**Final Rule: 42 CFR 482.13(e)(1)(i)(A-C) Page 71388**

*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

A restraint is— 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.

*A restraint does not include devices*, such as orthopedically prescribed devises, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conduction 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).

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However, the opportunity for individualized treatment of the patient is still available, since the regulation does not prohibit the use of any particular type of restraint.

This regulation requires individualized patient assessment and use of the least restrictive intervention when restraint is needed to protect the patient, a staff member, or others from harm.

Part IV

# Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 482

Medicare and Medicaid Programs; Hospital Conditions of Participation: Patients' Rights; Final Rule

(that is, with consideration for the differences between interventions such as a four-point restraint and a restraint used for frail patients). One commenter argued that physical and mechanical restraints should be defined separately rather than lumped into one category.

*Response:* We agree that a uniform definition of restraint across care settings is a good approach, adds clarity and avoids confusion. In the final rule, we have combined the regulations governing the use of restraint or seclusion into a single standard, and have adopted a single, consistent restraint definition. This definition applies to all uses of restraint in all hospital care settings. A restraint is 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 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. The final rule also clarifies that 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). This definition renders unnecessary the otherwise impossible task of naming each device and practices that can inhibit a patient's movement.

The concept of liberty of movement as proposed in this comment is incorporated in the final rule at the beginning of combined standard (e). 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 insure the immediate physical safety of the patient, staff, or others and must be discontinued at the earliest possible time.

However, we did not break restraints into three classes or view seclusion as a subset of restraint. We believe that the categorization proposed by the commenter is somewhat arbitrary, particularly in light of the fact that several of the deaths reported by the Hartford Courant occurred during physical holds, which the commenter would have categorized as "least restrictive." This fact makes us wary of suggesting, even implicitly, that physical holds are preferable to mechanical restraint. The deaths resulting from other traditional mechanical devices also persuade us of the hazards of using mechanical restraints. The type of restraint used is not the defining hazard—other variables, such as lack of patient assessment in choosing the restraint, inappropriate application of the physical restraint mechanism or technique, or inadequate patient monitoring could render many interventions dangerous. Accordingly, given the unique circumstances presented by each patient, we believe that it would be inappropriate and would place patients at risk to arbitrarily suggest that one form of restraint is categorically preferable to another.

Finally, we have streamlined and clarified monitoring requirements in combined standard (e). The final rule states that the condition of the patient who is restrained or secluded must be monitored by a physician, other licensed independent practitioner or trained staff at an interval determined by hospital policy. When restraint or seclusion is used to manage violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient must be seen and evaluated face-to-face within one hour after the initiation of the intervention. This final rule provides flexibility for trained staff to determine the monitoring parameters necessary when a restraint or seclusion is used. The more stringent continual monitoring requirements have been retained only for patients who are simultaneously restrained and secluded for management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others.

*Comment:* Some commenters asked whether the following constitute restraint: therapeutic holding; comforting children through holding; escorting or touching for de-escalation; virtually any type of touching, like holding a patient's arm to prevent him from hitting the wall; basket holds; or touching to encourage the patient to lie still for a procedure. Many commenters argued that therapeutic holding is necessary, and that the regulation should allow individualized treatment.

*Response:* Several commenters mentioned different types of holding, including therapeutic holding. For the purposes of this regulation, a staff member picking up, redirecting, or holding an infant, toddler, or preschool-aged child to comfort the patient is not considered restraint. If an intervention meets the regulatory definition of restraint, then that intervention constitutes a restraint and the standards for restraint use must be followed. A restraint is any 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. 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. The devices and methods listed here that would not be considered restraints, and thus not subject to these requirements, are typically used in medical surgical care.

The regulation permits the physical holding of a patient for the purpose of conducting routine physical examinations or tests. However, patients do have the right to refuse treatment. See § 482.13(b)(2). This includes the right to refuse physical examinations or tests. Holding a patient in a manner that restricts the patient's movement against his or her will would be considered a restraint. This includes therapeutic holds. Many deaths have involved these practices and may be just as restrictive and potentially dangerous as restraining methods that involve devices. However, the opportunity for individualized treatment of the patient is still available, since the regulation does not prohibit the use of any particular type of restraint. This regulation requires individualized patient assessment and use of the least restrictive intervention when restraint is needed to protect the patient, a staff member, or others from harm.

*Comment:* Several commenters asked whether a side rail was a physical restraint. One commenter stated that "the majority" of hospitals require that side rails be raised for safety reasons, and that patients do not perceive this common safety practice as a restraint. This commenter also cited a need for side rails to be raised to protect patients who are confused or disoriented by narcotics or controlled substances. Another commenter wanted to know if crib rails are a restraint.

*Response:* The final rule states that a restraint does not include methods that protect the patient from falling out of