PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

1. The authority citation for part 482 continues to read as follows:
Authority: Secs. 1102 and 1871 of the Social Security Act, unless otherwise noted (42 U.S.C. 1302 and 1395hh).

2. Section 482.13 is revised to read as follows:
§ 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 Quality Improvement 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.
(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.
(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).
(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.
(c) Standard: Privacy and safety. (1) The patient has the right to personal privacy.
(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.
(d) Standard: Confidentiality of patient records. (1) The patient has the right to the confidentiality of his or her clinical records.
(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 record keeping system permits.
(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 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.
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 orthopaedically 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.
(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:
   1. Each death that occurs while a patient is in restraint or seclusion.
   2. Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion.
   3. 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.