified in this section and provides for constant liaison with the hospital medical staff for recommendations on dietetic policies affecting patient treatment.
2301	(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:	**42 C.F.R. § 482.28(a) Standard: Organization.** (1) The hospital must have a full-time employee who— (i) Serves as director of the food and dietetic services; (ii) Is responsible for daily management of the dietary services; and (iii) Is qualified by experience or training… (3) There must be administrative and technical personnel competent in their respective duties.
2302	(i) Overall coordination and integration of the therapeutic and administrative aspects of the service;	
2303	(ii) Development and implementation of policies and procedures concerning the scope and conduct of dietary services, including food preparation and delivery systems;	
2304	(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;	
2305	(iv) The implementation of a system to ensure that prescribed diets are delivered to the correct inpatients;	**42 C.F.R. § 482.28(b) Standard: Diets.** Menus must meet the needs of the patients. (1) Individual patient nutritional needs must be met in accordance with recognized dietary practices. (2) All patient diets, including therapeutic diets, must be ordered by a practitioner responsible for the care of the patient, or by a qualified dietitian or qualified

		nutrition professional as authorized by the medical staff and in accordance with State law governing dietitians and nutrition professionals.
2306	(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;	
2307	(vi) Procurement of food, paper, chemical, and other supplies sufficient to meet the anticipated food service needs of the hospital; and	
2308	(vii) Implementation of procedures to rotate all food items to ensure use in a timely manner.	
2309	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:	**42 C.F.R. § 482.28(a)(2)** There must be a qualified dietician, full-time, part-time, or on a consultant basis.
2310	(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;	
2311	(ii) Review and approval of all menus, including menus for therapeutic or prescribed diets;	
2312	(iii) Participation in the development, revision, and review of policies and procedures for dietary services;	
2313	(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	
2314	(v) Appropriate documentation in the inpatients' medical records of any evaluation of nutritional status or needs.	
2315	(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.	
2316	(c) **Delivery of Dietary Services.** Dietary services shall be delivered in accordance with the nutritional needs of the hospital's patients.	
2317	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.	
2318	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.	**42 C.F.R. § 482.28(b) Standard: Diets.** Menus must meet the needs of the patients.

		(1) Individual patient nutritional needs must be met in accordance with recognized dietary practices. (2) All patient diets, including therapeutic diets, must be ordered by a practitioner responsible for the care of the patient, or by a qualified dietitian or qualified nutrition professional as authorized by the medical staff and in accordance with State law governing dietitians and nutrition professionals. (3) A current therapeutic diet manual approved by the dietitian and medical staff must be readily available to all medical, nursing, and food service personnel.
2319	3. Therapeutic diets shall be prescribed by the member of the medical staff responsible for the care of the inpatient.	**42 C.F.R. § 482.28(b) Standard: Diets.** Menus must meet the needs of the patients. (1) Individual patient nutritional needs must be met in accordance with recognized dietary practices. (2) All patient diets, including therapeutic diets, must be ordered by a practitioner responsible for the care of the patient, or by a qualified dietitian or qualified nutrition professional as authorized by the medical staff and in accordance with State law governing dietitians and nutrition professionals.
2320	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.	
2321	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.	
2322	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.	
2323	7. There shall be a system for providing means for inpatients outside the normal meal service hours, when necessary.	
2324	8. A system for meal requisition shall be in place and shall require a notation regarding the inpatients' food allergies, if any.	
2325	9. Snacks shall be available between meals and at night, as appropriate to each patient's needs and medical condition.	
2326	10. The dietary service shall follow policies and procedures approved by the medical staff for the management of possible food and drug interactions.	
2327	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. **History:** Original Rule entitled "Food and Dietary Services" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.	
2400	**111-8-40-.24 Imaging and Therapeutic Radiology Services**	
2401	(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.	**42 C.F.R. § 482.26 Condition of participation: Radiologic services.** The hospital must maintain, or have available, diagnostic radiologic services. If therapeutic services are also provided, they, as well as the diagnostic services, must meet professionally approved standards for safety and personnel qualifications. (a) Standard: Radiologic services. The hospital must maintain, or have available, radiologic services according to needs of the patients.

2402	(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.	**42 C.F.R. § 482.26(c) Standard: Personnel.** (1) A qualified full-time, part-time, or consulting radiologist must supervise the ionizing radiology services and must interpret only those radiologic tests that are determined by the medical staff to require a radiologist's specialized knowledge. For purposes of this section, a radiologist is a doctor of medicine or osteopathy who is qualified by education and experience in radiology.
2403	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.	**42 C.F.R. § 482.26(c)(2)** Only personnel designated as qualified by the medical staff may use the radiologic equipment and administer procedures.
2404	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.	**42 C.F.R. § 482.26(c)(2)** Only personnel designated as qualified by the medical staff may use the radiologic equipment and administer procedures.
2405	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.	
2406	4. The hospital shall have qualified staff performing imaging services.	**42 C.F.R. § 482.26(c)(2)** Only personnel designated as qualified by the medical staff may use the radiologic equipment and administer procedures.
2407	(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.	**42 C.F.R. § 482.26(b)(4)** Radiologic services must be provided only on the order of practitioners with clinical privileges or, consistent with State law, of other practitioners authorized by the medical staff and the governing body to order the services.
2408	(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.	**42 C.F.R. § 482.26(b)(4)** Radiologic services must be provided only on the order of practitioners with clinical privileges or, consistent with State law, of other practitioners authorized by the medical staff and governing body to order the services.
2409	(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.	
2410	(a) Reports of all imaging interpretations and consultations shall be included in the patient's medical record.	**42 C.F.R. § 482.26(d) Standards. Records.** Records of radiologic services must be maintained. (1) The radiologist or other practitioner who performs radiology services must sign reports of his or her interpretations.
2411	(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.	
2412	(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,	**42 C.F.R. § 482.26(d)(2)** The hospital must maintain the following for at least five years: (i) Copies of reports and printouts

	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.	(ii) Films, scans, and other image records, as appropriate.
2413	(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.	**42 C.F.R. § 482.26 Condition of participation: Radiologic services.** The hospital must maintain, or have available, diagnostic radiologic services. If therapeutic services are also provided, they, as well as the diagnostic services, must meet professionally approved standards for safety and personnel qualifications.
2414	(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.	
2415	(b) Reports of all imaging interpretations, consultations, and therapies shall be included in the patient's medical record.	
2416	(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.	**42 C.F.R. § 482.26(b) Standard: Safety for patients and personnel.** The radiologic services, particularly ionizing radiology procedures, must be free from hazards for patients and personnel. (1) Proper safety precautions must be maintained against radiation hazards. This includes adequate shielding for patients, personnel, and facilities, as well as appropriate storage, use, and disposal of radioactive materials. (2) Periodic inspection of equipment must be made and hazards identified must be promptly corrected. (3) Radiation workers must be checked periodically, by the use of exposure meters or badge tests, for amount of radiation exposure
2417	(d) Medical Emergencies. The hospital shall have written protocols for managing medical emergencies in the imaging area and therapeutic radiology area.	
2418	(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. **History:** Original Rule entitled "Imaging and Therapeutic Radiology Services" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.	
2500	**111-8-40-.25 Laboratory Services** The hospital shall maintain or arrange for clinical laboratory services to meet the needs of hospital patients.	**42 C.F.R. § 482.27 Condition of participation: Laboratory services.** The hospital must maintain, or have available, adequate laboratory services to meet the needs of its patients. The hospital must ensure that all laboratory services provided to its patients are performed in a facility certified in accordance with Part 493 of this chapter. (a) Standard: Adequacy of laboratory services. The hospital must have laboratory services available, either directly or through a contractual agreement with a certified laboratory that meets the requirements of Part 493 of this chapter.
2501	(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.	

2502	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.	
2503	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.	
2504	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.	
2505	(b) The hospital shall have emergency laboratory services available at all times.	**42 C.F.R. § 482.27(a)(1)** Emergency laboratory services must be available 24 hours a day.
2506	(c) The hospital shall provide for medical staff a written description of all laboratory services available.	**42 C.F.R. § 482.27(a)(2)** A written description of services provided must be available to the medical staff.
2507	(d) Reports of laboratory procedures and results shall be included in the patient's medical record.	**42 C.F.R. § 482.24(c)(4)** All records must document the following, as appropriate: (vi) All practitioners' orders, nursing notes, reports of treatment, medication records, radiology and laboratory reports, and vital signs and other information necessary to monitor the patient's condition.
2508	(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.	
2509	(f) The hospital shall require that the laboratory report any epidemiologically significant pathogens to the hospital's infection control program.	**42 C.F.R. § 482.27(b) Standard: Potentially infectious blood and blood components—(1) Potentially human immunodeficiency virus (HIV) infectious blood and blood components.** Potentially HIV infectious blood and blood components are prior collections from a donor— (i) Who tested negative at the time of donation but tests reactive for evidence of HIV infection on a later donation; (ii) Who tests positive on the supplemental (additional, more specific) test or other follow-up testing required by FDA; and (iii) For whom the timing of seroconversion cannot be precisely estimated. (2) Potentially hepatitis C virus (HCV) infectious blood and blood components. Potentially HCV infectious blood and blood components are the blood and blood components identified in 21 CFR 610.47. (3) Services furnished by an outside blood collecting establishment. If a hospital regularly uses the services of an outside blood collecting establishment, it must have an agreement with the blood collecting establishment that governs the procurement, transfer, and availability of blood and blood components. The agreement must require that the blood collecting establishment notify the hospital— (i) Within 3 calendar days if the blood collecting establishment supplied blood and blood components collected from a donor who tested negative at the time of donation but tests reactive for evidence of HIV or HCV infection on a later

		donation or who is determined to be at increased risk for transmitting HIV or HCV infection; (ii) Within 45 days of the test, of the results of the supplemental (additional, more specific) test for HIV or HCV, as relevant, or other follow-up testing required by FDA; (iii) Within 3 calendar days after the blood collecting establishment supplied blood and blood components collected from an infectious donor, whenever records are available, as set forth at 21 CFR 610.48(b)(3). (4) Quarantine of blood and blood components pending completion of testing. If the blood collecting establishment (either internal or under an agreement) notifies the hospital of the reactive HIV or HCV screening test results, the hospital must determine the disposition of the blood or blood component and quarantine all blood and blood components from previous donations in inventory. (i) If the blood collecting establishment notifies the hospital that the result of the supplemental (additional, more specific) test or other follow-up testing required by FDA is negative, absent other informative test results, the hospital may release the blood and blood components from quarantine. (ii) If the blood collecting establishment notifies the hospital that the result of the supplemental (additional, more specific) test or other follow-up testing required by FDA is positive, the hospital must – (A) Dispose of the blood and blood components; and (B) Notify the transfusion recipients as set forth in paragraph (b)(6) of this section. (iii) If the blood collecting establishment notifies the hospital that the result of the supplemental (additional, more specific) test or other follow-up testing required by FDA is indeterminate, the hospital must destroy or label prior collections of blood or blood components held in quarantine as set forth at 21 CFR 610.46(b)(2), 610.47(b)(2), and 610.48(c)(2). (5) Recordkeeping by the hospital. The hospital must maintain -- (i) Records of the source and disposition of all units of blood and blood components for at least 10 years from the date of disposition in a manner that permits prompt retrieval; and (ii) A fully funded plan to transfer these records to another hospital or other entity if such hospital ceases operation for any reason. (6) Patient notification. If the hospital has administered potentially HIV or HCV infectious blood or blood components (either directly through its own blood collecting establishment or under an agreement) or released such blood or blood components to another entity or appropriate individual, the hospital must take the following actions: (i) Make reasonable attempts to notify the patient, or to notify the attending physician who ordered the blood or blood component and ask the physician to notify the patient, or other individual as permitted under paragraph (b)(10) of this section, that potentially HIV or HCV infectious blood or blood components were transfused to the patient and that there may be a need for HIV or HCV testing and counseling.

		(ii) If the physician is unavailable or declines to make the notification, make reasonable attempts to give this notification to the patient, legal guardian or relative. (iii) Document in the patient's medical record the notification or attempts to give the required notification. (7) Time frame for notification. (i) For donors tested on or after February 20, 2008. For notifications resulting from donors tested on or after February 20, 2008 as set forth at 21 CFR 610.46 and 21 CFR 610.47 the notification effort begins when the blood collecting establishment notifies the hospital that it received potentially HIV or HCV infectious blood and blood components. The hospital must make reasonable attempts to give notification over a period of 12 weeks unless-- (A) The patient is located and notified; or (B) The hospital is unable to locate the patient and documents in the patient's medical record the extenuating circumstances beyond the hospital's control that caused the notification timeframe to exceed 12 weeks. (ii) For donors tested before February 20, 2008. For notifications from donors tested before February 20, 2008 as set forth at 21 CFR 610.48(b) and (c), the notification effort begins when the blood collecting establishment notifies the hospital that it received potentially HCV infectious blood and blood components. The hospital must make reasonable attempts to give notification and must complete the actions within 1 year of the date on which the hospital received notification from the outside blood collecting establishment. (8) Content of notification. The notification must include the following information: (i) A basic explanation of the need for HIV or HCV testing and counseling. (ii) Enough oral or written information so that an informed decision can be made about whether to obtain HIV or HCV testing and counseling. (iii) A list of programs or places where the person can obtain HIV or HCV testing and counseling, including any requirements or restrictions the program may impose. (9) Policies and procedures. The hospital must establish policies and procedures for notification and documentation that conform to Federal, State, and local laws, including requirements for the confidentiality of medical records and other patient information. (10) Notification to legal representative or relative. If the patient has been adjudged incompetent by a State court, the physician or hospital must notify a legal representative designated in accordance with State law. If the patient is competent, but State law permits a legal representative or relative to receive the information on the patient's behalf, the physician or hospital must notify the patient or his or her legal representative or relative. For possible HIV infectious transfusion recipients that are deceased, the physician or hospital must inform the deceased patient's legal representative or relative. If the patient is a minor, the parents or legal guardian must be notified.

		(11) Applicability. HCV notification requirements resulting from donors tested before February 20, 2008, as set forth at 21 CFR 610.48 will expire on August 24, 2015. **42 C.F.R. § 482.27(c) General blood safety issues.** For lookback activities only related to new blood safety issues that are identified after August 24, 2007, hospitals must comply with FDA regulations as they pertain to blood safety issues in the following areas: (1) Appropriate testing and quarantining of infectious blood and blood components. (2) Notification and counseling of recipients that may have received infectious blood and blood components.
2510	(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:	**42 C.F.R. § 482.27(a)** (3) The laboratory must make provision for proper receipt and reporting of tissue specimens. (4) The medical staff and a pathologist must determine which tissue specimens require a macroscopic (gross) examination and which require both macroscopic and microscopic examinations.
2511	1. Designation of those tissue specimens which require examination and for procedures for maintaining a tissue file; and	
2512	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. **History:** Original Rule entitled "Laboratory Services" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.	
2600	**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.	**42 C.F.R. § 482.57 Condition of participation: Respiratory services.** The hospital must meet the needs of the patients in accordance with acceptable standards of practice. The following requirements apply if the hospital provides respiratory care service. (a) Standard: Organization and Staffing. The organization of the respiratory care services must be appropriate to the scope and complexity of the services offered.
2601	(a) **Organization and Staffing of Respiratory/Pulmonary Services.**	
2602	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.	
2603	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.	**42 C.F.R. § 482.57(a)(1)** There must be a director of respiratory care services who is a doctor of medicine or osteopathy with the knowledge, experience, and capabilities to supervise and administer the services properly. The director may serve on either a full-time or part-time basis.
2604	(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.	

2605	(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:	
2606	(I) Routine inspection, cleaning, and maintenance procedures for respiratory equipment, as well as protocols for their assembly and operation;	
2607	(II) Adverse reaction protocols;	
2608	(III) Safety practices and interventions;	
2609	(IV) Staff participation in emergency situations at the facility;	
2610	(V) Infection control procedures;	
2611	(VI) Procedures for handling, storage, and dispensing of therapeutic gases;	
2612	(VII) Procedures for obtaining blood samples and analysis of samples, as applicable;	
2613	(VIII) Procedures for testing of pulmonary function, as applicable;	
2614	(IX) Procedures for therapeutic percussion and vibration and for broncho-pulmonary drainage, as applicable;	
2615	(X) Procedures for mechanical ventilation and oxygenation support and for administration of aerosol, humidification, and therapeutic gases, as applicable;	
2616	(XI) Policies for administration of medications;	
2617	(XII) A system for the reissuing and discontinuing of respiratory therapy orders; and	
2618	(XIII) Procedures for verbal/telephone orders taken by state-certified respiratory care professionals.	
2619	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.	**42 C.F.R. § 482.57(a)(2)** There must be adequate numbers of respiratory therapists, respiratory therapy technicians, and other personnel who meet the qualifications specified by the medical staff, consistent with State law. **42 C.F.R. § 482.57(b)(1)** Personnel qualified to perform specific procedures and the amount of supervision required for personnel to carry out specific procedures must be designated in writing.
2620	(b) **Delivery of Respiratory/Pulmonary Services.** Respiratory/ Pulmonary services shall be delivered in accordance with the needs of the patients.	
2621	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.	**42 C.F.R. § 482.57(b) Standard: Delivery of services.** Services must be delivered in accordance with medical staff directives. (3) Services must only be provided under the orders of a qualified and licensed practitioner who is responsible for the care of the patient, acting within his or her scope of practice under State law, and who is authorized by the hospital's medical staff to order the services in accordance with hospital policies and procedures and State laws.
2622	2. The hospital shall provide equipment and supplies sufficient to support the scope of the respiratory services offered.	

2623	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.	**42 C.F.R. § 482.57(b)(4)** All respiratory care services orders must be documented in the patient's medical record in accordance with the requirements at §482.24.
2624	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. **History:** Original Rule entitled "Respiratory/Pulmonary Services" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.	**42 C.F.R. § 482.57(b)(2)** If blood gases or other clinical laboratory tests are performed in the respiratory care unit, the unit must meet the applicable requirements for laboratory services specified in §482.27.
2700	**111-8-40-.27 Organ, Tissue, and Eye Procurement and Transplantation** The hospital shall participate, as appropriate, in the procurement of anatomical gifts.	**42 C.F.R. § 482.45(b) Standard: Organ transplantation responsibilities.** (1) A hospital in which organ transplants are performed must be a member of the Organ Procurement and Transplantation Network (OPTN) established and operated in accordance with §372 of the Public Health Service (PHS) Act (42 U.S.C. 274) and abide by its rules. The term "rules of the OPTN" means those rules provided for in regulations issued by the Secretary in accordance with section 372 of the PHS ACT which are enforceable under 42 CFR 121.10 No hospital is considered to be out of compliance with § 1138(a)(1)(B) of the Act, or with the requirements of this paragraph, unless the Secretary has given the OPTN formal notice that he or she approves the decision to exclude the hospital from the OPTN and has notified the hospital in writing (2) For purposes of these standards, the term "organ" means a human kidney, liver, heart, lung, or pancreas. (3) If a hospital performs any type of transplants, it must provide organ transplant related data, as requested by the OPTN, the Scientific Registry, and the OPO's. The hospital must also provide such data directly to the Department when requested by the Secretary.
2701	(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.	
2702	(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.	

2703	(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.	**42 C.F.R. § 482.45(a) Standard: Organ procurement responsibilities.** The hospital must have and implement written protocols that… (3) Ensure, in collaboration with the designated OPO, that the family of each potential donor is informed of its options to donate organs, tissues, or eyes, or to decline to donate. The individual designated by the hospital to initiate the request to the family must be an organ procurement representative or a designated requestor. A designated requestor is an individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community in the methodology for approaching potential donor families and requesting organ or tissue donation.
2704	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.	**42 C.F.R. § 482.45(a) Standard: Organ procurement responsibilities.** The hospital must have and implement written protocols that: (1) Incorporate an agreement with an OPO designated under part 486 of this chapter, under which it must notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the hospital. The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the hospital, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the hospital for this purpose. (2) Incorporate an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of tissues and eyes, as may be appropriate to assure that all usable tissues and eyes are obtained from potential donors, insofar as such an agreement does not interfere with organ procurement.
2705	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:	**42 C.F.R. § 482.45(a) Standard: Organ procurement responsibilities.** The hospital must have and implement written protocols that… (4) Encourage discretion and sensitivity with respect to the circumstances, views and beliefs of the families of potential donors.
2706	(i) Psychological and emotional considerations when dealing with bereaved families;	**42 C.F.R. § 482.45(a) Standard: Organ procurement responsibilities.** The hospital must have and implement written protocols that… (3) Ensure, in collaboration with the designated OPO, that the family of each potential donor is informed of its options to donate organs, tissues, or eyes or to decline to donate. The individual designated by the hospital to initiate the request to the family must be an organ procurement representative or a designated requestor. A designated requestor is an individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community in the methodology for approaching potential donor families and requesting organ or tissue donation; (4) Encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors. (5) Ensure that the hospital works cooperatively with the designated OPO, tissue bank and eye bank in education staff on donation issues; reviewing death records
2707	(ii) Social, cultural, ethical, and religious factors affecting attitudes toward donations;	
2708	(iii) General medical concepts and issues in organ, tissue, and eye donations;	
2709	(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;	
2710	(v) Procedures for notifying and involving banks or storage facilities; and	
2711	(vi) procedures for recording the outcomes of requests.	

		to improve identification of potential donors, and maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes take place.
2712	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.	
2713	(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. **History:** Original Rule entitled "Organ, Tissue, and Eye Procurement and Transplantation" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.	
2800	**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.	**42 C.F.R. § 482.51 Condition of participation: Surgical services.** If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered, the services must be consistent in quality with inpatient care in accordance with the complexity of the services offered. (a) Standard: Organization and Staffing. The organization of the surgical services must be appropriate to the scope of the services offered… (b) Standard: Delivery of Services. Surgical services must be consistent with needs and resources. Policies governing surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care… (4) There must be adequate provisions for immediate post-operative care. (5) The operating room register must be complete and up-to-date.
2801	(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.	**42 C.F.R. § 482.51(a)(1)** The operating rooms must be supervised by an experienced registered nurse or doctor of medicine or osteopathy.
2802	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).	**42 C.F.R. § 482.51(a)(4)** Surgical privileges must be delineated for all practitioners performing surgery in accordance with the competencies of each practitioner. The surgical service must maintain a roster of practitioners specifying the surgical privileges of each practitioner.
2803	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.	**42 C.F.R. § 482.51(b) Standard: Delivery of service.** Surgical services must be consistent with needs and resources. Policies governing surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care. (1) Prior to surgery or a procedure requiring anesthesia services and except in the case of emergencies: (i) A medical history and physical examination must be completed and documented no more than 30 days before or 24 hours after admission or registration.

		(ii) An updated examination of the patient, including any changes in the patient's condition, must be completed and documented within 24 hours after admission or registration when the medical history and physical examination are completed within 30 days before admission or registration.
2804	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.	
2805	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.	
2806	(i) The chief(s) of surgery shall be responsible for implementation of hospital policy related to medical staff utilizing the surgical suite.	
2807	(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.	
2808	(I) The operative report shall describe techniques, findings, complications, tissues removed or altered, and the general condition of the patient during and following surgery.	
2809	(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.	
2810	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:	**42 C.F.R. § 482.51(a)(1)** The operating rooms must be supervised by an experienced registered nurse or doctor of medicine or osteopathy.
2811	(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;	**42 C.F.R. § 482.51(a)** (2) Licensed practical nurses (LPNs) and surgical technologists (operating room technicians) may serve as "scrub nurses" under the supervision of a registered nurse. (3) Qualified registered nurses may perform circulating duties in the operating room. In accordance with applicable State laws and approved medical staff policies and procedures, LPNs and surgical technologists may assist in circulatory duties under the supervision of a qualified registered nurse who is immediately available to respond to emergencies.
2812	(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;	
2813	(iii) Delineating the duties of scrub personnel and circulating registered nurses in the surgical suite;	
2814	(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;	
2815	(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;	
2816	(vi) Developing criteria for the use of equipment and supplies brought into the surgical suite from other areas; and	
2817	(vii) Ensuring that the operating room register is current and complete.	
2818	(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:	
2819	1. Surgical attire;	
2820	2. Surgical scrub procedures;	
2821	3. Housekeeping functions;	
2822	4. Cleaning, disinfecting, and sanitizing the area;	
2823	5. Appropriate maintenance of the heating, ventilation, and air conditioning systems for the surgical suite;	
2824	6. Packaging, sterilizing, and storage of equipment and supplies;	
2825	7. Waste disposal;	
2826	8. Traffic control patterns, including who may enter the operating room areas and under what circumstances; and	
2827	9. A surgical site surveillance system appropriate to the population served.	
2828	(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:	**42 C.F.R. § 482.51(b)(3)** The following equipment must be available to the operating room suites: call-in-system, cardiac monitor, resuscitator, defibrillator, aspirator, and tracheotomy set.
2829	1. A call system;	
2830	2. Cardiac monitors;	
2831	3. Resuscitation equipment;	
2832	4. A defibrillator;	
2833	5. Aspiration/suction equipment;	
2834	6. A tracheostomy kit;	
2835	7. A pulse oximeter; and	
2836	8. A end-tidal carbon dioxide monitor.	
2837	(d) **Post-Anesthesia Care Unit.**	
2838	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.	
2839	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.	
2840	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. **History:** Original Rule entitled "Surgical Services" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.	

2900	**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.	**42 C.F.R. § 482.52(a) Standard: Organization and staffing.** The organization of anesthesia services must be appropriate to the scope of the services offered. Anesthesia must be administered only by— (1) A qualified anesthesiologist; (2) A doctor of medicine or osteopathy (other than an anesthesiologist); (3) A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law; (4) A certified registered nurse anesthetist (CRNA), as defined in §410.69(b) of this chapter, who, unless exempted in accordance with paragraph (c) of this section, is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed; or (5) An anesthesiologist's assistant, as defined in §410.69(b) of this chapter, who is under the supervision of an anesthesiologist who is immediately available if needed. **42 C.F.R. § 482.52(c) Standard: State exemption.** (1) A hospital may be exempted from the requirement for MD/DO supervision of CRNAs as described in paragraph (a)(4) of this section, if the State in which the hospital is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from MD/DO supervision of CRNAs. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current MD/DO supervision requirement, and that the opt-out is consistent with State law. (2) The request for exemption and recognition of State laws, and the withdrawal of the request may be submitted at any time, and are effective upon submission.]
2901	(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.	**42 C.F.R. § 482.52 Condition of participation: Anesthesia services.** If the hospital furnishes anesthesia services, they must be provided in a well-organized manner under the direction of a qualified doctor of medicine or osteopathy. The service is responsible for all anesthesia administered in the hospital. (a) Standard: Organization and staffing. The organization of anesthesia services must be appropriate to the scope of the services offered… (b) Standard: Delivery of services. Anesthesia services must be consistent with needs and resources. Policies on anesthesia procedures must include the delineation of preanesthesia and postanesthesia responsibilities. The policies must ensure that the following are provided for each patient: (1)A pre-anesthesia evaluation completed and documented by an individual qualified to administer anesthesia, as specified in paragraph (a) of this section, performed within 48 hours prior to surgery or a procedure requiring anesthesia services. (2) An intraoperative anesthesia record.

		(3) A post-anesthesia evaluation completed and documented by an individual qualified to administer anesthesia, as specified in paragraph (a) of this section, no later than 48 hours after surgery or a procedure requiring anesthesia services. The postanesthesia evaluation for anesthesia recovery must be completed in accordance with State law and with hospital policies and procedures that have been approved by the medical staff and that reflect current standards of anesthesia care.
2902	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.	
2903	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.	
2904	(b) **Anesthesia Service Delivery.**	
2905	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:	
2906	(i) Anesthesiologists;	**42 C.F.R. § 482.52(a) Standard: Organization and staffing.** Anesthesia must be administered only by— (1) A qualified anesthesiologist;
2907	(ii) Physicians;	**42 C.F.R. § 482.52(a) Standard: Organization and staffing.** Anesthesia must be administered only by— (2) A doctor of medicine or osteopathy (other than an anesthesiologist);
2908	(iii) Dentists or oral surgeons possessing an active permit for administration of general anesthesia as issued by the State of Georgia;	**42 C.F.R. § 482.52(a) Standard: Organization and staffing.** Anesthesia must be administered only by— (3) A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;
2909	(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	**42 C.F.R. § 482.52(a) Standard: Organization and staffing.** Anesthesia must be administered only by— (4) A certified registered nurse anesthetist (CRNA), as defined in §410.69 (b) of this chapter, who, unless exempted in accordance with paragraph (c) of this section, is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed; **42 C.F.R. § 482.52(c) Standard: State exemption.** (1) A hospital may be exempted from the requirement for MD/DO supervision of CRNAs as described in paragraph (a) (4) of this section, if the State in which the hospital is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from MD/DO supervision of CRNAs. The letter from the Governor must attest that he or she

		has consulted with the State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current MD/DO supervision requirement, and that the opt-out is consistent with state law. (2) The request for exemption and recognition of State laws, and the withdrawal of the request may be submitted at any time, and are effective upon submission.
2910	(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.	**42 C.F.R. § 482.52(a) Standard: Organization and staffing.** Anesthesia must be administered only by— (5) An anesthesiologist's assistant, as defined in §410.69 (b) of this chapter, who is under the supervision of an anesthesiologist who is immediately available if needed.
2911	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.	**42 C.F.R. § 482.52(b) Standard: Delivery of services.** Anesthesia services must be consistent with needs and resources. Policies on anesthesia procedures must include the delineation of pre-anesthesia and post-anesthesia responsibilities. The policies must ensure that the following are provided for each patient: (1) A pre-anesthesia evaluation completed and documented by an individual qualified to administer anesthesia, as specified in paragraph (a) of this section, performed within 48 hours prior to surgery or a procedure requiring anesthesia services.
2912	3. Checks of all anesthesia equipment shall be performed and documented immediately prior to each anesthesia administration.	
2913	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.	
2914	5. During the administration of anesthesia, patients shall be monitored as appropriate for the nature of the anesthesia. Such monitoring shall include as appropriate:	
2915	(i) Heart and breath sounds, using a precordial or esophageal stethoscope;	
2916	(ii) Oxygenation levels;	
2917	(iii) Ventilation;	
2918	(iv) Circulatory function;	
2919	(v) The qualitative content of expired gases, if the patient has an endotracheal tube; and	
2920	(vi) The patient's temperature.	
2921	6. The intraoperative anesthesia record shall document all pertinent actions and events that occur during the induction, maintenance, and emergence from anesthesia.	**42 C.F.R. § 482.52(b) Standard: Delivery of services.** Anesthesia services must be consistent with needs and resources. Policies on anesthesia procedures must include the delineation of pre-anesthesia and post-anesthesia responsibilities. The policies must ensure that the following are provided for each patient: (2) An intraoperative anesthesia record.
2922	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.	

2923	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.	**42 C.F.R. § 482.52(b) Standard: Delivery of services.** Anesthesia services must be consistent with needs and resources. Policies on anesthesia procedures must include the delineation of pre-anesthesia and post-anesthesia responsibilities. The policies must ensure that the following are provided for each patient: (3) A post-anesthesia evaluation completed and documented by an individual qualified to administer anesthesia, as specified in paragraph (a) of this section, no later than 48 hours after surgery or a procedure requiring anesthesia services. The postanesthesia evaluation for anesthesia recovery must be completed in accordance with State law and with hospital policies and procedures that have been approved by the medical staff and that reflect current standards of anesthesia care.
2924	(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.	
2925	(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.	**42 C.F.R. § 482.52(b) Standard: Delivery of services.** Anesthesia services must be consistent with needs and resources. Policies on anesthesia procedures must include the delineation of pre-anesthesia and post-anesthesia responsibilities. The policies must ensure that the following are provided for each patient: (3) A post-anesthesia evaluation completed and documented by an individual qualified to administer anesthesia, as specified in paragraph (a) of this section, no later than 48 hours after surgery or a procedure requiring anesthesia services. The postanesthesia evaluation for anesthesia recovery must be completed in accordance with State law and with hospital policies and procedures that have been approved by the medical staff and that reflect current standards of anesthesia care.
2926	(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:	
2927	1. Routine maintenance and inspection of anesthesia equipment, recorded in a service record for each machine;	
2928	2. Emergency preparedness plans;	
2929	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;	
2930	4. Infection control procedures sufficient to adequately sterilize or appropriately disinfect all equipment components; and	
2931	5. Procedures for ensuring patient safety.	
2932	(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:	

2933	1. Designation of the licensed personnel authorized to administer conscious sedation and/or monitor the patient during conscious sedation;	
2934	2. Drugs approved for use in administering conscious sedation;	
2935	3. Patient monitoring requirements; and	
2936	4. Criteria for discharge. Authority: O.C.G.A. §§ 31-7-2.1, 43-22-21 and 43-26-11.1. **History:** Original Rule entitled "Anesthesia Services" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.	
3000	**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.	**42 C.F.R. § 482.53 Condition of participation: Nuclear medicine services.** If the hospital provides nuclear medicine services, those services must meet the needs of the patients in accordance with acceptable standards of practice. (a) Standard: Organization and staffing. The organization of the nuclear medicine service must be appropriate to the scope and complexity of the services offered.
3001	(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.	**42 C.F.R. § 482.53(b) Standard: Delivery of service.** Radioactive materials must be prepared, labeled, used, transported, stored and disposed of in accordance with acceptable standards of practice. (1) In-house preparation of radiopharmaceuticals is by, or under the supervision of, an appropriately trained registered pharmacist or a doctor of medicine or osteopathy. (2) There is proper storage and disposal of radioactive material. **42 C.F.R. § 482.53(d)(3)** The hospital must maintain records of the receipt and distribution of radiopharmaceuticals.
3002	(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.	**42 C.F.R. § 482.53(b)(3)** If laboratory tests are performed in the nuclear medicine service, the service must meet the applicable requirement for laboratory services specified in §482.27. **42 C.F.R. § 482.53(c) Standard: Facilities.** Equipment and supplies must be appropriate for the types of nuclear medicine services offered and must be maintained for safe and efficient performance. The equipment must be— (1) Maintained in safe operating condition; and (2) Inspected, tested, and calibrated at least annually by qualified personnel.
3003	(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.	**42 C.F.R. § 482.53(a)(1)** There must be a director who is a doctor of medicine or osteopathy qualified in nuclear medicine.
3004	(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. **History:** Original Rule entitled "Nuclear Medicine Services" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.	**42 C.F.R. § 482.53(a)(2)** The qualifications, training, functions, and responsibilities of nuclear medicine personnel must be specified by the service director and approved by the medical staff. **42 C.F.R. § 482.53(d)(4)** Nuclear medicine services must be ordered only by practitioners whose scope of Federal or State licensure and whose defined staff privileges allow such referrals.

3100	**111-8-40-.31 Emergency Services** The hospital shall provide, within its capabilities, services to persons in need of emergency care.	**42 C.F.R. § 482.12(f) Standard: Emergency services.** (1) If emergency services are provided at the hospital, the hospital must comply with the requirements of §482.55. (3) If emergency services are provided at the hospital but are not provided at one or more off-campus departments of the hospital, the governing body of the hospital must assure that the medical staff has written policies and procedures in effect with respect to the off-campus department(s) for appraisal of emergencies and referral when appropriate. **42 C.F.R. § 482.55 Condition of participation: Emergency services.** The hospital must meet the emergency needs of patients in accordance with acceptable standards of practice.
3101	(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.	
3102	1. **Organization.** Supervision and organization of emergency services shall be under the direction of a qualified member of the medical staff.	**42 C.F.R. § 482.55(a) Standard: Organization and direction.** If emergency services are provided at the hospital— (1) The services must be organized under the direction of a qualified member of the medical staff; **42 C.F.R. § 482.55(b) Standard: Personnel.** (1) The emergency services must be supervised by a qualified member of the medical staff.
3103	(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.	**42 C.F.R. § 482.55(a)(3)** The policies and procedures governing medical care provided in the emergency service or department are established by and are a continuing responsibility of the medical staff.
3104	(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.	
3105	(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.	**42 C.F.R. § 482.55(b)(2)** There must be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility.
3106	(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.	
3107	2. **Delivery of Services.** When the hospital provides emergency services, the services shall comply with the following:	
3108	(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.	
3109	(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;	**42 C.F.R. § 489.20(r)** In case of a hospital as defined in §489.24(b) (including both the transferring and receiving hospitals), to maintain— (1) Medical and other records related to individuals transferred to or from the hospital for a period of 5 years from the date of transfer; (3) A central log on each individual who comes to the emergency department, as defined in §489.24(b), seeking assistance and whether he or she refused treatment, was refused treatment, or whether he or she was transferred, admitted and treated, stabilized and transferred, or discharged.
3110	(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;	
3111	(iv) Written protocols and standards of practice to guide emergency interventions by non-physician staff shall be available in the emergency services area;	
3112	(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;	**42 C.F.R. § 482.55(b) Standard: Personnel.** (1) The emergency services must be supervised by a qualified member of the medical staff.
3113	(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:	
3114	(I) An emergency call system;	
3115	(II) Oxygen;	
3116	(III) Manual breathing bags and masks;	
3117	(IV) Cardiac monitoring and defibrillator equipment;	
3118	(V) Laryngoscopes and endotracheal tubes;	
3119	(VI) Suction equipment; and	
3120	(VII) Emergency drugs and supplies as specified by the medical staff;	
3121	(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;	
3122	(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;	**42 C.F.R. § 482.55(a) Standard: Organization and direction.** If emergency services are provided at the hospital— (2) The services must be integrated with other departments of the hospital.
3123	(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;	
3124	(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	
3125	(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:	
3126	(I) Notify the ambulance zoning system when it is temporarily unable to deliver emergency services and is declaring itself on diversion;	
3127	(II) Notify the ambulance zoning system when diversion status is no longer determined to be necessary; and	
3128	(III) Monitor and evaluate its usage of diversion status and make changes within its control to minimize the use of diversion status.	
3129	(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. **History:** Original Rule entitled "Emergency Services" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.	**42 C.F.R. § 482.12(f)(2)** If emergency services are not provided at the hospital, the governing body must assure that the medical staff has written policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate.
3200	**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.	**42 C.F.R. § 482.51 Condition of participation: Surgical services.** If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered, the services must be consistent in quality with inpatient care in accordance with the complexity of the services offered.

		42 C.F.R. § 482.54 Condition of participation: Outpatient services. If the hospital provides outpatient services, the services must meet the needs of the patients in accordance with acceptable standards of practice. (a) Standard: Organization. Outpatient services must be appropriately organized and integrated with inpatient services.
3201	(a) **Organization of Outpatient Services.**	
3202	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.	**42 C.F.R. § 482.54 Condition of participation: Outpatient services.** If the hospital provides outpatient services, the services must meet the needs of the patients in accordance with acceptable standards of practice… (b) Standard: Personnel. The hospital must: (1) Assign one or more individuals to be responsible for outpatient services… (c) Standard: Orders for outpatient services. Outpatient services must be ordered by a practitioner who meets the following conditions: (1) Is responsible for the care of the patient. (2) Is licensed in the State where he or she provides care to the patient. (3) Is acting within his or her scope of practice under State law. (4) Is authorized in accordance with State law and policies adopted by the medical staff, and approved by the governing body, to order the applicable outpatient services. This applies to the following: (i) All practitioners who are appointed to the hospital's medical staff and who have been granted privileges to order the applicable outpatient services. (ii) All practitioners not appointed to the medical staff, but who satisfy the above criteria for authorization by the medical staff and the hospital for ordering the applicable outpatient services for their patients.
3203	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.	**42 C.F.R. § 482.54(b) Standard: Personnel.** The hospital must… (2) Have appropriate professional and nonprofessional personnel available at each location where outpatient services are offered, based on the scope and complexity of outpatient services.
3204	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.	
3205	(b) **Outpatient Service Delivery.**	
3206	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.	
3207	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.	
3208	3. Hospitals shall provide waiting areas for outpatients with sufficient seating for the expected volume of patients.	

3209	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. **History:** Original Rule entitled "Outpatient Services" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.	
3300	**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.	**42 C.F.R. § 482.56 Condition of participation: Rehabilitation services.** If the hospital provides rehabilitation, physical therapy, occupation therapy, audiology, or speech pathology services, the services must be organized and staffed to ensure the health and safety of patients.
3301	(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.	**42 C.F.R. § 482.56(a) Standard: Organization and staffing.** The organization of the service must be appropriate to the scope of the services offered. (1) The director of the services must have the necessary knowledge, experience, and capabilities to properly supervise and administer the services.
3302	(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.	
3303	(c) Professional and paraprofessional staff providing patient care shall meet licensing or registration requirements consistent with state law.	**42 C.F.R. § 482.56(a)(2)** Physical therapy, occupational therapy, or speech-language pathology or audiology services, if provided, must be provided by qualified physical therapists, physical therapist assistants, occupational therapists, occupational therapy assistants, speech-language pathologists, or audiologists as defined in part 484 of this chapter.
3304	(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.	**42 C.F.R. § 482.56(b) Standard: Delivery of services.** Services must only be provided under the orders of a qualified and licensed practitioner who is responsible for the care of the patient, acting within his or her scope of practice under State law, and who is authorized by the hospital's medical staff to order the services in accordance with hospital policies and procedures and State laws. (1) All rehabilitation services orders must be documented in the patient's medical record in accordance with the requirements at §482.24. (2) The provision of care and the personnel qualifications must be in accordance with national acceptable standards of practice and must also meet the requirements of §409.17 of this chapter.
3305	(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.	
3306	(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. **History:** Original Rule entitled "Rehabilitation Services" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.	
3400	**111-8-40-.34 Maternal and Newborn Services**	
3401	(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.	
3402	(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.	
3403	(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.	
3404	(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.	
3405	(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.	
3406	(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).	
3407	(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.	
3408	(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.	
3409	(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.	

3410	(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:	
3411	(a) **Organization of Basic Maternal and Newborn Services.**	
3412	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.	
3413	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.	
3414	3. The perinatal nurse manager shall be a licensed registered nurse with education and demonstrated knowledge and experience in perinatal nursing;	
3415	(b) **Delivery of Basic Maternal and Newborn Services.**	
3416	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.	
3417	(i) **Staffing for the Labor and Delivery Area.** For the delivery of newborns, the hospital shall provide for at least the following:	
3418	(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;	
3419	(II) A registered nurse present to assist with each delivery;	
3420	(III) An individual credentialed in neonatal resuscitation to be present in the delivery room for each delivery for the purpose of receiving the newborn;	
3421	(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	
3422	(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.	

3423	(ii) **Staffing for the Newborn Nursery.** The hospital shall provide for at least:	
3424	(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;	
3425	(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	
3426	(III) A staff member trained in newborn service provision present in the newborn nursery when it is occupied by any newborn.	
3427	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:	
2428	(i) Admission criteria for the services based on the level of service provided;	
3429	(ii) Guidelines and mechanisms for specialty consultations and transfer for high-risk patients whose needs exceed the range of services offered at the hospital;	
3430	(iii) The orientation program for maternal and newborn services staff;	
3431	(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;	
3432	(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;	
3433	(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;	
3434	(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;	
3435	(viii) Guidelines for induction and augmentation of labor and for designation of qualified personnel who must be in attendance during these procedures;	
3436	(ix) Indicators and procedures for vaginal birth after Cesarean section (VBAC);	
3437	(x) Indicators and procedures for operative vaginal deliveries;	
3438	(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;	

3439	(xii) Guidelines for the monitoring of newborns during the first twelve (12) hours after birth and until discharge;	
3440	(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;	
3441	(xiv) Requirements for newborn screening tests for metabolic disorders and hemoglobinopathies and other screenings, as required by law.	
3442	(xv) Procedures for continuous and unquestionable identification of newborns;	
3443	(xvi) Procedures for completing birth and death certificates in accordance with Georgia's official vital records registration system; and	
3444	(xvii) Guidelines for discharge of mothers and newborns, including early discharge, and for assessment of education and other discharge needs.	
3445	(c) **Physical Environment for Maternal and Newborn Services.**	
3446	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.	
3447	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.	
3448	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.	
3449	4. A newborn stabilization area shall be located within each delivery room or birthing room and shall be equipped with oxygen and suction outlets.	
3450	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%).	
3451	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.	
3452	7. Life-sustaining nursery equipment and lighting for the nursery areas shall be connected to outlets with an automatic transfer capability to emergency power.	
3453	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.	

3454	(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	
3455	(e) **Records Requirements.**	
3456	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:	
3457	(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;	
3458	(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	
3459	(iii) Labor and postpartum care notes shall be included.	
3460	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:	
3461	(i) Physical assessment of the newborn, including Apgar scores, presence or absence of three cord vessels, and vital signs;	
3462	(ii) Accommodation to extra uterine life including the ability to feed and description of maternal-newborn interaction;	
3463	(iii) Treatments and care provided to the newborn to include the specimens collected, newborn screening tests performed, and appropriate prophylaxes;	
3464	(iv) The infant's footprint and mother's fingerprint, or comparable positive newborn identification information; and	
3465	(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.	
3466	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.	
3467	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.	
3468	(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:	
3469	(a) **Organization of Intermediate Maternal and Newborn Services.**	
3470	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.	
3471	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.	
3472	3. A board eligible or board certified neonatologist shall be available to participate in care for the neonates.	
3473	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.	
3474	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.	
3475	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.	
3476	(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:	
3477	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;	
3478	2. Portable x-ray and ultrasound equipment and services shall be available on a twenty-four (24) hour basis;	
3479	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	
3480	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.	
3481	(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:	

3482	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;	
3483	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;	
3484	3. There shall be adequate lighting provided for patient care while avoiding extra illumination of adjacent neonates; and	
3485	4. The patient bed areas shall be designed to minimize the impact of noise on the infants.	
3486	(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:	
3487	(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;	
3488	(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;	
3489	(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;	
3490	(d) The hospital shall have available for consultation a maternal-fetal medicine specialist;	
3491	(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;	
3492	(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;	
3493	(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;	
3494	(h) The hospital shall have on staff pharmacology personnel competent in perinatal pharmacology. Total parenteral nutrition shall be available; and	
3495	(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. **History:** Original Rule entitled "Maternal and Newborn Services" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.	

3500	**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.	
3501	(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.	
3502	(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.	
3503	(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:	
3504	1. Chronological age, weight, and length or height;	
3505	2. For infants and young children, a measurement of head circumference;	
3506	3. Immunization history;	
3507	4. A statement as to the developmental age and growth of the child as related to established norms; and	
3508	5. Family relationships, including expected family involvement during treatment.	
3509	(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.	
3510	(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.	
3511	(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.	
3512	(g) The phone number for the Poison Control Center shall be available in a conspicuous place in the pediatric service area(s).	
3513	(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.	
3514	(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. **History:** Original Rule entitled "Pediatric Services" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.	
3600	**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.	
3601	(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.	
3602	(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.	
3603	(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.	
3604	(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:	
3605	1. Maintenance of dialysis equipment;	
3606	2. Water treatment system safety;	
3607	3. Infection control;	
3608	4. Reuse of dialyzers and dialysis supplies, if applicable, and	
3609	5. Care of dialysis patients experiencing common complications of dialysis treatments.	
3610	(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.	

3611	(3) **Appropriate Treatment.** The hospital shall provide dialysis services in accordance with accepted standards of care for the persons requiring dialysis services.	
3612	(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.	
3613	(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. **History:** Original Rule entitled "Dialysis Services" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.	
3700	**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.	
3701	(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.	
3702	(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.	**42 C.F.R. § 482.62(b)(1)** The clinical director, service chief, or equivalent must meet the training and experience requirements for examination by the American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry.
3703	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.	
3704	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.	

3705	(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.	**42 C.F.R. § 482.62 Condition of participation: Special staff requirements for psychiatric hospitals.** The hospital must have adequate numbers of qualified professionals and supportive staff to evaluate patients, formulate written, individualized comprehensive treatment plans, provide active treatment measures and engage in discharge planning. (b) Standard: Director of inpatient psychiatric services; medical staff. Inpatient psychiatric services must be under the supervision of a clinical director, service chief, or equivalent who is qualified to provide the leadership required for an intensive treatment program. The number and qualifications of doctors of medicine and osteopathy must be adequate to provide essential psychiatric services.
3706	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.	
3707	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.	**42 C.F.R. § 482.62(f) Standard: Social services.** There must be a director of social services who monitors and evaluates the quality and appropriateness of social services furnished…. (1) The director of the social work department or service must have a master's degree from an accredited school of social work or must be qualified by education and experience in the social services needs of the mentally ill. If the director does not hold a master's degree, at least one staff member must have this qualification.
3708	3. **Clinical Psychologist.** A licensed clinical psychologist shall be available to provide testing and treatment consultation for patients as needed.	**42 C.F.R. § 482.62(e) Standard: Psychological services.** The hospital must provide or have available psychological services to meet the needs of the patients.
3709	4. **Child Psychiatrist.** If psychiatric services are provided for children, a board eligible or board certified child psychiatrist shall be on staff.	
3710	5. **Special Staffing Requirements for Inpatient Psychiatric or Substance Abuse Services.** Hospitals providing inpatient psychiatric and/or substance abuse care shall provide:	
3711	(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;	
3712	(ii) At least one registered nurse on duty at all times; and	
3713	(iii) Rehabilitative and therapeutic activity staff, trained and qualified to meet the needs of the patients as specified in the patients' individualized service plans.	
3714	(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:	

3715	1. Admission and discharge criteria and procedures, which comply with Georgia laws concerning involuntary admissions or treatment;	
3716	2. Safety and security precautions for the prevention of suicide, assault, and patient injury;	
3717	3. The handling of medical emergencies, including but not limited to suicide attempts, cardiac arrest, aspiration, or seizures;	
3718	4. Special procedures, such as electro convulsive therapy (ECT) and medical detoxification, as applicable; and	
3719	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.	
3720	(3) **Patient's Rights in Psychiatric and Substance Abuse Services.**	
3721	(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:	
3722	1. Receive treatment in the hospital using the least restrictive methods possible; and	**42 C.F.R. § 482.13 (e) Standard: Restraint or seclusion.** All patients have the right to be free from physical or mental abuse, and corporal punishment. All patients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time. (1) Definitions. (i) A restraint is— (A) Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely; or (B) A drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition. (C) A restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort). (ii) Seclusion is the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. Seclusion may only be used for the management of violent or self-destructive behavior. (2) Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient a staff member or others from harm.(3) The type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient, a staff member, or others from harm. (4) The use of restraint or seclusion must be— (i) In accordance with a written modification to the patient's plan of care; and

		(ii) Implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by hospital policy in accordance with State law. (5) The use of restraint or seclusion must be in accordance with the order of a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under § 482.12(c) and authorized to order restraint or seclusion by hospital policy in accordance with State law. (6) Orders for the use of restraint or seclusion must never be written as a standing order or on an as needed basis (PRN). (7) The attending physician must be consulted as soon as possible if the attending physician did not order the restraint or seclusion. (8) Unless superseded by State law that is more restrictive— (i) Each order for restraint or seclusion used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others may only be renewed in accordance with the following limits for up to a total of 24 hours: (A) 4 hours for adults 18 years of age or older; (B) 2 hours for children and adolescents 9 to 17 years of age; or (C) 1 hour for children under 9 years of age; and (ii) After 24 hours, before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior, a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under § 482.12(c) of this part and authorized to order restraint or seclusion by hospital policy in accordance with State law must see and assess the patient.(iii) Each order for restraint used to ensure the physical safety of the nonviolent or non-self-destructive patient may be renewed as authorized by hospital policy. (9) Restraint or seclusion must be discontinued at the earliest possible time, regardless of the length of time identified in the order. (10) The condition of the patient who is restrained or secluded must be monitored by a physician, other licensed independent practitioner or trained staff that have completed the training criteria specified in paragraph (f) of this section at an interval determined by hospital policy. (11) Physician and other licensed independent practitioner training requirements must be specified in hospital policy. At a minimum, physicians and other licensed independent practitioners authorized to order restraint or seclusion by hospital policy in accordance with State law must have a working knowledge of hospital policy regarding the use of restraint or seclusion. (12) When restraint or seclusion is used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, staff member, or others, the patient must be seen face-to-face within 1 hour after the initiation of the intervention— (i) By a— (A) Physician or other licensed independent practitioner; or

		(B) Registered nurse or physician assistant who has been trained in accordance with the requirements specified in paragraph (f) of this section. (ii) To evaluate— (A) The patient's immediate situation; (B) The patient's reaction to the intervention; (C) The patient's medical and behavioral condition; and (D) The need to continue or terminate the restraint or seclusion. (13) States are free to have requirements by statute or regulation that are more restrictive than those contained in paragraph (e)(12)(i) of this section. (14) If the face-to-face evaluation specified in paragraph (e)(12) of this section is conducted by a trained registered nurse or physician assistant, the trained registered nurse or physician assistant must consult the attending physician or other licensed independent practitioner who is responsible for the care of the patient as specified under § 482.12(c) as soon as possible after the completion of the 1-hour face-to-face evaluation. (15) All requirements specified under this paragraph are applicable to the simultaneous use of restraint and seclusion. Simultaneous restraint and seclusion use is only permitted if the patient is continually monitored— (i) Face-to-face by an assigned, trained staff member; or (ii) By trained staff using both video and audio equipment. This monitoring must be in close proximity to the patient. (16) When restraint or seclusion is used, there must be documentation in the patient's medical record of the following: (i) The 1-hour face-to-face medical and behavioral evaluation if restraint or seclusion is used to manage violent or self-destructive behavior; (ii) A description of the patient's behavior and the intervention used; (iii) Alternatives or other less restrictive interventions attempted (as applicable); (iv) The patient's condition or symptom(s) that warranted the use of the restraint or seclusion; and (v) The patient's response to the intervention(s) used, including the rationale for continued use of the intervention. (f) Standard: Restraint or seclusion: Staff training requirements. The patient has the right to safe implementation of restraint or seclusion by trained staff. (1) Training intervals. Staff must be trained and able to demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a patient in restraint or seclusion— (i) Before performing any of the actions specified in this paragraph; (ii) As part of orientation; and (iii) Subsequently on a periodic basis consistent with hospital policy. (2) Training content. The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:

		(i) Techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require the use of a restraint or seclusion. (ii) The use of nonphysical intervention skills. (iii) Choosing the least restrictive intervention based on an individualized assessment of the patient's medical, or behavioral status or condition. (iv) The safe application and use of all types of restraint or seclusion used in the hospital, including training in how to recognize and respond to signs of physical and psychological distress (for example, positional asphyxia); (v) Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary. (vi) Monitoring the physical and psychological well-being of the patient who is restrained or secluded, including but not limited to, respiratory and circulatory status, skin integrity, vital signs, and any special requirements specified by hospital policy associated with the 1-hour face-to-face evaluation. (vii) The use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including required periodic recertification. (3) Trainer requirements. Individuals providing staff training must be qualified as evidenced by education, training, and experience in techniques used to address patients' behaviors. (4) Training documentation. The hospital must document in the staff personnel records that the training and demonstration of competency were successfully completed. (g) Standard: Death reporting requirements: Hospitals must report deaths associated with the use of seclusion or restraint. (1) The hospital must report the following information to CMS: (i) Each death that occurs while a patient is in restraint or seclusion. (ii) Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion. (iii) Each death known to the hospital that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death. ''Reasonable to assume'' in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing or asphyxiation. (2) Each death referenced in this paragraph must be reported to CMS by telephone no later than the close of business the next business day following knowledge of the patient's death. (3) Staff must document in the patient's medical record the date and time the death was reported to CMS.
3723	2. Participate to the extent possible in the development, implementation, and review of their individualized service plan.	
3724	(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.	
3725	(4) **Patient Assessment and Treatment.**	
3726	(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:	
3727	1. For inpatients:	
3728	(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	**42 C.F.R. § 482.61(b) Standard: Psychiatric evaluation.** Each patient must receive a psychiatric evaluation that must- (1) Be completed within 60 hours of admission (2) Include a medical history; (3) Contain a record of mental status; (4) Note the onset of illness and the circumstances leading to admission; (5) Describe attitudes and behavior; (6) Estimate intellectual functioning, memory functioning and orientation; and (7) Include an inventory of the patient's assets in descriptive, not interpretive fashion.
3729	(ii) An individualized service plan, initiated within the first twelve (12) hours after admission and updated as needs are identified through assessments;	**42 C.F.R. § 482.61(c)(1) Standard: Treatment plan.** Each patient must have an individual comprehensive treatment plan.
3730	2. For outpatients:	
3731	(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	
3732	(ii) Within ten (10) days following initiation of outpatient services, an individualized service plan developed and implemented to address needs identified;	
3733	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:	**42 C.F.R. § 482.61(c)(1)(i)** The written plan must include a substantiated diagnosis;
3734	(i) The patient's participation, to the extent possible, in the development of the individualized service plan;	
3735	(ii) Measurable goals and/or objectives to be met toward the established discharge criteria; and	**42 C.F.R. § 482.61(c)(1)(ii)** The written plan must include short term and long range goals.
3736	(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;	**42 C.F.R. § 482.61(c)(2)** The treatment received by the patient must be documented in such a way to assure that all active therapeutic efforts are included. (d) Standard: Recording progress. Progress notes must be recorded by the doctor of medicine or osteopathy responsible for the care of the patient as specified in §482.12(c), nurse, social worker when appropriate, others significantly involved in active treatment modalities. The frequency of progress notes is determined by

		the condition of the patient but must be recorded at least weekly for the first 2 months and at least once a month thereafter, and must contain recommendations for revisions in the treatment plan as indicated as well as a precise assessment of the patient's progress in accordance with the original or revised treatment plan.
3737	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	
3738	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.	
3739	(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.	
3740	(5) **Physical Space and Design Requirements for Inpatient Psychiatric and Substance Abuse Services.** Hospitals providing inpatient psychiatric and substance abuse services shall have:	
3741	(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;	
3742	(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;	
3743	(c) A day room that allows for social interaction, dining, and group therapy activities;	
3744	(d) Space for storage of patient's personal belongings and for securing valuables;	
3745	(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. **History:** Original Rule entitled "Psychiatric and Substance Abuse Services" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.	
3800	**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:	**42 C.F.R. § 485.608 Condition of participation: Compliance with federal, state, and local laws and regulations.** The CAH and its staff are in compliance with applicable Federal, State and local laws and regulations. (a) Standard: Compliance with Federal Laws and regulations. The CAH is in compliance with applicable Federal laws and regulations related to the health and safety of patients.

		(b) Standard: Compliance with State and local laws and regulation. All patient care services are furnished in accordance with applicable State and local laws and regulation. (c) Standard: Licensure of CAH. The CAH is licensed in accordance with applicable Federal, State and local laws and regulations. (d) Standard: Licensure, certification or registration of personnel. Staff of the CAH are licensed, certified, or registered in accordance with applicable Federal, State, and local laws and regulations.
3801	(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.	**42 C.F.R. § 485.610 Condition of participation: Standard: Status and location.** (a) Standard: Status. The facility is— (1) A currently participating hospital that meets all conditions of participation set forth in this subpart; (2) A recently closed facility, provided that the facility— (i) Was a hospital that ceased operations on or after the date that is 10 years before November 29, 1999; and (ii) Meets the criteria for designation under this subpart as of the effective date of its designation; or (3) A health clinic or a health center (as defined by the State) that— (i) Is licensed by the State as a health clinic or a health center; (ii) Was a hospital that was downsized to a health clinic or a health center; and (iii) As of the effective date of its designation, meets the criteria for designation set forth in this subpart. (b) Standard: Location in a Rural Area or Treatment as Rural. The CAH meets the requirements of either paragraph (b) (1) or (b) (2) of this section— (1) The CAH meeting following requirements: (i) The CAH is located outside any area that is a Metropolitan Statistical Area, as defined by the Office of Management and Budget, or that has been recognized as urban under §412.64(b), excluding paragraph (b)(3) of this chapter; (ii) The CAH has not been classified as an urban hospital for purposes of the standardized payment amount by CMS or the Medicare Geographic Classification Review Board under §412.230(e) of this chapter and is not among a group of hospitals have been redesignated to an adjacent urban area under §412.232 of this chapter. (2) The CAH is located within a Metropolitan Statistical Area, as defined by the Office of Management and Budget, but is being treated as being located in a rural area in accordance with §412.103 of this chapter. (3) Effective for October 1, 2004 through September 30, 2006, the CAH does not meet the location requirements in either paragraph (b)(1) or (b)(2) of this section and is located in a county that, in FY 2004, was not part of a Metropolitan Statistical Area as defined by the Office of Management and Budget, but as of FY 2005 was included as part of such Metropolitan Statistical Area as a result of the most recent census data and implementation of the new Metropolitan Statistical

		Area definitions announced by the Office of Management and Budget on June 3, 2003. (4) Effective for October 1, 2009 through September 30, 2011, the CAH does not meet the location requirements in either paragraph (b)(1) or (b)(2) of this section and is located in a county that, in FY 2009, was not part of a Metropolitan Statistical Area as defined by the Office of Management and Budget, but as of FY 2010, was included as part of such Metropolitan Statistical Area as a result of the most recent census data and implementation of the new Metropolitan Statistical Area definitions announced by the Office of Management and Budget on November 20, 2008. (c) Standard: Location Relative to Other Facilities or Necessary Provider Certification. The CAH is located more than a 35-mile drive (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from a hospital or another CAH, or before January 1, 2006, the CAH is certified by the State as being a necessary provider of health care services to residents in the area. A CAH that is designated as a necessary provider on or before December 31, 2005, will maintain its necessary provider designation after January 1, 2006. (d) Standard: Relocation of CAHs With a Necessary Provider Designation. A CAH that has a necessary provider designation from the State that was in effect prior to January 1, 2006, and relocates its facility after January 1, 2006, can continue to meet the location requirement of paragraph (c) of this section based on the necessary provider designation only if the relocated facility meets the requirements as specified in paragraph (d)(1) of this section. (1) If a necessary provider CAH relocates its facility and begins providing services in a new location, the CAH can continue to meet the location requirement of paragraph (c) of this section based on the necessary provider designation only if the CAH in its new location-- (i) Serves at least 75 percent of the same service area that it served prior to its relocation; (ii) Provides at least 75 percent of the same services that it provided prior to the relocation; and (iii)Is staffed by 75 percent of the same staff (including medical staff, contracted staff, and employees) that were on staff at the original location. (2) If a CAH that has been designated as a necessary provider by the State begins providing services at another location after January 1, 2006, and does not meet the requirements in paragraph (d)(1) of this section, the action will be considered a cessation of business as described in §489.52(b)(3). (e) Standard: Off-campus and co-location requirements for CAHs. A CAH may continue to meet the location requirement of paragraph(c) of this section based only if the CAH meets the following: (1) If a CAH with a necessary provider designation is co-located (that is, it shares a campus, as defined in §413.65(a)(2) of this chapter, with another hospital or CAH), the necessary provider CAH can continue to meet the location requirement

		of paragraph (c) of this section only if the co-location arrangement was in effect before January 1, 2008, and the type and scope of services offered by the facility co-located with the necessary provider CAH do not change. A change of ownership of any of the facilities with a co-location arrangement that was in effect before January 1, 2008, will not be considered to be a new co-location arrangement. (2) If a CAH or a necessary provider CAH operates an off-campus provider-based location, excluding an RHC as defined in §405.2401(b) of this chapter, but including a department or remote location, as defined in §413.65(a)(2) of this chapter, or an off-campus distinct part psychiatric or rehabilitation unit, as defined in §485.647, that was created or acquired by the CAH on or after January 1, 2008, the CAH can continue to meet the location requirement of paragraph (c) of this section only if the off-campus provider-based location or off-campus distinct part unit is located more than a 35 mile drive (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15 mile drive) from a hospital or another CAH. (3) If either a CAH or a CAH that has been designated as a necessary provider by the State does not meet the requirements in paragraph (e)(1) of this section, by co-locating with another hospital or CAH on or after January 1, 2008, or creates or acquires an off-campus provider-based location or off-campus distinct part unit on or after January 1, 2008, that does not meet the requirements in paragraph (e)(2) of this section, the CAH's provider agreement will be subject to termination in accordance with the provisions of §489.53(a)(3) of this subchapter, unless the CAH terminates the off-campus arrangement or the co-location arrangement, or both. **42 C.F.R. § 485.612 Condition of participation: Compliance with CAH requirements at the time of application.** Except for recently closed facilities as described in §485.610(a)(2), or health clinics or health centers as described in §485.610(a)(3), the facility is a hospital that has a provider agreement to participate in the Medicare program as a hospital at the time the hospital applies for designation as a CAH.
3802	(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:	**42 C.F.R. § 485.616 (a) Standard: Agreements with network hospitals.** In the case of a CAH that is a member of a rural health network as defined in §485.603 of this chapter, the CAH has in effect an agreement with at least one hospital that is a member of the network for— (1) Patient referral and transfer; (2) The development and use of communications systems of the network, including the network's system for the electronic sharing of patient data, and telemetry and medical records, if the network has in operation such a system; and (3) The provision of emergency and non-emergency transportation between the facility and the hospital.

3803	1. Patient referral and transfer between the facilities, with the use of emergency and non-emergency transportation;	**42 C.F.R. § 485.616 (a) Standard: Agreements with network hospitals.** In the case of a CAH that is a member of a rural health network as defined in §485.603 of this chapter, the CAH has in effect an agreement with at least one hospital that is a member of the network for— (1) Patient referral and transfer;
3804	2. Credentialing of medical and professional staff; and	**42 C.F.R. § 485.616 Condition of participation: Agreements.** (a) Standard: Agreements with network hospitals In the case of a CAH that is a member of a rural health network as defined in §485.603 of this chapter, the CAH has in effect an agreement with at least one hospital that is a member of the network for— (1) Patient referral and transfer; (2) The development and use of communications systems of the network, including the network's system for the electronic sharing of patient data, and telemetry and medical records, if the network has in operation such a system; and (3) The provision of emergency and nonemergency transportation between the facility and the hospital. (b) Standard: Agreement for credentialing and quality assurance. Each CAH that is a member of a rural health network shall have an agreement with respect to credentialing and quality assurance with at least— (1) One hospital that is a member of the network; (2) One QIO or equivalent entity; or (3) One other appropriate and qualified entity identified in the State rural health care plan. (c) Standard: Agreements for credentialing and privileging of telemedicine physicians and practitioners. (1) The governing body of the CAH must ensure that, when telemedicine services are furnished to the CAH's patients through an agreement with a distant-site hospital, the agreement is written and specifies that it is the responsibility of the governing body of the distant-site hospital to meet the following requirements with regard to its physicians or practitioners providing telemedicine services: (i) Determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff. (ii) Appoint members of the medical staff after considering the recommendations of the existing members of the medical staff. (iii) Assure that the medical staff has bylaws. (iv) Approve medical staff bylaws and other medical staff rules and regulations. (v) Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients. (vi) Ensure the criteria for selection are individual character, competence, training, experience, and judgment. (vii) Ensure that under no circumstances is the accordance of staff membership or professional privileges in the hospital dependent solely upon certification, fellowship or membership in a specialty body or society.

		(2) When telemedicine services are furnished to the CAH's patients through an agreement with a distant-site hospital, the CAH's governing body or responsible individual may choose to rely upon the credentialing and privileging decisions made by the governing body of the distant-site hospital regarding individual distant-site physicians or practitioners. The CAH's governing body or responsible individual must ensure, through its written agreement with the distant-site hospital, that the following provisions are met: (i) The distant-site hospital providing telemedicine services is a Medicare-participating hospital. (ii) The individual distant-site physician or practitioner is privileged at the distant-site hospital providing the telemedicine services, which provides a current list of the distant-site physician's or practitioner's privileges; (iii) The individual distant-site physician or practitioner holds a license issued or recognized by the State in which the CAH is located; and (iv) With respect to a distant-site physician or practitioner, who holds current privileges at the CAH whose patients are receiving the telemedicine services, the CAH has evidence of an internal review of the distant-site physician's or practitioner's performance of these privileges and sends the distant-site hospital such information for use in the periodic appraisal of the individual distant-site physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the CAH's patients and all complaints the CAH has received about the distant-site physician or practitioner. (3) The governing body of the CAH must ensure that when telemedicine services are furnished to the CAH's patients through an agreement with a distant-site telemedicine entity, the agreement is written and specifies that the distant-site telemedicine entity is a contractor of services to the CAH and as such, in accordance with §485.635(c)(4)(ii), furnishes the contracted services in a manner that enables the CAH to comply with all applicable conditions of participation for the contracted services, including, but not limited to, the requirements in this section with regard to its physicians and practitioners providing telemedicine services. (4) When telemedicine services are furnished to the CAH's patients through an agreement with a distant-site telemedicine entity, the CAH's governing body or responsible individual may choose to rely upon the credentialing and privileging decisions made by the governing body of the distant-site telemedicine entity regarding individual distant-site physicians or practitioners. The CAH's governing body or responsible individual must ensure, through its written agreement with the distant-site telemedicine entity, that the following provisions are met: (i) The distant-site telemedicine entity's medical staff credentialing and privileging process and standards at least meet the standards at (c)(1)(i) through (c)(1)(vii). (ii) The individual distant-site physician or practitioner is privileged at the distant-site telemedicine entity providing the telemedicine services, which provides a

		current list to the CAH of the distant-site physician's or practitioner's privileges at the distant-site telemedicine entity. (iii) The individual distant-site physician or practitioner holds a license issued or recognized by the State in which the CAH whose patients are receiving the telemedicine services is located. (iv) With respect to a distant-site physician or practitioner, who holds current privileges at the CAH whose patients are receiving the telemedicine services, the CAH has evidence of an internal review of the distant-site physician's or practitioner's performance of these privileges and sends the distant-site telemedicine entity such information for use in periodic appraisal of the distant-site physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the CAH's patients and all complaints the CAH has received about the distant-site physician or practitioner. **42 C.F.R. § 485.631 Condition of participation: Staffing and staff responsibilities.** (a) Standard: Staffing—(1) The CAH has a professional health care staff that includes one or more doctors of medicine or osteopathy, and may include one or more physician assistants, nurse practitioners, or clinical nurse specialists. (2) Any ancillary personnel are supervised by the professional staff. (3) The staff is sufficient to provide the services essential to the operation of the CAH. (4) A doctor of medicine or osteopathy, nurse practitioner, clinical nurse specialist, or physician assistant is available to furnish patient care services at all times the CAH operates. (5) a registered nurse, clinical nurse specialist, or licensed practical nurse is on duty whenever the CAH has one or more inpatients. (b) Standard: Responsibilities of the doctor of medicine or osteopathy. (1) The doctor of medicine or osteopathy— (i) Provides medical direction for the CAH'S health care activities and consultation for, and medical supervision of, the health care staff; (ii) In conjunction with the physician assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the CAH'S written policies governing the services it furnishes. (iii) In conjunction with the physician assistant and/or nurse practitioner members, periodically reviews the CAH'S patient records, provides medical orders, and provides medical care services to the patients of the CAH; and (iv) Periodically reviews and signs the records of patients cared for by nurse practitioners, clinical nurse specialists, or physician assistants. (v) Periodically reviews and signs a sample of outpatient records of patients cared for by nurse practitioners, clinical nurse specialists, certified nurse midwives, or physician assistants only to the extent required under State law where State law requires record reviews or co-signatures, or both, by a collaborating physician.

		(2) A doctor of medicine or osteopathy is present for sufficient periods of time to provide medical direction, consultation, and supervision for the services provided in the CAH, and is available through direct radio or telephone communication or electronic communication for consultation, assistance with medical emergencies, or patient referral. (c) Standard: Physician assistant, nurse practitioner, and clinical nurse specialist responsibilities. (1) The physician assistant, the nurse practitioner, or clinical nurse specialist members of the CAH'S staff— (i) Participate in the development, execution and periodic review of the written policies governing the services the CAH furnishes; and (ii) Participate with a doctor of medicine or osteopathy in a periodic review of the patients' health records. (2) The physician assistant, nurse practitioner, or clinical nurse specialist performs the following functions to the extent they are not being performed by a doctor of medicine or osteopathy: (i) Provides services in accordance with the CAH'S policies. (ii) Arranges for, or refers patients to, needed services that cannot be furnished at the CAH, and assures that adequate patient health records are maintained and transferred as required when patients are referred. (3) Whenever a patient is admitted to the CAH by a nurse practitioner, physician assistant, or clinical nurse specialist, a doctor of medicine or osteopathy on the staff of the CAH is notified of the admission. **42 C.F.R. § 485.604 Personnel qualifications.** Staff that furnish services in a CAH must meet the applicable requirements of this section. (a) Clinical nurse specialist. A clinical nurse specialist must be a person who— (1) Is a registered nurse and is licensed to practice nursing in the State in which the clinical nurse specialist services are performed in accordance with State nurse licensing laws and regulations; and (2) Holds a master's or doctoral level degree in a defined clinical area of nursing from an accredited educational institution. (b) Nurse practitioner. A nurse practitioner must be a registered professional nurse who is currently licensed to practice in the State, who meets the State's requirements governing the qualification of nurse practitioners, and who meets one of the following conditions: (1) Is currently certified as a primary care nurse practitioner by the American Nurses' Association or by the National Board of Pediatric Nurse Practitioners and Associates. (2) Has successfully completed a 1 academic year program that— (i) Prepares registered nurses to perform an expanded role in the delivery of primary care; (ii) Includes at least 4 months (in the aggregate) of classroom instruction and a component of supervised clinical practice; and

		(iii) Awards a degree, diploma, or certificate to persons who successfully complete the program. (3) Has successfully completed a formal educational program (for preparing registered nurses to perform an expanded role in the delivery of primary care) that does not meet the requirements of paragraph (a)(2) of this section, and has been performing an expanded role in the delivery of primary care for a total of 12 months during the 18-month period immediately preceding June 25, 1993. (c) Physician assistant. A physician assistant must be a person who meets the applicable State requirements governing the qualifications for assistants to primary care physicians, and who meets at least one of the following conditions: (1) Is currently certified by the National Commission on Certification of Physician Assistants to assist primary care physicians. (2) Has satisfactorily completed a program for preparing physician assistants that— (i) Was at least one academic year in length; (ii) Consisted of supervised clinical practice and at least 4 months (in the aggregate) of classroom instruction directed toward preparing students to deliver health care; and (iii) Was accredited by the American Medical Association's Committee on Allied Health Education and Accreditation. (3) Has satisfactorily completed a formal educational program (for preparing physician assistants) that does not meet the requirements of paragraph (c)(2) of this section and has been assisting primary care physicians for a total of 12 months during the 18-month period immediately preceding June 25, 1993.
3805	3. Participation in quality management activities.	**42 C.F.R. § 485.616 Condition of participation: Agreements.** (a) Standard: Agreements with network hospitals. In the case of a CAH that is a member of a rural health network as defined in §485.603 of this chapter, the CAH has in effect an agreement with at least one hospital that is a member of the network for— (b) Standard: Agreement for credentialing and quality assurance. Each CAH shall have an agreement with respect to credentialing and quality assurance with at least-- (1) One hospital that is a member of the network; (2) One QIO or equivalent entity; or (3) One other appropriate and qualified entity identified in the State rural health care plan. **42 C.F.R. § 485.641 Condition of participation: Periodic evaluation and quality assurance review.** (a) Standard: Periodic Evaluation—(1) The CAH carries out or arranges for a periodic evaluation of its total program. The evaluation is done at least once a year and includes review of— (i) The utilization of CAH services, including at least the number of patients served and the volume of services;

		(ii) A representative sample of both active and closed clinical records; and (iii) The CAH'S health care policies. (2) The purpose of the evaluation is to determine whether the utilization of services was appropriate, the established policies were followed, and any changes are needed. (b) Standard: Quality Assurance. The CAH has an effective quality assurance program to evaluate the quality and appropriateness of the diagnosis and treatment furnished in the CAH and of the treatment outcomes. The program requires that— (1) All patient care services and other services affecting patient health and safety, are evaluated; (2) Nosocomial infections and medication therapy are evaluated; (3) The quality and appropriateness of the diagnosis and treatment furnished by nurse practitioners, clinical nurse specialists, and physician assistants at the CAH are evaluated by a member of the CAH staff who is a doctor of medicine or osteopathy or by another doctor of medicine or osteopathy under contract with the CAH; (4) The quality and appropriateness of the diagnosis and treatment furnished by doctors of medicine or osteopathy at the CAH are evaluated by-- (i) One hospital that is a member of the network, when applicable; (ii) One QIO or equivalent entity; (iii) One other appropriate and qualified entity identified in the State rural health care plan; (iv) In the case of distant-site physicians and practitioners providing telemedicine services to the CAH's patients under a written agreement between the CAH and a distant-site hospital, the distant-site hospital; or (v) In the case of distant-site physicians and practitioners providing telemedicine services to the CAH's patients under a written agreement between the CAH and a distant-site telemedicine entity, one of the entities listed in paragraphs (b)(4)(i) through (iii)of this section; (5)(i) The CAH staff considers the findings of the evaluations, including any findings or recommendations of the QIO, and takes corrective action if necessary. (ii) The CAH also takes appropriate remedial action to address deficiencies found through the quality assurance program. (iii) The CAH documents the outcome of all remedial action.
3806	(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:	**42 C.F.R. § 485.627 Condition of participation: Organizational structure.** (a) Standard: Governing Body or Responsible Individual The CAH has a governing body or an individual that assumes full legal responsibility for determining, implementing and monitoring policies governing the CAH'S total operation and for ensuring that those policies are administered so as to provide quality health care in a safe environment**.** (b) Standard: Disclosure The CAH discloses the names and addresses of--

		(1) Its owners, or those with a controlling interest in the CAH or in any subcontractor in which the CAH directly or indirectly has a 5 percent or more ownership interest, in accordance with subpart C of part 420 of this chapter; (2) The person principally responsible for the operation of the CAH; and (3) The person responsible for medical direction. **42 C.F.R. § 485.645 Special Requirements for CAH providers of long-term care services ("Swing-Beds").** A CAH must meet the following requirements in order to be granted an approval from CMS to provide post-CAH SNF care, as specified in §409.30 of this chapter, and to be paid for SNF-level services, in accordance with paragraph (c) of this section. (a) Eligibility. A CAH must meet the following eligibility requirements: (1) The facility has been certified as a CAH by CMS under §485.606(b) of this subpart; and (2) The facility provides not more than 25 inpatient beds, and the number of beds used at any time for acute care inpatient services does not exceed 15 beds. Any bed of a unit of the facility that is licensed as a distinct-part SNF at the time the facility applies to the State for designation as a CAH is not counted under paragraph (a) of this section. (b) Facilities Participating as Rural Primary Care Hospitals (RPCHs) on September 30, 1997 These facilities must meet the following requirements: (1) Notwithstanding paragraph (a) of this section, a hospital that participated in Medicare as a RPCH on September 30, 1997, and on that date had in effect an approval from CMS to use its inpatient facilities to provide post-hospital SNF care may continue in that status under the same terms, conditions, and limitations that were applicable at the time these approvals were granted.. (2) A CAH that was granted swing-bed approval under paragraph (b)(1) of this section may request that its application to be a CAH and swing-bed provider be reevaluated under paragraph (a) of this section. If this request is approved, the approval is effective not earlier than October 1, 1997. As of the date of approval, the CAH no longer has any status under paragraph (b)(1) of this section and may not request reinstatement under paragraph (b)(1) of this section. (c) Payment Payment for inpatient RPCH services to a CAH that has qualified as a CAH under the provisions in paragraph (a) of this section is made in accordance with §413.70 of this chapter. Payment for post-hospital SNF-level of care services is made in accordance with the payment provisions in §413.114 of this chapter. (d) SNF Services The CAH is substantially in compliance with the following SNF requirements contained in subpart B of part 483 of this chapter: (1) Resident rights (§483.10(b)(3) through (b)(6), (d), (e), (h), (i), (j)(1)(vii) and (viii), (1), and (m) of this chapter). (2) Admission, transfer, and discharge rights (§483.12(a) of this chapter).

		(3) Resident behavior and facility practices (§483.13 of this chapter). (4) Patient activities (§483.15(f) of this chapter), except that the services may be directed either by a qualified professional meeting the requirements of §483.15(f)(2), or by an individual on the facility staff who is designated as the activities director and who serves in consultation with a therapeutic recreation specialist, occupational therapist, or other professional with experience or education in recreational therapy. (5) Social services (§483.15(g) of this chapter). (6) Comprehensive assessment, comprehensive care plan, and discharge planning (§483.20(b), (k), and (l) of this chapter, except that the CAH is not required to use the resident assessment instrument (RAI) specified by the State that is required under §483.20(b), or to comply with the requirements for frequency, scope, and number of assessments prescribed in §413.343(b) of this chapter). (7) Specialized rehabilitative services (§483.45 of this chapter). (8) Dental services (§483.55 of this chapter). (9) Nutrition (§483.25(i) of this chapter). **42 C.F.R. § 485.647 Condition of participation: Psychiatric and rehabilitation distinct part units.** (a) Conditions. (1) If a CAH provides inpatient psychiatric services in a distinct part unit, the services furnished by the distinct part unit must comply with the hospital requirements specified in subparts A, B, C, and D of part 482 of this subchapter, the common requirements of §412.25(a)(2) through (f) of part 412 of this chapter for hospital units excluded from the prospective payment systems, and the additional requirements of §412.27 of part 412 of this chapter for excluded psychiatric units. (2) If a CAH provides inpatient rehabilitation services in a distinct part unit, the services furnished by the distinct part unit must comply with the hospital requirements specified in subparts A, B, C, and D of part 482 of this subchapter, the common requirements of §412.25(a)(2) through (f) of part 412 of this chapter for hospital units excluded from the prospective payments systems, and the additional requirements of §§412.29 and §412.30 of part 412 of this chapter related specifically to rehabilitation units. (b) Eligibility requirements. (1) To be eligible to receive Medicare payments for psychiatric or rehabilitation services as a distinct part unit, the facility provides no more than 10 beds in the distinct part unit. (2) The beds in the distinct part are excluded from the 25 inpatient-bed count limit specified in §485.620(a). (3) The average annual 96-hour length of stay requirement specified under §485.620(b) does not apply to the 10 beds in the distinct part units specified in paragraph (b)(1) of this section, and admissions and days of inpatient care in the distinct part units are not taken into account in determining the CAH's compliance with the limits on the number of beds and length of stay in §485.620.

3807	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;	**42 C.F.R. § 485.623 Condition of participation: Physical plant and environment.** (a) Standard: Construction. The CAH is constructed, arranged, and maintained to ensure access to and safety of patients, and provides adequate space for the provision of services. (b) Standard: Maintenance. The CAH has housekeeping and preventive maintenance programs to ensure that— (1) All essential mechanical, electrical, and patient-care equipment is maintained in safe operating condition; (2) There is proper routine storage and prompt disposal of trash; (3) Drugs and biologicals are appropriately stored; (4) The premises are clean and orderly; and (5) There is proper ventilation, lighting, and temperature control in all pharmaceutical, patient care, and food preparation areas. (c) Standard: Life safety from fire. (1) Except as otherwise provided in this section— (i) The CAH must meet the applicable provisions and must proceed in accordance with the Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4.) (ii) Notwithstanding paragraph (d)(1)(i) of this section, corridor doors and doors to rooms containing flammable or combustible materials must be provided with positive latching hardware. Roller latches are prohibited on such doors. (2) In consideration of a recommendation by the State survey agency or Accrediting Organization or at the discretion of the Secretary, may waive, for periods deemed appropriate, specific provisions of the Life Safety Code, which would result in unreasonable hardship upon a CAH, but only if the waiver will not adversely affect the health and safety of the patients. (3) After consideration of State survey agency findings, CMS may waive specific provisions of the Life Safety Code that, if rigidly applied, would result in unreasonable hardship on the CAH, but only if the waiver does not adversely affect the health and safety of patients. (4) The CAH maintains written evidence of regular inspection and approval by State or local fire control agencies. (5) A CAH may install alcohol-based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects against inappropriate access. (6) When a sprinkler system is shut down for more than 10 hours, the CAH must: (i) Evacuate the building or portion of the building affected by the system outage until the system is back in service, or (ii) Establish a fire watch until the system is back in service. (7) Buildings must have an outside window or outside door in every sleeping room, and for any building constructed after July 5, 2016 the sill height must not exceed 36 inches above the floor. Windows in atrium walls are considered outside windows for the purposes of this requirement.

		(i) The sill height requirement does not apply to newborn nurseries and rooms intended for occupancy for less than 24 hours. (ii) Special nursing care areas of new occupancies shall not exceed 60 inches. (d) Standard: Building safety. Except as otherwise provided in this section, the CAH must meet the applicable provisions and must proceed in accordance with the Health Care Facilities Code (NFPA 99 and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5 and TIA 12-6). (1) Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code do not apply to a CAH. (2) If application of the Health Care Facilities Code required under paragraph (e) of this section would result in unreasonable hardship for the CAH, CMS may waive specific provisions of the Health Care Facilities Code, but only if the waiver does not adversely affect the health and safety of patients. (e) The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the Federal Register to announce the changes. (1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, www.nfpa.org,1.617.770.3000. (i) NFPA 99, Standards for Health Care Facilities Code of the National Fire Protection Association 99, 2012 edition, issued August 11, 2011. (ii) TIA 12-2 to NFPA 99, issued August 11, 2011. (iii) TIA 12-3 to NFPA 99, issued August 9, 2012. (iv) TIA 12-4 to NFPA 99, issued March 7, 2013. (v) TIA 12-5 to NFPA 99, issued August 1, 2013. (vi) TIA 12-6 to NFPA 99, issued March 3, 2014. (vii) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011; (viii) TIA 12-1 to NFPA 101, issued August 11, 2011. (ix) TIA 12-2 to NFPA 101, issued October 30, 2012. (x) TIA 12-3 to NFPA 101, issued October 22, 2013. (xi) TIA 12-4 to NFPA 101, issued October 22, 2013. **42 C.F.R. § 485.635 Condition of participation: Provision of services.** (a) Standard: Patient care policies. (1) The CAH'S health care services are furnished in accordance with appropriate written policies that are consistent with applicable State law. (2) The policies are developed with the advice of members of the CAH's professional healthcare staff, including one or more doctors of medicine or

		osteopathy and one or more physician assistants, nurse practitioners, or clinical nurse specialists, if they are on staff under the provisions of § 485.631(a)(1).
3808	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;	**42 C.F.R. § 485.635 Condition of participation: Provision of services.** (a)(3) The policies include the following: (i) A description of the services the CAH furnishes, including those furnished through agreement or arrangement**.** (ii) Policies and procedures for emergency medical services. (iii) Guidelines for the medical management of health problems that include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the CAH. (iv) Rules for the storage, handling, dispensation, and administration of drugs and biologicals. These rules must provide that there is a drug storage area that is administered in accordance with accepted professional principles, that current and accurate records are kept of the receipt and disposition of all scheduled drugs, and that outdated, mislabeled, or otherwise unusable drugs are not available for patient use. (v) Procedures for reporting adverse drug reactions and errors in the administration of drugs. (vi) A system for identifying, reporting, investigating and controlling infections and communicable diseases of patients and personnel. (vii) If the CAH furnishes inpatient services, procedures that ensure that the nutritional needs of inpatients are met in accordance with recognized dietary practices and the orders of the practitioner responsible for the care of the patients, and that the requirement of §483.25(i) is met with respect to inpatients receiving post CAH SNF care. (4) These policies are reviewed at least annually by the group of professional personnel required under paragraph (a)(2) of this section, and reviewed as necessary by the CAH. (b) Standard: Patient Services—(1) General. (i) The CAH provides those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at another entry point into the health care delivery system, such as a low intensity hospital outpatient department or emergency department. These CAH services include medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions. (ii) The CAH furnishes acute care inpatient services. (2) Laboratory Services. The CAH provides basic laboratory services essential to the immediate diagnosis and treatment of the patient that meet the standards imposed under section 353 of the Public Health Service Act (42 U.S.C. 236a). (See the laboratory requirements specified in part 493 of this chapter.) The services provided include the following: (i) Chemical examination of urine by stick or tablet method or both (including urine ketones). (ii) Hemoglobin or hematocrit.

		(iii) Blood glucose. (iv) Examination of stool specimens for occult blood. (v) Pregnancy tests. (vi) Primary culturing for transmittal to a certified laboratory. (3) Radiology services. Radiology services furnished by the CAH are provided by personnel qualified under State law, and do not expose CAH patients or personnel to radiation hazards. (4) Emergency procedures. In accordance with the requirements of §485.618, the CAH provides medical services as a first response to common life-threatening injuries and acute illness. (c) Standard: Services Provided Through Agreements or Arrangements. (1) The CAH has agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including— (i) Services of doctors of medicine or osteopathy; (ii) Additional or specialized diagnostic and clinical laboratory services that are not available at the CAH; and (iii) Food and other services to meet inpatients' nutritional needs to the extent these services are not provided directly by the CAH. (2) If the agreements or arrangements are not in writing, the CAH is able to present evidence that patients referred by the CAH are being accepted and treated. (3) The CAH maintains a list of all services furnished under arrangements or agreements. The list describes the nature and scope of the services provided. (4) The person principally responsible for the operation of the CAH under §485.627(b)(2) of this chapter is also responsible for the following: (i) Services furnished in the CAH whether or not they are furnished under arrangements or agreements. (ii) Ensuring that a contractor of services (including one for shared services and joint ventures) furnishes services that enable the CAH to comply with all applicable conditions of participation and standards for the contracted services. (5) In the case of distant-site physicians and practitioners providing telemedicine services to the CAH's patients under a written agreement between the CAH and a distant-site telemedicine entity, the distant-site telemedicine entity is not required to be a Medicare-participating provider or supplier. (f) Standard: Patient visitation rights. A CAH must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the CAH may need to place on such rights and the reasons for the clinical restriction or limitation. A CAH must meet the following requirements: (1) Inform each patient (or support person, where appropriate) of his or her visitation rights, including any clinical restriction or limitation on such rights, in advance of furnishing patient care whenever possible. (2) Inform each patient (or support person, where appropriate) of the right, subject to his or her consent, to receive the visitors whom he or she designates, including,

		but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend, and his or her right to withdraw or deny such consent at any time. (3) Not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability. (4) Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences. **42 C.F.R. § 485.638 Condition of participation: Clinical records.** (a) Standard: Records system—(1) The CAH maintains a clinical records system in accordance with written policies and procedures. (2) The records are legible, complete, accurately documented, readily accessible, and systematically organized. (3) A designated member of the professional staff is responsible for maintaining the records and for ensuring that they are completely and accurately documented, readily accessible, and systematically organized. (4) For each patient receiving health care services, the CAH maintains a record that includes, as applicable— (i) Identification and social data, evidence of properly executed informed consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient; (ii) Reports of physical examinations, diagnostic and laboratory test results, including clinical laboratory services, and consultative findings; (iii) All orders of doctors of medicine or osteopathy or other practitioners, reports of treatments and medications, nursing notes and documentation of complications, and other pertinent information necessary to monitor the patient's progress, such as temperature graphics, progress notes describing the patient's response to treatment; and (iv) Dated signatures of the doctor of medicine or osteopathy or other health care professional. (b) Standard: Protection of record information—(1) The CAH maintains the confidentially of record information and provides safeguards against loss, destruction, or unauthorized use. (2) Written policies and procedures govern the use and removal of records from the CAH and the conditions for the release of information. (3) The patient’s written consent is required for release of information not required by law. (c) Standard: Retention of records. The records are retained for at least 6 years from date of last entry, and longer if required by State statute, or if the records may be needed in any pending proceeding.

		42 C.F.R. § 485.639 Condition of participation: Surgical services. If a CAH provides surgical services, surgical procedures must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body, or responsible individual, of the CAH in accordance with the designation requirements under paragraph (a) of this section. (a) Standard: Designation of qualified practitioners. The CAH designates the practitioners who are allowed to perform surgery for CAH patients, in accordance with its approved policies and procedures, and with State scope of practice laws. Surgery is performed only by— (1) A doctor of medicine or osteopathy, including an osteopathic practitioner recognized under section 1101(a)(7) of the Act; (2) A doctor of dental surgery or dental medicine; or (3) A doctor of podiatric medicine. (b) Standard: Anesthetic risk and evaluation. (1) A qualified practitioner, as specified in paragraph (a) of this section, must examine the patient immediately before surgery to evaluate the risk of the procedure to be performed. (2) A qualified practitioner, as specified in paragraph (c) of this section, must examine each patient before surgery to evaluate the risk of anesthesia. (3) Before discharge from the CAH, each patient must be evaluated for proper anesthesia recovery by a qualified practitioner, as specified in paragraph (c) of this section. (c) Administration of Anesthesia. The CAH designates the person who is allowed to administer anesthesia to CAH patients in accordance with its approved policies and procedures and with State scope-of-practice laws. (1) Anesthesia must be administered by only— (i) A qualified anesthesiologist; (ii) A doctor of medicine or osteopathy other than an anesthesiologist; including an osteopathic practitioner recognized under section 1101(a)(7) of the Act; (iii) A doctor of dental surgery or dental medicine; (iv) A doctor of podiatric medicine; (v) A certified registered nurse anesthetist (CRNA), as defined in Sec. 410.69(b) of this chapter; (vi) An anesthesiologist's assistant, as defined in Sec. 410.69(b) of this chapter; or (vii) A supervised trainee in an approved educational program, as described in §§ 413.85 or 413.86 of this chapter. (2) In those cases in which a CRNA administers the anesthesia, the anesthetist must be under the supervision of the operating practitioner except as provided in paragraph (e) of this section. An anesthesiologist's assistant who administers anesthesia must be under the supervision of an anesthesiologist. (d) Standard: Discharge All patients are discharged in the company of a responsible adult, except those exempted by the practitioner who performed the surgical procedure. (e) Standard: State Exemption. (1) A CAH may be exempted from the requirement for MD/DO supervision of CRNAs as described in paragraph (c)(2)

		of this section, if the State in which the CAH is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from MD/DO supervision for CRNAs. The letter from the Governor must attest that he or she has consulted with the State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current MD/DO supervision requirement, and that the opt-out is consistent with State law. (2) The request for exemption and recognition of State laws and the withdrawal of the request may be submitted at any time, and are effective upon submission. **42 C.F.R. § 485.643 Condition of participation: Organ, tissue, and eye procurement.** The CAH must have and implement written protocols that: (a) Incorporate an agreement with an OPO designated under part 486 of this chapter, under which it must notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the CAH. The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the CAH, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the CAH for this purpose; (b) Incorporate an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of tissues and eyes, as may be appropriate to assure that all usable tissues and eyes are obtained from potential donors, insofar as such an agreement does not interfere with organ procurement; (c) Ensure, in collaboration with the designated OPO, that the family of each potential donor is informed of its option to either donate or not donate organs, tissues, or eyes. The individual designated by the CAH to initiate the request to the family must be a designated requestor. A designated requestor is an individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community in the methodology for approaching potential donor families and requesting organ or tissue donation; (d) Encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of the family of potential donors; (e) Ensure that the CAH works cooperatively with the designated OPO, tissue bank and eye bank in educating staff on donation issues, reviewing death records to improve identification of potential donors, and maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes takes place. (f) For purpose of these standards, the term "organ" means a human kidney, liver, heart, lung, pancreas, or intestines (or multivisceral organs).
3809	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	**42 C.F.R. § 485.620(a) Standard: Number of beds.** Except as permitted for CAHs having distinct part units under §485.647, the CAH maintains no more than

	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;	25 inpatient beds after January 1, 2004, that can be used for either inpatient or swing-bed services.
3810	4. An average length of stay for patients of no more than ninety-six (96) hours or as currently defined in federal regulations;	**42 C.F.R. § 485.620(b) Standard: Length of stay.** The CAH provides acute inpatient care for a period that does not exceed, on an annual average basis, 96 hours per patient.
3811	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.	**42 C.F.R. § 485.618 Condition of participation: Emergency services.** The CAH provides emergency care necessary to meet the needs of its inpatients and outpatients. (a) Standard: Availability. Emergency services are available on a 24-hours a day basis.
3812	(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.	**42 C.F.R. § 485.618(e) Standard: Coordination with emergency response systems.** The CAH must, in coordination with emergency response systems in the area, establish procedures under which a doctor of medicine or osteopathy is immediately available by telephone or radio contact on a 24-hours-a-day basis to receive emergency calls, provide information on treatment of emergency patients, and refer patients to the CAH or other appropriate locations for treatment.
3813	(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.	**42 C.F.R. § 485.618(d) Standard: Personnel.** (1) Except as specified in paragraph (d)(3) of this section, there must be a doctor of medicine or osteopathy, a physician assistant, a nurse practitioner, or a clinical nurse specialist, with training or experience in emergency care, on call and immediately available by telephone or radio contact, and available on site within the following timeframes: (i) Within 30 minutes, on a 24-hour a day basis, if the CAH is located in an area other than an area described in paragraph (d)(1)(ii) of this section; or (ii) Within 60 minutes, on a 24-hour a day basis, if all of the following requirements are met: (A) The CAH is located in an area designated as a frontier area (that is, an area with fewer than six residents per square mile based on the latest population data published by the Bureau of the Census) or in an area that meets the criteria for a remote location adopted by the State in its rural health care plan, and approved by CMS, under section 1820(b) of the Act. (B) The State has determined, under criteria in its rural health care plan, that allowing an emergency response time longer than 30 minutes is the only feasible method of providing emergency care to residents of the area served by the CAH. (C) The State maintains documentation showing that the response time of up to 60 minutes at a particular CAH it designates is justified because other available alternatives would increase the time needed to stabilize a patient in an emergency. (2) A registered nurse with training and experience in emergency care can be utilized to conduct specific medical screening examinations only if— (i) The registered nurse is on site and immediately available at the CAH when a patient requests medical care; and (ii) The nature of the patient's request for medical care is within the scope of practice of a registered nurse and consistent with applicable State laws and the CAH's bylaws or rules and regulations.

		(3) A registered nurse satisfies the personnel requirement specified in paragraph (d)(1) of this section for a temporary period if— (i) The CAH has no greater than 10 beds; (ii) The CAH is located in an area designated as a frontier area or remote location as described in paragraph (d)(1)(ii)(A) of this section; (iii) The State in which the CAH is located submits a letter to CMS signed by the Governor, following consultation on the issue of using RNs on a temporary basis as part of their State rural healthcare plan with the State Boards of Medicine and Nursing, and in accordance with State law, requesting that a registered nurse with training and experience in emergency care be included in the list of personnel specified in paragraph (d)(1) of this section. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of emergency services in the States. The letter from the Governor must also describe the circumstances and duration of the temporary request to include the registered nurses on the list of personnel specified in paragraph (d)(1) of this section; (iv) Once a Governor submits a letter, as specified in paragraph (d)(3)(iii) of this section, a CAH must submit documentation to the State survey agency demonstrating that it has been unable, due to the shortage of such personnel in the area, to provide adequate coverage as specified in this paragraph (d). (4) The request, as specified in paragraph (d)(3)(iii) of this section, and the withdrawal of the request, may be submitted to us at any time, and are effective upon submission.
3814	(iii) The CAH shall have equipment, supplies, and medications available for treating emergencies, as are required of other organized hospital emergency services.	**42 C.F.R. § 485.618** (b) Standard: Equipment, supplies, and medication. Equipment, supplies, and medication used in treating emergency cases are kept at the CAH and are readily available for treating emergency cases. The items available must include the following: (1) Drugs and biologicals commonly used in life saving procedures, including analgesics, local anesthetics, antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids, antiarrythmics, cardiac glycosides, antihypertensives, diuretics, and electrolytes and replacement solutions. (2) Equipment and supplies commonly used in life saving procedures, including airways, endotracheal tubes, ambu bag/valve/mask, oxygen, tourniquets, immobilization devices, nasogastric tubes, splints, IV therapy supplies, suction machine, defibrillator, cardiac monitor, chest tubes, and indwelling urinary catheters. (c) Standard: Blood and blood products. The facility provides, either directly or under arrangements, the following: (1) Services for the procurement, safekeeping, and transfusion of blood, including the availability of blood products needed for emergencies on a 24-hours a day basis. (2) Blood storage facilities that meet the requirements of 42 CFR part 493, subpart K, and are under the control and supervision of a pathologist or other qualified

		doctor of medicine or osteopathy. If blood banking services are provided under an arrangement, the arrangement is approved by the facility's medical staff and by the persons directly responsible for the operation of the facility.
3815	(iv) Staff assigned to provide emergency patient care shall have training in handling medical and non-medical emergencies; and	
3816	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. **History:** Original Rule entitled "Special Requirements for Critical Access Hospitals" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.	**42 C.F.R. § 485.631(a) Standard: Staffing.** (5) A registered nurse, clinical nurse specialist, or licensed practical nurse is on duty whenever the CAH has one or more inpatients. **42 C.F.R. § 485.635(d) Standard: Nursing services**. Nursing services must meet the needs of patients. (1) A registered nurse must provide (or assign to other personnel) the nursing care of each patient, including patients at a SNF level of care in a swing-bed CAH. The care must be provided in accordance with the patient's needs and the specialized qualifications and competence of the staff available. (2) A registered nurse or, where permitted by State law, a physician assistant, must supervise and evaluate the nursing care for each patient, including patients at a SNF level of care in a swing-bed CAH. (3) All drugs, biologicals, and intravenous medications must be administered by or under the supervision of a registered nurse, a doctor of medicine or osteopathy, or, where permitted by State law, a physician assistant, in accordance with written and signed orders, accepted standards of practice, and Federal and State laws. (4) A nursing care plan must be developed and kept current for each inpatient.
3900	**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:	
3901	(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.	
3902	(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.	
3903	(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.	
3904	(d) A Rural Freestanding Emergency Department that is not otherwise subject to the federal Emergency Medical Treatment & Labor Act, 42 U.S.C. 1395 dd 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. **History**: Original Rule entitled "Physical Plant Design and Construction" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013. Amended: Renumbered as 111-8-40-.40. New Rule entitled "Special Requirements for Rural Free Standing Emergency Departments" adopted. F. Apr. 29, 2014; eff. May 19, 2014.	
4000	**111-8-40-.40 Physical Plant Design and Construction**	
4001	(1) **General.** The hospital shall be designed and constructed in accordance with the needs of the patients being served.	**42 C.F.R. § 482.41 Condition of participation: Physical environment.** The hospital must be constructed, arranged, and maintained to ensure the safety of the patient and to provide facilities for diagnosis and treatment and for special hospital services appropriate to the needs of the community. (a) Standard: Buildings. The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients are assured.
4002	(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:	
4003	1. The time of construction of the hospital when the initial permit was obtained; or	
4004	2. The time of request for approval for renovation(s) or addition(s) to areas of the hospital which impact patient care.	
4005	(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.	
4006	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.	
4007	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.	
4008	(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.	
4009	(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.	
4010	(e) Electrical, mechanical, and plumbing work and equipment shall be designed and installed in accordance with local and state ordinances.	
4011	(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:	
4012	(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;	
4013	(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;	
4014	(c) The unit shall have means of preventing unit movement, either by blocking the wheels or use of pad anchors;	
4015	(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;	
4016	(e) Each unit shall be accessible to wheelchair and stretcher bound patients;	
4017	(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;	
4018	(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;	
4019	(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;	
4020	(i) If stairs are used to access the unit, they shall have stable handrails; and	
4021	(j) The hospital shall ensure that approaches to the unit have adequate lighting for safe negotiation at all hours of operation.	
4022	(3) **Emergency Lighting and Power.** The hospital shall have access to emergency lighting and electrical power meeting the following requirements:	**42 C.F.R. § 482.41(a) Standard: Buildings.** (1) There must be emergency power and lighting in at least operating, recovery, intensive care, and emergency rooms and stairwells. In all other areas not serviced by the emergency supply source, battery lamps and flashlights must be available. (2) There must be facilities for emergency gas and water supply.
4023	(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	

4024	(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. **History:** Original Rule entitled "Physical Plant Design and Construction" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.	
4100	**111-8-40-.41 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:	
4101	(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:	
4102	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.	
4103	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.	
4104	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;	
4105	(b) Waivers and variances granted by the Department shall be for a time certain, as determined by the Department; and	
4106	(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. **History:** Original Rule entitled "Requests for Waiver or Variance" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.	
4200	**111-8-40-.42 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. **History:** Original Rule entitled "Enforcement of Rules and Regulations" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.	
4300	**111-8-40-.43 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. **History:** Original Rule entitled "Severability of These Rules" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.	