

Centers for Medicare and Medicaid Services, State Operations Manual Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals

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§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.

Interpretive Guidelines §482.13(e):

The intent of this standard is to identify patients' basic rights, ensure patient safety, and eliminate the inappropriate use of restraint or seclusion. Each patient has the right to receive care in a safe setting. The safety of the patient, staff, or others is the basis for initiating and discontinuing the use of restraint or seclusion. Each patient has the right to be free from all forms of abuse and corporal punishment. Each patient has 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 not be used unless the use of restraint or seclusion is necessary to ensure the immediate physical safety of the patient, a staff member, or others. The use of restraint or seclusion must be discontinued as soon as possible based on an individualized patient assessment and re-evaluation. A violation of any of these patients' rights constitutes an inappropriate use of restraint or seclusion and would be subject to a condition level deficiency.

The patient protections contained in this standard apply to all hospital patients when the use of restraint or seclusion becomes necessary, regardless of patient location. The requirements contained in this standard are not specific to any treatment setting within the hospital. They are not targeted only to patients on psychiatric units or those with behavioral/mental health care needs. Instead, the requirements are specific to the patient behavior that the restraint or seclusion intervention is being used to address.

In summary, these restraint and seclusion regulations apply to:

- All hospitals (acute care, long-term care, psychiatric, children's, and cancer);
- All locations within the hospital (including medical/surgical units, critical care units, forensic units, emergency department, psychiatric units, etc.); and
- All hospital patients, regardless of age, who are restrained or secluded (including both inpatients and outpatients).

The decision to use a restraint or seclusion is not driven by diagnosis, but by a comprehensive individual patient assessment. For a given patient at a particular point in time, this comprehensive individualized patient assessment is used to determine whether the use of less restrictive measures poses a greater risk than the risk of using a restraint or seclusion. The comprehensive assessment should include a physical assessment to identify medical problems that may be causing behavior changes in the patient. For example, temperature elevations, hypoxia, hypoglycemia, electrolyte imbalances, drug interactions,

and drug side effects may cause confusion, agitation, and combative behaviors. Addressing these medical issues may eliminate or minimize the need for the use of restraints or seclusion.

Staff must assess and monitor a patient's condition on an ongoing basis to ensure that the patient is released from restraint or seclusion at the earliest possible time. Restraint or seclusion may only be employed while the unsafe situation continues. Once the unsafe situation ends, the use of restraint or seclusion should be discontinued. However, the decision to discontinue the intervention should be based on the determination that the need for restraint or seclusion is no longer present, or that the patient's needs can be addressed using less restrictive methods.

Hospital leadership is responsible for creating a culture that supports a patient's right to be free from restraint or seclusion. Leadership must ensure that systems and processes are developed, implemented, and evaluated that support the patients' rights addressed in this standard, and that eliminate the inappropriate use of restraint or seclusion. Through their QAPI program, hospital leadership should:

- Assess and monitor the use of restraint or seclusion in their facility;
- Implement actions to ensure that restraint or seclusion is used only to ensure the physical safety of the patient, staff and others; and
- Ensure that the hospital complies with the requirements set forth in this standard as well as those set forth by State law and hospital policy when the use of restraint or seclusion is necessary.

Patients have a right to receive safe care in a safe environment. However, the use of restraint is inherently risky. When the use of restraint is necessary, the least restrictive method must be used to ensure a patient's safety. The use of restraint for the management of patient behavior should not be considered a routine part of care.

The use of restraints for the prevention of falls should not be considered a routine part of a falls prevention program. Although restraints have been traditionally used as a falls prevention approach, they have major, serious drawbacks and can contribute to serious injuries. There is no evidence that the use of physical restraint, (including, but not limited to, raised side rails) will prevent or reduce falls. Additionally, falls that occur while a person is physically restrained often result in more severe injuries. In fact in some instances reducing the use of physical restraints may actually decrease the risk of falling.

Consider, for example, a patient who is displaying symptoms of Sundowner's Syndrome, a syndrome in which a patient's dementia becomes more apparent at the end of the day than at the beginning of the day. The patient is not acting out or behaving in a violent or self-destructive manner. However, the patient has an unsteady gait and continues to get out of bed even after staff has tried alternatives to keep the patient from getting out of bed. There is nothing inherently dangerous about a patient being able to walk or wander, even at night. Under the provisions of this regulation, the rationale that the patient should be restrained because he "might" fall does not constitute an adequate basis for using a restraint for the purposes of this regulation. When assessing a patient's risk for falls and planning care for the patient, staff should consider whether the patient has a medical condition or symptom that indicates a current need for a protective intervention to prevent the patient from walking or getting out of bed. A history of falling without a current clinical basis for a restraint intervention is inadequate to demonstrate the need for restraint. It is important to note that the regulation specifically states that

convenience is not an acceptable reason to restrain a patient. In addition, a restraint must not serve as a substitute for the adequate staffing needed to monitor patients. An individualized patient assessment is critical. In this example, an assessment should minimally address the following questions:

- Are there safety interventions or precautions (other than restraint) that can be taken to reduce the risk of the patient slipping, tripping, or falling if the patient gets out of bed?
 - Is there a way to enable the patient to safely ambulate?
 - Is there some assistive device that will improve the patient's ability to self ambulate?
 - Is a medication or a reversible condition causing the unsteady gait?
 - Would the patient be content to walk with a staff person?
 - Could the patient be brought closer to the nurse's station where he or she could be supervised?
- If an assessment reveals a medical condition or symptom that indicates the need for an intervention to protect the patient from harm, the regulation requires the hospital to use the least restrictive intervention that will effectively protect the patient from harm. Upon making this determination, the hospital may consider the use of a restraint; however, that consideration should weigh the risks of using a restraint (which are widely documented in research) against the risks presented by the patient's behavior. If the hospital chooses to use the restraint, it must meet the requirements contained in this standard.

In addition, a request from a patient or family member for the application of a restraint, which they would consider to be beneficial, is not a sufficient basis for the use of a restraint intervention. A patient or family member request for a restraint intervention, such as a vest restraint or raising all four side rails, to keep the patient from getting out of bed or falling should prompt a patient and situational assessment to determine whether such a restraint intervention is needed. If a need for restraint is confirmed, the practitioner must then determine the type of restraint intervention that will meet the patient's needs with the least risk and most benefit to the patient. If restraint (as defined by the regulation) is used, then the requirements of the regulation must be met.

Patient care staff must demonstrate through their documentation in the patient's medical record that the restraint intervention used is the least restrictive intervention that protects the patient's safety, and that the use of restraint is based on individual assessments of the patient. The assessments and documentation of those assessments must be ongoing in order to demonstrate a continued need for restraint. Documentation by the physician or other staff once a day may not be adequate to support that the restraint intervention needs to continue and may not comply with the requirement to end the restraint as soon as possible. A patient's clinical needs often change over time.

CMS does not consider the use of weapons in the application of restraint or seclusion as a safe, appropriate health care intervention. For the purposes of this regulation, the term "weapon" includes, but is not limited to, pepper spray, mace, nightsticks, tazers, cattle prods, stun guns, and pistols. Security staff may carry weapons as allowed by hospital policy, and State and Federal law. However, the use of weapons by security staff is considered a law enforcement action, not a health care intervention. CMS does not support the use of weapons by any hospital staff as a means of subduing a patient in order to place that patient in restraint or seclusion. If a weapon is used by security or law enforcement personnel on a person in a hospital (patient, staff, or visitor) to protect people or hospital property from harm, we would expect the situation to be handled as a criminal activity and the perpetrator be placed in the custody of local law enforcement.

From: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf, p. 110-113

The use of handcuffs, manacles, shackles, other chain-type restraint devices, or other restrictive devices applied by non-hospital employed or contracted law enforcement officials for custody, detention, and public safety reasons are not governed by this rule. The use of such devices are considered law enforcement restraint devices and would not be considered safe, appropriate health care restraint interventions for use by hospital staff to restrain patients. The law enforcement officers who maintain custody and direct supervision of their prisoner (the hospital's patient) are responsible for the use, application, and monitoring of these restrictive devices in accordance with Federal and State law. However, the hospital is still responsible for an appropriate patient assessment and the provision of safe, appropriate care to its patient (the law enforcement officer's prisoner).