

§ 482.21

42 CFR Ch. IV (10-1-99 Edition)

a means of coercion, discipline, convenience, or retaliation by staff. The term "restraint" includes either a physical restraint or a drug that is being used as a restraint. A physical restraint is any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient's body that he or she cannot easily remove that restricts freedom of movement or normal access to one's body. A drug used as a restraint is a medication used to control behavior or to restrict the patient's freedom of movement and is not a standard treatment for the patient's medical or psychiatric condition. Seclusion is the involuntary confinement of a person in a room or an area where the person is physically prevented from leaving.

(2) Seclusion or a restraint can only be used in emergency situations if needed to ensure the patient's physical safety and less restrictive interventions have been determined to be ineffective.

(3) The use of a restraint or seclusion must be—

(i) Selected only when less restrictive measures have been found to be ineffective to protect the patient or others from harm;

(ii) In accordance with the order of a physician or other licensed independent practitioner permitted by the State and hospital to order seclusion or restraint. The following requirements will be superseded by existing State laws that are more restrictive:

(A) Orders for the use of seclusion or a restraint must never be written as a standing order or on an as needed basis (that is, PRN).

(B) The treating physician must be consulted as soon as possible, if the restraint or seclusion is not ordered by the patient's treating physician.

(C) A physician or other licensed independent practitioner must see and evaluate the need for restraint or seclusion within 1 hour after the initiation of this intervention.

(D) Each written order for a physical restraint or seclusion is limited to 4 hours for adults; 2 hours for children and adolescents ages 9 to 17; or 1 hour for patients under 9. The original order may only be renewed in accordance with these limits for up to a total of 24

hours. After the original order expires, a physician or licensed independent practitioner (if allowed under State law) must see and assess the patient before issuing a new order.

(iii) In accordance with a written modification to the patient's plan of care;

(iv) Implemented in the least restrictive manner possible;

(v) In accordance with safe appropriate restraining techniques; and

(vi) Ended at the earliest possible time.

(4) A restraint and seclusion may not be used simultaneously unless the patient is—

(i) Continually monitored face-to-face by an assigned staff member; or

(ii) Continually monitored by staff using both video and audio equipment. This monitoring must be in close proximity the patient.

(5) The condition of the patient who is in a restraint or in seclusion must continually be assessed, monitored, and reevaluated.

(6) All staff who have direct patient contact must have ongoing education and training in the proper and safe use of seclusion and restraint application and techniques and alternative methods for handling behavior, symptoms, and situations that traditionally have been treated through the use of restraints or seclusion.

(7) The hospital must report to HCFA any death that occurs while a patient is restrained or in seclusion, or where it is reasonable to assume that a patient's death is a result of restraint or seclusion.

[64 FR 36088, July 2, 1999]

**Subpart C—Basic Hospital Functions**

**§ 482.21 Condition of participation: Quality assurance.**

The governing body must ensure that there is an effective, hospital-wide quality assurance program to evaluate the provision of patient care.

(a) *Standard: Clinical plan.* The organized, hospital-wide quality assurance program must be ongoing and have a written plan of implementation.

(1) All organized services related to patient care, including services furnished by a contractor, must be evaluated.

(2) Nosocomial infections and medication therapy must be evaluated.

(3) All medical and surgical services performed in the hospital must be evaluated as they relate to appropriateness of diagnosis and treatment.

(b) *Standard: Medically-related patient care services.* The hospital must have an ongoing plan, consistent with available community and hospital resources, to provide or make available social work, psychological, and educational services to meet the medically-related needs of its patients.

(c) *Standard: Implementation.* The hospital must take and document appropriate remedial action to address deficiencies found through the quality assurance program. The hospital must document the outcome of the remedial action.

[51 FR 22042, June 17, 1986, as amended at 59 FR 64152, Dec. 13, 1994]

**§ 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 is responsible for the quality of medical care provided to patients by the hospital.

(a) *Standard: Composition of the medical staff.* The medical staff must be composed of doctors of medicine or osteopathy and, in accordance with State law, may also be composed of other practitioners appointed by the governing body.

(1) The medical staff must periodically conduct appraisals of its members.

(2) The medical staff must examine credentials of candidates for medical staff membership and make recommendations to the governing body on the appointment of the candidates.

(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.

(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 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.

(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.

(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.

(5) Include a requirement that a physical examination and medical history be done no more than 7 days before or 48 hours after an admission for each patient by a doctor of medicine or osteopathy, or, for patients admitted only for oromaxillofacial surgery, by an oromaxillofacial surgeon who has been granted such privileges by the medical staff in accordance with State law.

(6) Include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges.

(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.

[51 FR 22042, June 17, 1986, as amended at 59 FR 64152, Dec. 13, 1994]