A-0154

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§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.[1]
In fact in some instances reducing the use of physical restraints may actually decrease the risk of falling.[2]

FOOTNOTES

[1]- *American Geriatrics Society, British Geriatrics Society, and American Academy of Orthopaedic Surgeons Panel on Falls Prevention. Guideline for the prevention of falls in older persons. Journal of the American Geriatrics Society. 49(5):664-72, 2001 May.*

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[2]*University of California at San Francisco (UCSF)-Stanford University Evidence-based Practice Center Subchapter 26.2. Interventions that Decrease the Use of Physical Restraints" of the Evidence Report/Technology Assessment, No. 43 entitled, "Making Health Care Safer: A Critical Analysis of Patient Safety Practices." The full report can be accessed at: http://www.ahrq.gov/qual/errorsix.htm*

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.

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).

Survey Procedures §482.13(e)

- Review hospital restraint and seclusion policies and procedures to determine if they address, at a minimum:

- Who has the authority to discontinue the use of restraint or seclusion (based on State law and hospital policies); and

- Circumstances under which restraint or seclusion should be discontinued. (Also see §482.13(e)(3)).

- Review a sample of medical records of patients for whom restraints were used to manage non-violent, non-self-destructive behavior, as well as a sample of medical records of patients for whom restraint or seclusion was used to manage violent or self-destructive behavior;

- Include in the review patients who are currently in restraint or seclusion, as well as those who have been in restraint or seclusion during their hospital stay (include both violent or self-destructive patients as well as non-violent, non-self-destructive patients).

- What evidence is there that hospital staff identified the reason for the restraint or seclusion, and determined that other less restrictive measures would not be effective before applying the restraint?

- Interview staff who work directly with patients to determine their understanding of the restraint and seclusion policies. If any patients are currently in restraint or seclusion, ascertain the rationale for use and when the patient was last monitored and assessed.

- Is the actual use of restraints or seclusion consistent with hospital restraint and seclusion policies and procedures, as well as CMS requirements?

- Review incident and accident reports to determine whether patient injuries occurred proximal to or during a restraint or seclusion intervention. Are incidents and accidents occurring more frequently with restrained or secluded patients?

- If record review indicates that restrained or secluded patients sustained injuries, determine what the hospital did to prevent additional injury. Determine if the hospital investigated possible changes to its restraint or seclusion policies.

- Obtain data on the use of restraint and seclusion for a specified time period (e.g., 3 months) to determine any patterns in their use for specific units, shifts, days of the week, etc.

- Does the number of patients who are restrained or secluded increase on weekends, on holidays, at night, on certain shifts; where contract nurses are used; in one unit more than other units? Such patterns of restraint or seclusion use may suggest that the intervention is not based on the patient's need, but on issues such as

convenience, inadequate staffing or lack of staff training. Obtain nursing staffing schedules during time periods in question to determine if staffing levels impact the use of restraint or seclusion.

- Interview a random sample of patients who were restrained to manage non-violent, non-self-destructive behavior. Were the reasons for the use of a restraint to manage non-violent, non-self-destructive behavior explained to the patient in understandable terms? Could the patient articulate his/her understanding?

A-0159

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§482.13(e) (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

Interpretive Guidelines §482.13(e)(1)(i)(A)

This restraint definition applies to **all** uses of restraint in **all** hospital care settings. Under this definition, commonly used hospital devices and other practices could meet the definition of a restraint, such as:

- Tucking a patient's sheets in so tightly that the patient cannot move;
- Use of a "net bed" or an "enclosed bed" that prevents the patient from freely exiting the bed. **EXCEPTION**: Placement of a toddler in an "enclosed" or "domed" crib;
- Use of "Freedom" splints that immobilize a patient's limb;
- Using side rails to prevent a patient from voluntarily getting out of bed; or
- Geri chairs or recliners, **only** if the patient cannot easily remove the restraint appliance and get out of the chair on his or her own.

NOTE: Generally, if a patient can easily remove a device, the device would not be considered a restraint. In this context, **"easily remove"** means that the manual method, device, material, or equipment can be removed intentionally by the patient in the same manner as it was applied by the staff (e.g., side rails are put down, not climbed over; buckles are intentionally unbuckled; ties or knots are intentionally untied; etc.) considering the patient's physical

condition and ability to accomplish objective (e.g., transfer to a chair, get to the bathroom in time).

Survey Procedures §482.13(e)(1)(i)(A)

- Determine whether the hospital's policy and procedures employ a definition or description of what constitutes a restraint that is consistent with the regulation.

- While touring hospital units look for restraints in use. Where a restraint is in use, check the medical record for appropriate documentation.

- Interview hospital staff to determine whether they know the definition of a restraint.

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§482.13(e)(1)(i)(B) [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.

Interpretive Guidelines §482.13(e)(1)(i)(B)

Drugs or medications that are used as part of a patient's standard medical or psychiatric treatment, and are administered within the standard dosage for the patient's condition, would not be subject to the requirements of standard (e). These regulations are not intended to interfere with the clinical treatment of patients who are suffering from serious mental illness and who need therapeutic doses of medication to improve their level of functioning so that they can more actively participate in their treatment. Similarly, these regulations are not intended to interfere with appropriate doses of sleeping medication prescribed for patients with insomnia, anti-anxiety medication prescribed to calm a patient who is anxious, or analgesics prescribed for pain management. The regulatory language is intended to provide flexibility and recognize the variations in patient conditions.

Whether or not an order for a drug or medication is PRN (Latin abbreviation for pro re nata - as needed; as circumstances require) or a standing-order does not determine whether or not the use of that drug or medication is considered a restraint. The use of PRN or standing-order drugs or medications is only prohibited if the drug or medication meets the definition of a drug or medication used as a restraint.

Criteria used to determine whether the use of a drug or medication, or combination of drugs or medications is a standard treatment or dosage for the patient's condition includes all of the following:

- The drug or medication is used within the pharmaceutical parameters approved by the Food and Drug Administration (FDA) and the manufacturer for the indications that it is manufactured and labeled to address, including listed dosage parameters;

- The use of the drug or medication follows national practice standards established or recognized by the medical community, or professional medical associations or organizations; and,

- The use of the drug or medication to treat a specific patient's clinical condition is based on that patient's symptoms, overall clinical situation, and on the physician's or other licensed independent practitioner's (LIP) knowledge of that patient's expected and actual response to the medication.

Another component of "standard treatment or dosage" for a drug or medication is the expectation that the standard use of a drug or medication to treat the patient's condition enables the patient to more effectively or appropriately function in the world around them than would be possible without the use of the drug or medication. If the overall effect of a drug or medication, or combination of drugs or medications, is to reduce the patient's ability to effectively or appropriately interact with the world around the patient, then the drug or medication is **not** being used as a standard treatment or dosage for the patient's condition.

As with any use of restraint or seclusion, staff must conduct a comprehensive patient assessment to determine the need for other types of interventions before using a drug or medication as a restraint. For example, a patient may be agitated due to pain, an adverse reaction to an existing drug or medication, or other unmet care need or concern.

There are situations where the use of a drug or medication is clearly outside the standard for a patient or a situation, or a medication is not medically necessary but is used for patient discipline or staff convenience (neither of which is permitted by the regulation).

- **EXAMPLE 1:** A patient has Sundowner's Syndrome, a syndrome in which a patient's dementia becomes more apparent at the end of the day rather than at the beginning of the day. The patient may become agitated, angry, or anxious at sundown. This may lead to wandering, pacing the floors, or other nervous behaviors. The staff finds the patient's behavior bothersome, and asks the physician to order a high dose of a sedative to "knock out" the patient and keep him in bed. The patient has no medical symptoms or condition that indicates the need for a sedative. In this case, for this patient, the sedative is being used inappropriately as a restraint for staff convenience. Such use is not permitted by the regulation.

A drug or medication that is not being used as a standard treatment for the patient's medical or psychiatric condition, and that results in restricting the patient's freedom of movement would be a drug used as a restraint.

In addition, the regulation does not permit a drug or medication to be used to restrain the patient for staff convenience, to coerce or discipline the patient, or as a method of retaliation. While drugs or medications can be a beneficial part of a carefully constructed, individualized treatment plan for the patient, drug and medication use should be based on the assessed needs of the individual patient, and the effects of drugs and medications on the patient should be carefully monitored.

- **EXAMPLE 2:** A patient is in a detoxification program. The patient becomes violent and aggressive. Staff administers a PRN medication ordered by the patient's physician or other LIP to address these types of outbursts. The use of the medication enables the patient to better interact with others or function more effectively. In this case, the medication used for this patient is not considered a "drug used as a restraint." The availability of a PRN medication to manage outbursts of specific behaviors, such as aggressive, violent behavior is standard for this patient's medical condition (i.e., drug or alcohol withdrawal). Therefore, this patient's medication does not meet the definition of "drug used as a restraint" since it is a standard treatment or dosage for the patient's medical or psychiatric condition. The use of this medication for this patient is not affected by standard (e).

  If a drug or medication is used as a standard treatment (as previously defined) to address the assessed symptoms and needs of a patient with a particular medical or psychiatric condition, its use is **not** subject to the requirements of this regulation. However, the patient would still need to receive assessments, monitoring, interventions, and care that are appropriate for that patient's needs.

The regulation supports existing State laws that provide more vigorous promotion of the patient's choice and rights. Therefore, when a State's law prohibits the administration of drugs against the wishes of the patient without a court order, the State law applies.

Survey Procedures §482.13(e)(1)(i)(B)

- Determine whether the hospital's policies and procedures employ a definition or description of what constitutes the use of drugs or medications as a restraint that is consistent with the regulation.

- Interview hospital staff to determine whether they can identify when the use of a drug or medication is considered a chemical restraint.

A-0161

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§482.13(e)(1)(i)(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).

Interpretive Guidelines §482.13(e)(1)(i)(C)

The devices and methods listed here would not be considered restraints, and, therefore, not subject to these requirements. These devices and methods are typically used in medical-surgical care.

Use of an **IV arm board** to stabilize an IV line is generally not considered a restraint. However, if the arm board is tied down (or otherwise attached to the bed), or the entire limb is immobilized such that the patient cannot access his or her body, the use of the arm board would be considered a restraint.

A **mechanical support** used to achieve proper body position, balance, or alignment so as to allow greater freedom of mobility than would be possible without the use of such a mechanical support is not considered a restraint. For example, some patients lack the ability to walk without the use of leg braces, or to sit upright without neck, head, or back braces.

A medically necessary **positioning or securing device** used to maintain the position, limit mobility, or temporarily immobilize the patient during medical, dental, diagnostic, or surgical procedures is not considered a restraint.

Recovery from anesthesia that occurs when the patient is in a critical care or postanesthesia care unit is considered part of the surgical procedure; therefore, medically necessary restraint use in this setting would not need to meet the requirements of the regulation. However, if the intervention is maintained when the patient is transferred to another unit, or recovers from the effects of the anesthesia (whichever occurs first), a restraint order would be necessary and the requirements of standard (e) would apply.

Many types of **hand mitts** would not be considered restraint. However, pinning or otherwise attaching those same mitts to bedding or using a wrist restraint in conjunction with the hand mitts would meet the definition of restraint and the requirements would apply. In addition, if the mitts are applied so tightly that the patient's hand or fingers are immobilized, this would be considered restraint and the requirements would apply. Likewise, if the mitts are so bulky that the patient's ability to use their hands is

significantly reduced, this would be considered restraint and the requirements would apply.

NOTE: Because this definition of physical restraint does not name each device and situation that can be used to immobilize or reduce the ability of the patient to move his or her arms, legs, body or head freely, it promotes looking at each patient situation on a case-by-case basis.

In addition, if a patient can easily remove a device, the device would not be considered a restraint. In this context, **"easily remove"** means that the manual method, device, material, or equipment can be removed intentionally by the patient in the same manner as it was applied by the staff (e.g., side rails are put down, not climbed over; buckles are intentionally unbuckled; ties or knots are intentionally untied; etc.) considering the patient's physical condition and ability to accomplish the objective (e.g., transfer to a chair, get to the bathroom in time).

Age or developmentally appropriate protective safety interventions (such as stroller safety belts, swing safety belts, high chair lap belts, raised crib rails, and crib covers) that a safety-conscious child care provider outside a health care setting would utilize to protect an infant, toddler, or preschool-aged child would not be considered restraint or seclusion for the purposes of this regulation. The use of these safety interventions needs to be addressed in the hospital's policies or procedures.

Physical Escort

A physical escort would include a "light" grasp to escort the patient to a desired location. If the patient can easily remove or escape the grasp, this would not be considered physical restraint. However, if the patient cannot easily remove or escape the grasp, this would be considered physical restraint and all the requirements would apply.

Physical holding

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 the patient's will is considered restraint. This includes holds that some member of the medical community may term **"therapeutic holds."** Many deaths have occurred while employing these practices. Physically holding a patient can be just as restrictive, and just as dangerous, as restraining methods that involve devices. Physically holding a patient during a forced psychotropic medication procedure is considered a restraint and is **not** included in this exception.

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.

Physical Holding for Forced Medications

The application of force to physically hold a patient, in order to administer a medication against the patient's wishes, is considered restraint. The patient has a right to be free of restraint and, in accordance with §482.13(b)(2), also has a right to refuse medications, unless a court has ordered medication treatment. A court order for medication treatment only removes the patient's right to refuse the medication. Additionally, in accordance with State law, some patients may be medicated against their will in certain emergency circumstances. However, in both of these circumstances, health care staff is expected to use the least restrictive method of administering the medication to avoid or reduce the use of force, when possible. The use of force in order to medicate a patient, as with other restraint, must have a physician's order prior to the application of the restraint (use of force). If physical holding for forced medication is necessary with a violent patient, the 1-hour face-to-face evaluation requirement would also apply.

In certain circumstances, a patient may consent to an injection or procedure, but may not be able to hold still for an injection, or cooperate with a procedure. In such circumstances, and at the patient's request, staff may "hold" the patient in order to safely administer an injection (or obtain a blood sample, or insert an intravenous line, if applicable) or to conduct a procedure. This is **not** considered restraint.

Side rails

A restraint does not include methods that protect the patient from falling out of bed. Examples include raising the side rails when a patient is: on a stretcher, recovering from anesthesia, sedated, experiencing involuntary movement, or on certain types of therapeutic beds to prevent the patient from falling out of the bed. The use of side rails in these situations protects the patient from falling out of bed and, therefore, would not be subject to the requirements of standard (e).

However, side rails are frequently not used as a method to prevent the patient from falling out of bed, but instead, used to restrict the patient's freedom to exit the bed. The use of side rails to prevent the patient from exiting the bed would be considered a restraint and would be subject to the requirements of standard (e). The use of side rails is inherently risky, particularly if the patient is elderly or disoriented. Frail elderly patients may be at risk for entrapment between the mattress or bed frame and the side rail. Disoriented patients may view a raised side rail as a barrier to climb over, may slide between raised, segmented side rails, or may scoot to the end of the bed to get around a raised side rail and exit the bed. When attempting to leave the bed by any of these routes, the patient is at risk for entrapment, entanglement, or falling from a greater height posed by the raised side rail, with a possibility for sustaining greater injury or death than if the patient had fallen from the height of a lowered bed without raised side rails. In short, the patient may have an increased risk for a fall or other injury by attempting to exit the bed with the side

rails raised. The risk presented by side rail use should be weighed against the risk presented by the patient's behavior as ascertained through individualized assessment.

When the clinician raises all four side rails in order to restrain a patient, defined in this regulation as immobilizing or reducing the ability of a patient to move his or her arms, legs, body, or head freely to ensure the immediate physical safety of the patient, then the requirements of this rule apply. Raising fewer than four side rails when the bed has segmented side rails would not necessarily immobilize or reduce the ability of a patient to move freely as defined in the regulation. For example, if the side rails are segmented and all but one segment are raised to allow the patient to freely exit the bed, the side rail is not acting as a restraint and the requirements of this rule would not apply. Conversely, if a patient is not physically able to get out of bed regardless of whether the side rails are raised or not, raising all four side rails for this patient would not be considered restraint because the side rails have no impact on the patient's freedom of movement. In this example, the use of all four side rails would not be considered restraint. Therefore, the requirements of this rule would **not** apply.

When a patient is on a bed that constantly moves to improve circulation or prevents skin breakdown, raised side rails are a safety intervention to prevent the patient from falling out of bed and are not viewed as restraint.

When a patient is placed on **seizure precautions** and all side rails are raised, the use of side rails would not be considered restraint. The use of padded side rails in this situation should protect the patient from harm; including falling out of bed should the patient have a seizure.

Placement in a crib with raised rails is an age-appropriate standard safety practice for every infant or toddler. Therefore, placement of an infant or toddler in the crib with raised rails would not be considered restraint.

If the patient is on a **stretcher** (a narrow, elevated, and highly mobile cart used to transport patients and to evaluate or treat patients), there is an increased risk of falling from a stretcher without raised side rails due to its narrow width, and mobility. In addition, because stretchers are elevated platforms, the risk of patient injury due to a fall is significant. Therefore, the use of raised side rails on stretchers is not considered restraint but a prudent safety intervention. Likewise, the use of a seat belt when transporting a patient in a wheelchair is not considered restraint.

Survey Procedures §482.13(e)(1)(i)(C)

- Determine whether the hospital's policies and procedures employ a definition or description of what constitutes a restraint that is consistent with the regulation.

- While touring hospital units look for bed side rail use to determine whether it is consistent with the definition of a restraint. Where bed side rails are being used as a restraint, check the medical record for appropriate documentation.

- Interview hospital staff to determine whether they know the definition of a restraint, particularly with respect to use of bed side rails.

A-0162
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§482.13(e)(1)(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.

Interpretive Guidelines §482.13(e)(1)(ii)

Seclusion may **only** be used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others.

Seclusion is not just confining a patient to an area, but involuntarily confining the patient alone in a room or area where the patient is physically prevented from leaving. If a patient is restricted to a room alone and staff are physically intervening to prevent the patient from leaving the room or giving the perception that threatens the patient with physical intervention if the patient attempts to leave the room, the room is considered locked, whether the door is actually locked or not. In this situation, the patient is being secluded.

A patient physically restrained alone in an unlocked room does not constitute seclusion.

Confinement on a locked unit or ward where the patient is with others does not constitute seclusion.

Timeout is not considered seclusion. Timeout is an intervention in which the patient consents to being alone in a designated area for an agreed upon timeframe from which the patient is not physically prevented from leaving. Therefore, the patient can leave the designated area when the patient chooses.

Survey Procedures §482.13(e)(1)(ii)

- Determine whether the hospital's policy and procedures employ a definition or description of what constitutes seclusion that is consistent with the regulation.

- While touring hospital units look for cases where a patient is in seclusion.

- Interview hospital staff to determine whether they know the definition of seclusion.

A-0164

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.13(e)(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.

Interpretive Guidelines §482.13(e)(2)

A comprehensive assessment of the patient must determine that the risks associated with the use of the restraint or seclusion is outweighed by the risk of not using the restraint or seclusion. Less restrictive interventions do not always need to be tried, but less restrictive interventions must be determined by staff to be ineffective to protect the patient or others from harm prior to the introduction of more restrictive measures. Alternatives attempted or the rationale for not using alternatives must be documented.

The underpinning of this regulation is the concept that safe patient care hinges on looking at the patient as an individual and assessing the patient's condition, needs, strengths, weaknesses, and preferences. Such an approach relies on caregivers who are skilled in individualized assessment and in tailoring interventions to the individual patient's needs after weighing factors such as the patient's condition, behaviors, history, and environmental factors.

Resources are available to assist clinicians in identifying less restrictive interventions. For example, the American Psychiatric Association (APA), American Psychiatric Nurses Association (APNA), and the National Association of Psychiatric Health Systems (NAPHS), with support from the American Hospital Association (AHA), have sponsored the publication of a document entitled, "Learning from Each Other—Success Stories and Ideas for Reducing Restraint/Seclusion in Behavioral Health." This document, published in 2003, was developed through dialogue with clinicians in the field and included extensive input from behavioral healthcare providers throughout the country who have been working to reduce the use of restraint and seclusion and to improve care within their facilities. To access this document and other useful resources, visit the web sites of the sponsoring organizations: http://www.naphs.org; http://www.psych.org; http://www.apna.org; http://www.aha.org.

Survey Procedures §482.13(e)(2)

- Do physician's or other LIP's orders specify the reason for restraint or seclusion, the type of restraint, and the duration of restraint or seclusion?

- Does the severity of the behavior justify seclusion or restraint usage by identifying an immediate and serious danger to the physical safety of the patient or others?

- Is there evidence that the hospital considers factors other than the individual patient in determining causes for the need for restraints or seclusion (i.e., environmental factors)?

- Does the medical record include documentation of an individual patient assessment and a revision of the plan of care?

- Does the medical record reflect changes in behavior and staff concerns regarding safety risks to the patient, staff, or others prompting use of seclusion or restraints?

- Did the patient's behavior place the patient or others at risk for harm? Was the patient's behavior violent or self-destructive?

- Were other, less restrictive interventions tried and documented, or is there evidence that alternatives were considered and determined to be insufficient?

A-0165

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.13(e)(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.

Interpretive Guidelines §482.13(e)(3)

Resources are available to assist clinicians in identifying less restrictive restraint or seclusion interventions. For example, the American Psychiatric Association (APA), American Psychiatric Nurses Association (APNA), and the National Association of Psychiatric Health Systems (NAPHS), with support from the American Hospital Association (AHA), have sponsored the publication of a document entitled, "Learning from Each Other—Success Stories and Ideas for Reducing Restraint/Seclusion in Behavioral Health." This document, published in 2003, was developed through dialogue with the field and extensive input from behavioral healthcare providers throughout the country who have been working to reduce the use of restraint and seclusion and to improve care within their facilities. To access this document and other useful resources, visit the web sites of the sponsoring organizations: http://www.naphs.org; http://www.psych.org; http://www.apna.org; http://www.aha.org

Survey Procedures §482.13(e)(3)

- Is there clear documentation in the patient's medical record describing the steps or interventions used prior to the use of the needed restraint or seclusion? That is, what documentation is in the medical record to explain the rationale for the use of restraint or seclusion?

- Is there documentation that less restrictive measures were tried or considered?

    - Is the restraint or seclusion intervention the least restrictive intervention that meets the patient's clinical needs and protects the safety of the patient, staff, or others?

    - Did the staff determine that less restrictive alternatives would not meet the patient's clinical needs, or protect the patient's safety or the safety of others?

    - Do ongoing documented assessments demonstrate that the restraint or seclusion intervention is needed at this time (or at a time in the past) and that the restraint or seclusion intervention remains the least restrictive way to protect the patient's safety?

    - If the time of restraint or seclusion use is lengthy, look for evidence that the symptoms necessitating the use of restraint or seclusion have persisted. Is there evidence to indicate that the staff have evaluated whether or not the restraint or seclusion can be safely discontinued?

A-0166

§482.13(e)(4) - The use of restraint or seclusion must be --

(i) in accordance with a written modification to the patient's plan of care.

Interpretive Guidelines §482.13(e)(4)(i)

The use of restraint or seclusion (including drugs or medications used as restraint as well as physical restraint) must be documented in the patient's plan of care or treatment plan. The use of restraint or seclusion constitutes a change in a patient's plan of care.

The regulation does not require that a modification to the patient's plan of care be made before initiating or obtaining an order for the use of restraint or seclusion. The use of a restraint or seclusion intervention should be reflected in the patient's plan of care or treatment plan based on an assessment and evaluation of the patient. The plan of care or treatment plan should be reviewed and updated in writing within a timeframe specified by hospital policy.

Survey Procedures §482.13(e)(4)(i)

- Determine whether the hospital's procedures are consistent with the requirements of this regulation. Does the plan of care or treatment reflect a process of assessment, intervention, and evaluation when restraint or seclusion is used?
- Is there evidence of assessment of the identified problem or of an individual patient assessment?
- Does the patient's plan of care reflect that assessment?
- What was the goal of the intervention?
- What was the described intervention?
- Who is responsible for implementation?
- Was the patient informed of the changes in his or her treatment plan or plan of care?
- Did the physician or other LIP write orders that included a time limit? Were these orders incorporated into the plan of care?
- After the discontinuation of the restraint or seclusion intervention, was this information documented in an update of the plan of care or treatment plan?

A-0167

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

[The use of restraint or seclusion must be --]

§482.13(e)(4)(ii) - implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by hospital policy in accordance with State law.

Interpretive Guidelines §482.13(e)(4)(ii)

Restraint or seclusion must be implemented appropriately and safely, and reflect hospital policy in accordance with State law.

The use of restraint or seclusion must never act as a barrier to the provision of other interventions to meet the patient's needs.

Survey Procedures §482.13(e)(4)(ii)

- Review the hospital's policies and procedures to determine if they reflect current standards of practice regarding safe and appropriate restraint and seclusion techniques. Are there any references to State law statutes or any indication State laws were reviewed and incorporated?

- Review a sample of patient medical records that include patients who required the use of restraint or seclusion for the management of both violent, self-destructive behaviors, and non-violent, non-self-destructive behaviors.
- After restraints were applied, was an assessment immediately made to ensure that restraints were properly and safely applied?

- Were the hospital policies and procedures followed?

- Was the use of restraint or seclusion effective in achieving the purpose for which it was ordered? If not, were timely changes made?

- Was there any evidence of injury to the patient?

A-0168

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.13(e)(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 §481.12(c) and authorized to order restraint or seclusion by hospital policy in accordance with State law.

Interpretive Guidelines §482.13(e)(5)

Hospitals must have policies and procedures for the initiation of restraint or seclusion that identify the categories of LIPs that are permitted to order restraint or seclusion in that hospital, consistent with State law.

The regulation requires that a physician or other LIP responsible for the care of the patient to order restraint or seclusion prior to the application of restraint or seclusion. In some situations, however, the need for a restraint or seclusion intervention may occur so quickly that an order cannot be obtained prior to the application of restraint or seclusion.

In these **emergency application situations,** the order must be obtained either during the emergency application of the restraint or seclusion, or immediately (within a few minutes) after the restraint or seclusion has been applied. The failure to immediately obtain an order is viewed as the application of restraint or seclusion without an order. The hospital should address this process in its restraint and seclusion policies and procedures. The policies and procedures should specify who can initiate the emergency application of restraint or seclusion prior to obtaining an order from a physician or other LIP.

Licensed Independent Practitioner (LIP)

For the purpose of ordering restraint or seclusion, an LIP is any practitioner permitted by State law and hospital policy as having the authority to independently order restraints or seclusion for patients.

A resident who is authorized by State law and the hospital's residency program to practice as a physician can carry out functions reserved for a physician or LIP by the regulation. A medical school student holds no license, and his/her work is reviewed and must be countersigned by the attending physician; therefore, he or she is not licensed or independent. A medical school student is not an LIP.

Protocols

A protocol cannot serve as a substitute for obtaining a physician's or other LIP's order prior to initiating each episode of restraint or seclusion use. If a hospital uses protocols that include the use of restraint or seclusion, a specific physician or LIP order is still required for each episode of restraint or seclusion use. The philosophy that serves as a foundation for the regulation is that restraint or seclusion use is an exceptional event, not a routine response to a certain patient condition or behavior. Each patient must be assessed, and interventions should be tailored to meet the individual patient's needs. The creation of a protocol can run counter to this philosophy if it sets up the expectation that restraint or seclusion will be used as a routine part of care. The use of restraint or seclusion is a last resort when less restrictive measures have been determined ineffective to ensure the safety of the patient, staff or others, should not be a standard response to a behavior or patient need.

Survey Procedures §482.13(e)(5)

- Review hospital policies and medical staff by-laws to ascertain clinical practice guidelines that describe the responsibilities of medical staff and clinicians who are privileged to order restraint and seclusion.

- Do the hospital's written policies identify what categories of practitioners the State recognizes as an LIP or as having the authority to order restraint and seclusion?

- Does the hospital have written policies indicating which practitioners are permitted to order restraint or seclusion in the facility?

- Do the hospital's written policies conform to State law?

- Does the hospital have established policies for who can initiate restraint or seclusion?

- Does the hospital utilize protocols for the use of restraint or seclusion? If so, is the use of protocols consistent with the requirements of the regulation?

- Do the medical records reviewed identify the physician or LIP who ordered each use of restraint or seclusion?

- During the medical record review, verify that a physician or LIP order was obtained prior to the initiation of restraint or seclusion. When emergency application of restraint or seclusion was necessary, verify that a physician or LIP order was obtained immediately (within a few minutes) after application of the restraint or seclusion.

A-0169

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.13(e)(6) - Orders for the use of restraint or seclusion must never be written as a standing order or on an as needed basis (PRN).

Interpretive Guidelines §482.13(e)(6)

This regulation prohibits the use of standing or PRN (Latin abbreviation for pro re nata - as needed; as circumstances require) orders for the use of restraint or seclusion. The ongoing authorization of restraint or seclusion is not permitted. Each episode of restraint or seclusion must be initiated in accordance with the order of a physician or other LIP. If a patient was recently released from restraint or seclusion, and exhibits behavior that can only be handled through the reapplication of restraint or seclusion, a new order would be required. Staff cannot discontinue a restraint or seclusion intervention, and then re-start it under the same order. This would constitute a PRN order. A "trial release" constitutes a PRN use of restraint or seclusion, and, therefore, is not permitted by this regulation.

When a staff member ends an ordered restraint or seclusion intervention, the staff member has no authority to reinstitute the intervention without a new order. For example, a patient is released from restraint or seclusion based on the staff's assessment of the patient's condition. If this patient later exhibits behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others that can only be handled through the use of restraint or seclusion, a new order would be required.

NOTE: A temporary, directly-supervised release, however, that occurs for the purpose of caring for a patient's needs (e.g., toileting, feeding, or range of motion exercises) is **not** considered a discontinuation of the restraint or seclusion intervention. As long as the patient remains under direct staff supervision, the restraint is not considered to be discontinued because the staff member is present and is serving the same purpose as the restraint or seclusion.

The use of PRN orders for drugs or medications is only prohibited when a drug or medication is being used as a restraint. A drug or medication is deemed to be a restraint only if it is not a standard treatment or dosage for the patient's condition, and the drug or medication is a restriction to manage the patient's behavior or restricts the patient's freedom of movement Using a drug to restrain the patient for staff convenience is expressly prohibited.

EXCEPTIONS

- **Geri chair**. If a patient requires the use of a Geri chair with the tray locked in place in order for the patient to safely be out of bed, a standing or PRN order is permitted. Given that a patient may be out of bed in a Geri chair several times a day, it is not necessary to obtain a new order each time.

- **Raised side rails.** If a patient's status requires that all bedrails be raised (restraint) while the patient is in bed, a standing or PRN order is permitted. It is not necessary to obtain a new order each time the patient is returned to bed after being out of bed.

- **Repetitive self-mutilating behavior**. If a patient is diagnosed with a chronic medical or psychiatric condition, such as Lesch-Nyham Syndrome, and the patient engages in repetitive self-mutilating behavior, a standing or PRN order for restraint to be applied in accordance with specific parameters established in the treatment plan would be permitted. Since the use of restraints to prevent self-injury is needed for these types of rare, severe, medical and psychiatric conditions, the specific requirements (1-hour face-to-face evaluation, time-limited orders, and evaluation every 24 hours before renewal of the order) for the management of violent or self- destructive behavior do not apply.

Survey Procedures §482.13(e)(6)

Review a random sample of medical records for patients that have been restrained or secluded. Review orders, progress notes, flow sheets, and nursing notes to:

- Verify that there is a physician or other LIP order for each episode of restraint or seclusion;

- Evaluate patterns of use and verify that orders were obtained when necessary;

- Verify that the documentation specifically addresses the patients' behaviors or symptoms; and,

- Determine if restraint or seclusion is being improperly implemented on a PRN basis.

A-0170

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.13(e)(7) - The attending physician must be consulted as soon as possible if the attending physician did not order the restraint or seclusion.

Interpretive Guidelines §482.13(e)(7)

The attending physician is the MD/DO who is responsible for the management and care of the patient. Hospital medical staff policies determine who is considered the attending physician. The intent of this requirement is to ensure that the physician who has overall responsibility and authority for the management and care of the patient is aware of the patient's condition and is aware of the restraint or seclusion intervention. It is important to consult with the attending physician to promote continuity of care, to ensure patient safety, and to elicit information that might be relevant in choosing the most appropriate intervention for the patient. The attending physician may have information regarding the patient's history that may have a significant impact on the selection of a restraint or seclusion intervention or an alternative intervention, and the subsequent course of treatment. Therefore, consultation should occur as soon as possible. Hospital policies and procedures should address the definition of "as soon as possible" based on the needs of their particular patient population(s). However, any established time frames must be consistent with "as soon as possible."

The hospital CoPs do permit the patient to be under the care of a treating LIP other than a physician. Section 482.12(c)(1) requires every Medicare patient to be under the care of a doctor of medicine or osteopathy; or, within the scope of their respective licenses, a doctor of dental surgery or dental medicine, a doctor of podiatry, chiropractor, or clinical psychologist. The individual overseeing the patient's care may be the attending physician or a health professional practicing with the delegated authority or supervision of a doctor of medicine or osteopathy as permitted by State law and hospital policy.

When the attending physician of record is unavailable, responsibility for the patient must be delegated to another physician, who would then be considered the attending physician.

This provision does not specify that consultation with the attending physician be face-to-face. The consultation can occur via telephone.

Survey Procedures §482.13(e)(7)

- Review the patient's medical record for documentation that the attending physician was notified immediately if the attending physician did not order the restraint or seclusion. Was the attending physician notified "as soon as possible?"

- Review the hospital's policies and procedures regarding consultation with the attending physician if the attending physician did not order the restraint or seclusion.

- Interview staff to determine if actual practice is consistent with written hospital policies and procedures.

A-0171

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.13(e)(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

Interpretive Guidelines §482.13(e)(8)(i)

Patients of all ages are vulnerable and at risk when restrained or secluded to manage violent or self-destructive behavior. Therefore, time limits have been established for each order for restraint or seclusion used to manage violent or self-destructive behavior. State law may require more restrictive time limits. These time limits **do not** apply to orders for restraint used to manage non-violent or non-self-destructive behavior. However, the requirement that restraint use be ended at the earliest possible time applies to all uses of restraint.

In the final rule on the use of restraint or seclusion, CMS did not include specific criteria for differentiating between emergency situations where the patient's behavior is violent or self-destructive and jeopardizes the immediate physical safety of the patient, a staff member, or others, and non-emergency use of restraint. Clinicians are adept at identifying various behaviors and symptoms, and can readily recognize violent and self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others. Asking clinicians to act based on an evaluation of the patient's

behavior is no different than relying on the clinical judgment that they use daily in assessing the needs of each patient and taking actions to meet those individual needs.

The regulation identifies **maximum** time limits on the length of each order for restraint or seclusion based on age. The physician or other LIP has the discretion to write the order for a shorter length of time. The length-of-order requirement identifies critical points at which there is mandatory contact with a physician or other LIP responsible for the care of the patient. In addition, the time limits do not dictate how long a patient should remain in restraint or seclusion. Staff is expected to continually assess and monitor the patient 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. The regulation explicitly states that the intervention must be discontinued at the earliest possible time, regardless of the length of time identified in the order. For example, if a patient's behavior is no longer violent or self-destructive 20 minutes after the intervention is initiated, then the restraint or seclusion should be discontinued, even if the order was given for up to 4 hours. If restraint or seclusion is discontinued prior to the expiration of the original order, **a new order** must be obtained prior to reinitiating the use of restraint or seclusion.

At the end of the time frame, if the continued use of restraint or seclusion to manage violent or self-destructive behavior is deemed necessary based on an individualized patient assessment, another order is required. When the original order is about to expire, an RN must contact the physician or other LIP, report the results of his or her most recent assessment and request that the original order be renewed (not to exceed the time limits established in the regulation). Whether or not an onsite assessment is necessary prior to renewing the order is left to the discretion of the physician or other LIP in conjunction with a discussion with the RN who is over-seeing the care of the patient. Another 1-hour face-to-face patient evaluation (see §482.13(e)(12) and the related interpretive guidance) is not required when the original order is renewed.

The original restraint or seclusion order may only be renewed within the required time limits for up to a total of 24 hours. After the original order expires, a physician or other LIP must see and assess the patient before issuing a new order.

EXCEPTION: Repetitive self-mutilating behaviors – see interpretive guidance for §482.13(e)(6).

Survey Procedures §482.13(e)(8)(i)

- When restraint or seclusion is used to manage violent or self-destructive behavior, do orders contain the appropriate time frames based on the patient's age? Does the total number of hours covered by an order or its renewal exceed 24 hours?

    - If more restrictive State laws apply, are they being followed?

- Is the renewal order for restraint or seclusion based on a comprehensive individual patient assessment?

- Is there evidence in the patient's medical record that the symptoms necessitating the continued use of restraint or seclusion have persisted?

A-0172

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

[Unless superseded by State law that is more restrictive --]

§482.13(e)(8)(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.

Interpretive Guidelines §482.13(e)(8)(ii)

At a minimum, if a patient remains in restraint or seclusion for the management of violent or self-destructive behavior 24 hours after the original order, the physician or other LIP must see the patient and conduct a face-to-face re-evaluation before writing a new order for the continued use of restraint or seclusion. Twenty-four hours of restraint or seclusion for the management of violent or self-destructive behavior is an extreme measure with the potential for serious harm to the patient.

State laws may be more restrictive and require the physician or other LIP to conduct a face-to-face re-evaluation within a shorter timeframe.

When the physician or other LIP renews an order or writes a new order authorizing the continued use of restraint or seclusion, there must be documentation in the patient's medical record that describes the findings of the physician's or other LIP's re-evaluation supporting the continued use of restraint or seclusion.

EXCEPTION: Repetitive self-mutilating behaviors – see interpretive guidance for §482.13(e)(6).

Survey Procedures §482.13(e)(8)((ii)

- If restraint or seclusion is used to manage violent or self-destructive behavior for longer than 24 hours, is there documentation of a new written order, patient assessments, and a re-evaluation by a physician or other LIP in the medical

record? Does the documentation provide sufficient evidence to support the need to continue the use of restraint or seclusion? Is there evidence in the medical record that the symptoms necessitating the continued use of restraint or seclusion have persisted?

- Does the patient's plan of care or treatment plan address the use of restraint or seclusion?

- What is the patient's documented clinical response to the continued need for restraint or seclusion?

A-0173
(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

[Unless superseded by State law that is more restrictive --]

§482.13(e)(8)(iii) - Each order for restraint used to ensure the physical safety of the non-violent or non-self-destructive patient may be renewed as authorized by hospital policy.

Interpretive Guidelines §482.13(e)(8)(iii)

Hospitals have the flexibility to determine time frames for the renewal of orders for restraint of the non-violent, non-self-destructive patient. These time frames should be addressed in hospital policies and procedures.

Survey Procedures §482.13(e)(8)(iii)

- Review the hospital policy on renewal of restraint orders for the management of non-violent, non-self-destructive patient behavior.

- Interview staff and review the medical record documentation to ensure that practice is consistent with the hospital policy.

A-0174
(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.13(e)(9) - Restraint or seclusion must be discontinued at the earliest possible time, regardless of the length of time identified in the order.

Interpretive Guidelines §482.13(e)(9)

Restraint or seclusion may only be employed while the unsafe situation continues. Once the unsafe situation ends, the use of restraint or seclusion must be discontinued.

Staff members are expected to assess and monitor the patient's condition on an ongoing basis to determine whether restraint or seclusion can safely be discontinued. The regulation requires that these interventions be ended as quickly as possible. However, the decision to discontinue the intervention should be based on the determination that the patient's behavior is no longer a threat to self, staff members, or others. When the physician or LIP renews an order or writes a new order authorizing the continued use of restraint or seclusion, there must be documentation in the medical record that describes the patient's clinical needs and supports the continued use of restraint or seclusion.

The hospital policies and procedures should address, at a minimum:

- Categories of staff that the hospital authorizes to discontinue restraint or seclusion in accordance with State law; and

- The circumstances under which restraint or seclusion is to be discontinued.

Survey Procedures §482.13(e)(9)

- Does the hospital have policies and procedures for ending restraint or seclusion? Do the policies include a requirement to end the restraint or seclusion as soon as is safely possible?

- Does the medical record contain evidence that the decision to continue or discontinue the use of restraint or seclusion was based on an assessment and re-evaluation of the patient's condition?

- Interview staff to determine whether they are aware that use of a restraint or seclusion must be discontinued as soon as is safely possible.

A-0175

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§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.

Interpretive Guidelines §482.13(e)(10)

Ongoing assessment and monitoring of the patient's condition by a physician, other LIP or trained staff is crucial for prevention of patient injury or death, as well as ensuring that

the use of restraint or seclusion is discontinued at the earliest possible time. Hospital policies are expected to guide staff in determining appropriate intervals for assessment and monitoring based on the individual needs of the patient, the patient's condition, and the type of restraint or seclusion used. The selection of an intervention and determination of the necessary frequency of assessment and monitoring should be individualized, taking into consideration variables such as the patient's condition, cognitive status, risks associated with the use of the chosen intervention, and other relevant factors. In some cases, checks every 15 minutes or vital signs taken every 2 hours may not be sufficient to ensure the patient's safety. In others, it may be excessive or disruptive to patient care (e.g., it may be unnecessary to mandate that a patient with wrist restraints, and who is asleep, be checked every 15 minutes and awakened every 2 hours to take the patient's vital signs). Similarly, depending on the patient's needs and situational factors, the use of restraint or seclusion may require either periodic (e.g., every 15 minutes, every 30 minutes, etc.) or continual (i.e., moment to moment) monitoring and assessment.

Hospital policies should address: frequencies of monitoring and assessment; assessment content (e.g., vital signs, circulation, hydration needs, elimination needs, level of distress and agitation, mental status, cognitive functioning, skin integrity, etc.); providing for nutritional needs, range of motion exercises, and elimination needs; and mental status and neurological evaluations.

With the exception of the simultaneous use of restraint and seclusion, one-to-one observation with a staff member in constant attendance is not required by this regulation unless deemed necessary based on a practitioner's clinical judgment. For example, placing staff at the bedside of a patient with wrist restraints may be unnecessary. However, for a more restrictive or risky intervention and/or a patient who is suicidal, self injurious, or combative, staff may determine that continual face-to-face monitoring is needed. The hospital is responsible for providing the level of monitoring and frequency of reassessment that will protect the patient's safety.

Hospitals have flexibility in determining which staff performs the patient assessment and monitoring. This determination must be in accordance with the practitioner's scope of clinical practice and State law. For example, assessment and monitoring are activities within a registered nurse's scope of practice. However, some trained, unlicensed staff may perform components of monitoring (e.g., checking the patient's vital signs, hydration and circulation; the patient's level of distress and agitation; or skin integrity), and may also provide for general care needs (e.g., eating, hydration, toileting, and range of motion exercises). Section 482.13(f) requires that before applying restraints, implementing seclusion, or performing associated monitoring and care tasks, staff must be trained and able to demonstrate competency in the performance of these actions.

Survey Procedures §482.13(e)(10)

- Review hospital policies regarding assessment and monitoring of a patient in restraint or seclusion.
    - What evidence do you find that the hospital's monitoring policies are put into practice for all restrained or secluded patients?
    - Do hospital policies identify which categories of staff are responsible for assessing and monitoring the patient?
    - Do hospital policies include time frames for offering fluids and nourishment, toileting/elimination, range of motion, exercise of limbs and systematic release of restrained limbs? Is this documented in the patient's medical record?
- Review patient medical records:
    - Was there a valid rationale for the decision regarding the frequency of patient assessment and monitoring documented in the medical record?
    - Was documentation consistent, relevant, and reflective of the patient's condition?
    - Are time frames described for how often a patient is monitored for vital signs, respiratory and cardiac status, and skin integrity checks?
    - Is there documentation of ongoing patient monitoring and assessment (e.g., skin integrity, circulation, respiration, intake and output, hygiene, injury, etc)?
    - Is the patient's mental status assessed? Is this documented in the medical record?
    - Is the patient assessed regarding continued need for the use of seclusion or restraint?
    - Is there adequate justification for continued use and is this documented?
    - Is the level of supervision appropriate to meet the safety needs of the patient who is at a higher risk for injury (e.g., self-injurious, suicidal)?

§482.13(e)(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.

Interpretive Guidelines §482.13(e)(11)

At a minimum, physicians and other LIPs authorized to order restraint and seclusion must have a working knowledge of hospital policy regarding the use of restraint and seclusion.

Hospitals have the flexibility to identify training requirements above this minimum requirement based on the competency level of their physicians and other LIPs, and the needs of the patient population(s) that they serve. Physicians receive training in the assessment, monitoring, and evaluation of a patient's condition as part of their medical school education. However, physicians generally do not receive training regarding application of restraint or implementation of seclusion as part of their basic education. Depending on the level and frequency of involvement that a physician or other LIP has in the performance of these activities, additional training may or may not be necessary to ensure the competency of these individuals in this area. The hospital is in the best position to determine if additional physician or other LIP training is necessary based on the model of care, level of physician competency, and the needs of the patient population(s) that the hospital serves.

Survey Procedures §482.13(e)(11)

- Review the hospital policy regarding restraint and seclusion training requirements for physicians and other LIPs. Are the minimum training requirements addressed?

- Review medical staff credentialing and privileging files to determine if physicians or other LIPs involved in restraint and seclusion activities have completed the required training.

A-0178

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.13(e)(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.

Interpretive Guidelines §482.13(e)(12)(i)

When restraint or seclusion is used to manage violent or self-destructive behavior, a physician or other LIP, or a registered nurse (RN) or physician assistant (PA) trained in accordance with the requirements specified under §482.13(f), must see the patient face-to-face within 1-hour after the initiation of the intervention. This requirement also applies when a drug or medication is used as a restraint to manage violent or self-destructive behavior.

The 1-hour face-to-face patient evaluation must be conducted in person by a physician or other LIP, or trained RN or PA. A telephone call or telemedicine methodology is not permitted.
If a patient's violent or self-destructive behavior resolves and the restraint or seclusion intervention is discontinued before the practitioner arrives to perform the 1-hour face-to-face evaluation, the practitioner is still required to see the patient face-to-face and conduct the evaluation within 1 hour after the initiation of this intervention. The fact that the patient's behavior warranted the use of a restraint or seclusion indicates a serious medical or psychological need for prompt evaluation of the patient behavior that led to the intervention. The evaluation would also determine whether there is a continued need for the intervention, factors that may have contributed to the violent or self-destructive behavior, and whether the intervention was appropriate to address the violent or self-destructive behavior.

EXCEPTION: Repetitive self-mutilating behaviors – see interpretive guidance for §482.13(e)(6).

Survey Procedures §482.13(e)(12)(i)

- Review the hospital policy regarding the 1-hour face-to-face evaluation.
- What categories of practitioners does the hospital policy authorize to conduct the 1-hour face-to-face evaluation?
- Interview staff to determine if practice is consistent with hospital policy.

A-0179

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

[the patient must be seen face-to-face within 1 hour after the initiation of the intervention --]

§482.13(e)(12)(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.

Interpretive Guidelines §482.13(e)(12)(ii)

The 1-hour face-to-face evaluation includes both a physical and behavioral assessment of the patient that must be conducted by a qualified practitioner within the scope of their practice. An evaluation of the patient's medical condition would include a complete review of systems assessment, behavioral assessment, as well as review and assessment of the patient's history, drugs and medications, most recent lab results, etc. The purpose is to complete a comprehensive review of the patient's condition to determine if other factors, such as drug or medication interactions, electrolyte imbalances, hypoxia, sepsis, etc., are contributing to the patient's violent or self-destructive behavior.

Training for an RN or PA to conduct the 1-hour face-to-face evaluation would include all of the training requirements at §482.13(f) as well as content to evaluate the patient's immediate situation, the patient's reaction to the intervention, the patient's medical and behavioral condition (documented training in conducting physical and behavioral assessment); and the need to continue or terminate the restraint or seclusion.

Survey Procedures §482.13(e)(12)(ii):

- Was the 1-hour face-to-face evaluation conducted by a practitioner authorized by hospital policy in accordance with State law to conduct this evaluation?

- If the 1-hour face-to-face evaluations are conducted by RNs who are not advanced practice nurses (APN), verify that those RNs have documented training that demonstrates they are qualified to conduct a physical and behavioral assessment of the patient that addresses: the patient's immediate situation, the patient's reaction to the intervention, the patient's medical and behavioral condition, and the need to continue or terminate the restraint or seclusion.

- Does documentation of the 1-hour face-to-face evaluation in the patient's medical record include all the listed elements of this requirement?

- Did the evaluation indicate whether changes in the patient's care were required, and, if so, were the changes made?

- Is practice consistent with hospital policy and State law?

A-0180
(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.13(e)(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.

Interpretive Guidelines §482.13(e)(13)

States are free to have requirements that are more restrictive regarding the types of practitioners who may conduct the 1-hour face-to-face evaluation. Generally, States may have more restrictive requirements as long as they do not conflict with Federal requirements.

Survey Procedures §482.13(e)(13):

- When preparing for the hospital survey, determine whether there are State provisions governing the use of restraint or seclusion that are more restrictive than those found in this section.

- When State requirements are more restrictive, apply those requirements instead of those found in this section.

A-0182
(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.13(e)(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.

Interpretive Guidelines §482.13(e)(14)

When a trained RN or PA conducts the required face-to-face evaluation, he or she must consult the attending physician or other LIP responsible for the patient's care as soon as possible after the completion of the evaluation. Hospital policy should address the expected time frame for and the components of the consultation with the attending physician or other LIP consistent with "as soon as possible." This consultation should include, at a minimum, a discussion of the findings of the 1-hour face-to-face evaluation, the need for other interventions or treatments, and the need to continue or discontinue the

use of restraint or seclusion. A consultation that is not conducted prior to a renewal of the order would not be consistent with the requirement, "as soon as possible."

Survey Procedures §482.13(e)(14):

- Review the relevant hospital restraint and seclusion policy.
- Does the hospital policy clarify expectations regarding the requirement, "as soon as possible"?
- Does documentation in the patient's medical record indicate consultation with the attending physician or other LIP when the 1-hour face-to-face evaluation was conducted by a trained RN or PA?
- Is practice consistent with hospital policy?

A-0183

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.13(e)(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.

Interpretive Guidelines §482.13(e)(15)

When the simultaneous use of restraint and seclusion is employed, there must be adequate documentation that justifies the decision for simultaneous use as well as vigilance in continuously monitoring the patient so that the patient's care needs are met.

All requirements specified under standard (e) apply to the simultaneous use of restraint and seclusion. The simultaneous use of restraint and seclusion is not permitted unless the patient is continually monitored by trained staff, either through face-to-face observation or through the use of both video and audio equipment. Monitoring with video and audio equipment further requires that staff perform the monitoring in close proximity to the patient. For the purposes of this requirement, "continually" means ongoing without interruption. The use of video and audio equipment does not eliminate the need for frequent monitoring and assessment of the patient.

An individual who is physically restrained alone in his or her room is not necessarily being simultaneously secluded. The individual's privacy and dignity should be protected

to the extent possible during any intervention. In fact, the purpose of restraining a patient alone in his or her room may be to promote privacy and dignity versus simultaneously using seclusion and restraint. While this distinction may be difficult to make, it is helpful to consider whether the patient would, in the absence of the physical restraint, be able to voluntarily leave the room. If so, then the patient is not also being secluded. However, if the physical restraint was removed and the patient was still unable to leave the room because the door was locked or staff were otherwise physically preventing the patient from doing so, then the patient is also being secluded.

Staff must take extra care to protect the safety of the patient when interventions that are more restrictive are used. Monitoring must be appropriate to the intervention chosen, so that the patient is protected from possible abuse, assault, or self injury during the intervention.

Survey Procedures §482.13(e)(15):

- Review the hospital's policy regarding simultaneous use of restraint and seclusion to determine whether it provides for continual monitoring and otherwise complies with all requirements of §482.13.

- Conduct document review and staff interviews to determine if practice is consistent with the hospital policy and required uninterrupted audio and visual monitoring is provided as required.

- Is the staff member monitoring the patient with video and audio equipment trained and in close proximity to ensure prompt emergency intervention if a problem arises?

- Does the video equipment cover all areas of the room or location where the patient is restrained or secluded?

- Is the audio and video equipment located in an area that assures patient privacy?

- Is the equipment appropriately maintained and in working condition?

A-0184

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.13(e)(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;

Interpretive Guidelines §482.13(e)(16)(i)

When restraint or seclusion is used to manage violent or self-destructive behavior, the 1 hour face-to-face medical and behavioral evaluation must be documented in the patient's medical record.

Survey Procedures §482.13(e)(16)(i)

Does the patient's medical record include documentation of the1 hour face-to-face medical and behavioral evaluation when restraint or seclusion is used to manage violent or self-destructive behavior?

A-0185

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

[When restraint or seclusion is used, there must be documentation in the patient's medical record of the following:]

§482.13(e)(16)(ii) - A description of the patient's behavior and the intervention used.

Interpretive Guidelines §482.13(e)(16)(ii)

Documentation that must be included in the patient's medical record when the patient is restrained or secluded includes a description of the patient's behavior and the intervention used. The patient's behavior should be documented in descriptive terms to evaluate the appropriateness of the interventions used. The documentation should include a detailed description of the patient's physical and mental status assessments, and of any environmental factors (e.g., physical, milieu, activities, etc.) that may have contributed to the situation at the time of the intervention.

Survey Procedures §482.13(e)(16(ii)

- Does the patient's medical record include a clear description of the patient's behavior that warranted the use of restraint or seclusion?
- Was the intervention employed appropriate for the identified behavior?
- What was the patient's clinical response to the intervention(s)?

A-0186

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

[When restraint or seclusion is used, there must be documentation in the patient's medical record of the following:]

§482.13(e)(16)(iii) - Alternatives or other less restrictive interventions attempted (as applicable).

Interpretive Guidelines §482.13(e)(16)(iii)

The use of restraint or seclusion must be selected only when less restrictive measures have been judged to be ineffective to protect the patient or others from harm. It is not always appropriate for less restrictive alternatives to be attempted prior to the use of restraint or seclusion. When a patient's behavior presents an immediate and serious danger to his- or herself, or others, immediate action is needed. For example, when a patient physically attacks someone, immediate action is needed. While staff should be mindful of using the least intrusive intervention, it is critical that the intervention selected be effective in protecting the patient or others from harm.

Survey Procedures §482.13(e)(16)(iii):

- Does the patient's medical record document any alternatives or less restrictive interventions attempted by staff, if appropriate?
- What was the effect of less restrictive interventions, if attempted by staff?
- Were the interventions selected appropriate to the targeted patient behaviors?
- When an immediate and serious danger to the patient or others occurred, was the more restrictive intervention(s) effective? Could a less restrictive intervention have been used to ensure the safety of the patient, staff or others?

A-0187

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

[When restraint or seclusion is used, there must be documentation in the patient's medical record of the following:]

§482.13(e)(16)(iv) - The patient's condition or symptom(s) that warranted the use of the restraint or seclusion.

Interpretive Guidelines §482.13(e)(16)(iv)

A comprehensive, individualized patient assessment is necessary to identify the most appropriate intervention to effectively manage a patient's condition or symptom(s).

When using a restraint or seclusion intervention, the patient's condition or symptom(s) must be identified and documented in the patient's medical record.

Survey Procedures §482.13(e)(16)(iv):

Does the patient's medical record include descriptions of the patient's condition or symptom(s) that warranted the use of restraint or seclusion?

A-0188

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

[When restraint or seclusion is used, there must be documentation in the patient's medical record of the following:]

§482.13(e)(16)(v) - The patient's response to the intervention(s) used, including the rationale for continued use of the intervention.

Survey Procedures §482.13(e)(16)(v):

- Does the patient's medical record include descriptions of the impact of the intervention on the patient behavior that resulted in the use of restraint or seclusion?

- Does the patient's medical record include a detailed assessment of the patient's response to the intervention and a well-reasoned plan for the continued use of restraint or seclusion?

A-0194

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§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.

Interpretive Guidelines §482.13(f)

Without adequate staff training and competency, the direct care staff, patients, and others are placed at risk. Patients have a right to the safe application of restraint or seclusion by trained and competent staff. Staff training and education play a critical role in the reduction of restraint and seclusion use in a hospital.

Survey Procedures §482.13(f)

- Determine whether the hospital has staff training and education program that protects the patient's right to safe implementation of restraint or seclusion.

- Observe patients in restraint or seclusion to verify safe application of the restraint or seclusion.

A-0196

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.13(f)(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.

Interpretive Guidelines §482.13(f)(1)(i) - (iii)

All staff designated by the hospital as having direct patient care responsibilities, including contract or agency personnel, must demonstrate the competencies specified in standard (f) prior to participating in the application of restraints, implementation of seclusion, monitoring, assessment, or care of a patient in restraint or seclusion. These competencies must be demonstrated initially as part of orientation and subsequently on a periodic basis consistent with hospital policy. Hospitals have the flexibility to identify a time frame for ongoing training based on the level of staff competency, and the needs of the patient population(s) served.

Training for an RN or PA to conduct the 1-hour face-to-face evaluation would include all of the training requirements at §482.13(f) as well as content to evaluate the patient's immediate situation, the patient's reaction to the intervention, the patient's medical and behavioral condition, and the need to continue or terminate the restraint or seclusion. An evaluation of the patient's medical condition would include a complete review of systems assessment, behavioral assessment, as well as review and assessment of the patient's history, medications, most recent lab results, etc. The purpose of the 1-hour face-to-face evaluation is to complete a comprehensive review of the patient's condition and determine if other factors, such as drug or medication interactions, electrolyte imbalances, hypoxia, sepsis, etc., are contributing to the patient's violent or self-destructive behavior.

Once initial training takes place, training must be provided frequently enough to ensure that staff possesses the requisite knowledge and skills to safely care for restrained or secluded patients in accordance with the regulations. The results of skills and knowledge

assessments, new equipment, or QAPI data may indicate a need for targeted training or more frequent or revised training.

Hospitals are required to have appropriately trained staff for the proper and safe use of seclusion and restraint interventions. It would not be appropriate for a hospital to routinely call upon a law enforcement agency or agencies as a means of applying restraint or initiating seclusion. If hospital security guards, or other non-healthcare staff, as part of hospital policy, may assist direct care staff, when requested, in the application of restraint or seclusion, the security guards, or other non-healthcare staff, are also expected to be trained and able to demonstrate competency in the safe application of restraint and seclusion (in accordance with §482.13(f))

Survey Procedures §482.13(f)(1)(i) - (iii)

- Does the hospital have a documented training program for the use of restraint and seclusion interventions employed by the hospital?
- Does the hospital have documented evidence that all levels of staff, including agency or contract staff, that have direct patient care responsibilities and any other individuals who may be involved in the application of restraints (e.g., security guards) have been trained and are able to demonstrate competency in the safe use of seclusion and the safe application and use of restraints?
- Review and verify restraint and seclusion education staff training documentation for all new employees and contract staff.
- Does the training include demonstration of required competencies?
- What areas were included in this training program?

A-0199

§482.13(f)(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.

Interpretive Guidelines §482.13(f)(2)(i)

The term "appropriate staff" includes all staff that apply restraint or seclusion, monitor, assess, or otherwise provide care for patients in restraint or seclusion.

All staff, including contract or agency personnel, designated by the hospital as having direct patient care responsibilities are required to receive training in the areas of clinical techniques used to identify patient and staff behaviors, events and environmental factors that may trigger circumstances that require the use of restraint or seclusion. This training should be targeted to the specific needs of the patient populations being served, and to the competency level of staff.

Staff needs to be able to employ a broad range of clinical interventions to maintain the safety of the patient and others. The hospital is expected to provide education and training at the appropriate level to the appropriate staff based upon the specific needs of the patient population being served. For example, staff routinely providing care for patients who exhibit violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others (such as in an emergency department or on a psychiatric unit) generally require more in-depth training in the areas included in the regulation than staff routinely providing medical/surgical care. Hospitals may develop and implement their own training programs or use an outside training program. However, standard (f) specifies that individuals providing staff training must be qualified as evidenced by education, training, and experience.

Hospitals have the flexibility to develop their own training program to meet the staff training requirements at §482.13(f) or purchase a training program from the outside. CMS does not specify that any particular outside vendor must be used to provide the required training. Each hospital must assess the learning needs and competency of their staff to determine how extensive periodic training and staff competency demonstration must be subsequent to initial training. The training program must be provided to all appropriate staff. Any person monitoring or providing care to a restrained patient must demonstrate the knowledge and abilities required by the regulations.

At a minimum, physicians and other LIPs 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 and seclusion. Hospitals have the flexibility to identify training requirements above this minimum based on the competency level of their physicians and other LIPs and the needs of the patient population that they serve.

Survey Procedures §482.13(f)(2)(i):

- Does the hospital educational program include techniques related to the specific patient populations being served?

- Does the hospital educational program include techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require the use of restraint or seclusion?

- Does the hospital educational program provide more in-depth training in the areas included in the regulation for staff members who routinely provide care to patients who exhibit violent or self-destructive behavior (e.g., staff who work in the emergency department or psychiatric unit)?

- Interview staff to assess their knowledge of the restraint and seclusion techniques addressed in this requirement.

A-0200

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

[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:]

§482.13(f)(2)(ii) - The use of nonphysical intervention skills.

Interpretive Guidelines §482.13(f)(2)(ii)

Although we recognize that there may be circumstances in which the use of restraint or seclusion may be necessary to prevent a patient situation from escalating, staff often skillfully intervene with alternative techniques to redirect a patient, engage the patient in constructive discussion or activity, or otherwise help the patient maintain self-control and avert escalation.

The use of nonphysical intervention skills does not mean attempting a complex series of interventions or a lengthy checklist of steps to initiate before restraining or secluding a patient. Rather, a whole toolbox of possible interventions can be implemented during the course of a patient's treatment based upon the assessment of an individual patient's responses.

Survey Procedures §482.13(f)(2)(ii)

- Does the hospital educational program address the use of nonphysical intervention skills?

- Does the hospital's training program comply with the regulatory requirements?

- Interview staff to assess their non-physical intervention skills.

A-0201

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

[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:]

§482.13(f)(2)(iii) - Choosing the least restrictive intervention based on an individualized assessment of the patient's medical, or behavioral status or condition.

Interpretive Guidelines §482.13(f)(2)(iii)

The underpinning of this regulation is the concept that safe patient care hinges on looking at the patient as an individual and assessing the patient's condition, needs, strengths, weaknesses, and preferences. Such an approach relies on caregivers who are skilled in individualized assessment and in tailoring interventions to individual patient's needs after weighing factors such as the patient's condition, behaviors, history, and environmental factors.

Resources are available to assist clinicians in identifying less restrictive interventions. For example, the American Psychiatric Association (APA), American Psychiatric Nurses Association (APNA), and the National Association of Psychiatric Health Systems (NAPHS), with support from the American Hospital Association (AHA), have sponsored the publication of a document entitled, "Learning from Each Other—Success Stories and Ideas for Reducing Restraint/Seclusion in Behavioral Health." This document, published in 2003, was developed through dialogue with the field and extensive input from behavioral healthcare providers throughout the country who have been working to reduce the use of restraint and seclusion, and to improve care within their facilities. To access this document and other useful resources, visit the web sites of the sponsoring organizations: http://www.naphs.org; http://www.psych.org; http://www.apna.org; http://www.aha.org

Survey Procedures §482.13(f)(2)(iii)

- Does the hospital educational program address choosing the least restrictive intervention based on an individualized assessment of the patient's medical or behavioral status or condition?

- Does the hospital educational program address how to conduct an assessment of a patient's medical and behavioral conditions?

- Does the hospital educational program address types of interventions appropriate to the specific needs of the patient population(s) served and ranging from less to more restrictive?

- Interview staff to determine if they are able to demonstrate the abilities addressed in this requirement.

A-0202

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

[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:]

§482.13(f)(2)(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).

Interpretive Guidelines §482.13(f)(2)(iv)

Patients have a right to the safe application of restraint or seclusion by trained and competent staff.

Survey Procedures §482.13(f)(2)(iv)

- Is all staff, including contract or agency personnel, identified by the hospital as direct caregivers trained and able to demonstrate competency in the safe use of all types of restraints or seclusion used in the hospital?

- Does the hospital educational program address recognition and response to patient signs of physical and psychological distress?

- Is staff able to identify signs of physical and psychological distress in a timely manner?

- Is staff able to respond to and appropriately treat signs of physical and psychological distress?

- Review hospital data (i.e., incident reports, patient injury or death reports, etc.) to identify any patterns of patient injuries or death that may indicate that staff are not adequately trained to recognize and respond to patient signs of physical and psychological distress.

A-0204

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

[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:]
§482.13(f)(2)(v) - Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary.

Interpretive Guidelines §482.13(f)(2)(v)

The use of restraint or seclusion must be ended at the earliest possible time regardless of the length of time identified in the order. Staff must be trained and demonstrate competency in their ability to identify specific patient behavioral changes that may indicate that restraint or seclusion is no longer necessary and can be safely discontinued.

Survey Procedures **§482.13(f)(2)(v)**

Does the hospital educational program address identification of specific behavioral changes that may indicate that restraint or seclusion is no longer necessary?

Interview staff to determine if they are able to demonstrate the abilities addressed in this requirement.

A-0205

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

[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:]

§482.13(f)(2)(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.

Interpretive Guidelines §482.13(f)(2)(vi)

Staff must be trained and demonstrate competency in monitoring the physical and psychological well-being of a patient who is restrained or secluded, including but not limited to, respiratory and circulatory status, skin integrity, vital signs, and as well as any special requirements specified by hospital policy associated with the 1-hour face-to-face evaluation.

Survey Procedures §482.13(f)(2)(vi)

- Does the hospital educational program address monitoring the physical and psychological needs of patients who are 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?

- Does the hospital educational program address the specific requirements for the training of RNs and PAs that the hospital authorizes to conduct the 1-hour face-to-face evaluation?

- Interview staff to determine if they are able to demonstrate the competencies addressed in this regulation.

A-0206

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

[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:]

§482.13(f)(2)(vii) - The use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including required periodic recertification.

Interpretive Guidelines §482.13(f)(2)(vii)

Hospitals are required to provide a safe environment for the patients in their care. When restraint or seclusion techniques are used, patients are placed at a higher risk for injuries or even death. Hospitals must require appropriate staff (all staff who apply restraint or seclusion, monitor, access or provide care for a patient in restraint or seclusion) to receive education and training in the use of first aid techniques as well as training and certification in the use of cardiopulmonary resuscitation.

Hospitals are not required to use any particular recognized first aid course. Additionally, such courses may not adequately address the immediate interventions, the "first aid", that needs to be rendered to a restrained or secluded patient who is in distress or injured. The goal is for staff to be able to render the appropriate "first aid" required if a restrained or secluded patient is in distress or injured. For example, a patient is found hanging in a vest restraint, a restrained patient is choking on food, a secluded suicidal patient is found hanging, a secluded suicidal patient has cut himself, etc. Hospital staff need to assess their patient population and identify likely scenarios, develop a first aid training that addresses those scenarios, and provide that "first aid" training to all staff that care for restrained or secluded patients.

Survey Procedures §482.13(f)(2)(vii)

- Does the hospital educational program address first aid techniques?
- Is appropriate staff certified in cardiopulmonary resuscitation?
- Does the hospital educational program include, or provide for, staff training and certification in cardiopulmonary resuscitation (including provisions for recertification)?

A-0207

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.13(f)(3) Trainer Requirements. - Individuals providing staff training must be qualified as evidenced by education, training, and experience in techniques used to address patients' behaviors.

Interpretive Guidelines §482.13(f)(3)

There is no requirement that training be obtained from Federally-specified programs. Hospitals may develop and implement their own training programs or use an outside training program. However, individuals providing the training must be qualified as evidenced by education, training and experience in techniques used to address patients' behaviors for the patient populations being served. Trainers should demonstrate a high level of knowledge regarding all the requirements of these regulations as well as the hospital's policies and procedures that address these requirements.

Survey Procedures §482.13(f)(3)

Review personnel files of individuals responsible for providing staff education and training.

Do the individuals providing the education and training possess education, training, and experience to qualify them to teach the staff? Are they qualified to identify and meet the needs of the patient population(s) being served?
Does the hospital have a system for documenting and ensuring that the individuals providing education and training have the appropriate qualifications required by this regulation?

A-0208

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.13(f)(4) Training Documentation. - The hospital must document in the staff personnel records that the training and demonstration of competency were successfully completed.

Interpretive Guidelines §482.13(f)(4)

Staff personnel records must contain documentation that the training and demonstration of competency were successfully completed initially during orientation and on a periodic basis consistent with hospital policy.

Survey Procedure §482.13(f)(4)

- Review a sample of staff personnel records, including contract or agency staff, to determine if the training and demonstration of competency have been completed during orientation and on a periodic basis consistent with hospital policy.

A-0213

(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

§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….

(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….

Interpretive Guidelines §482.13(g)(1) & (3)(i)

The hospital must report to its CMS Regional Office each death that occurs:

- While a patient is in restraint or in seclusion, except when no seclusion has been used and the only restraint used was a soft, cloth-like two-point wrist restraints;

- Within 24 hours after the patient has been removed from restraint or seclusion, except when no seclusion has been used and the only restraint used was a soft, two-point wrist restraint; or,

- Within 1 week after use of restraint or seclusion where the death is known to the hospital and it is reasonable to assume that the use of restraint or seclusion contributed directly or indirectly to the patient's death, regardless of the type(s) of restraint used on the patient during this time.

    - "Reasonable to assume" applies only to those deaths that occur on days 2-7 after restraint or seclusion has been discontinued.

    - This criterion applies regardless of the type of restraint that was used on the patient. In other words, it applies to all uses of restraint or seclusion where the patient has died on days 2-7 after the restraint or seclusion was discontinued, and it is reasonable to assume the use of the restraint or seclusion contributed to the patient's death. In a case where only two-point soft wrist restraints were used and there was no seclusion, it may reasonably be presumed that the patient's death was not caused by the use of restraints.

    - In cases involving death within one week after use of restraint or seclusion where the intervention may have contributed to the patient's death, it is possible that the patient's death might occur outside the hospital and that the hospital might not learn of the patient's death, or that there might be a delay in the hospital's learning of the patient's death.

See the guidance for §482.13(g)(2) for handling of deaths while a patient was in, or within 24 hours after removal of a soft, two-point wrist restraint, when no other restraint or seclusion was used.

The reports required under §482.13(g)(1) must be submitted to the CMS Regional Office by telephone, facsimile, or electronically, as determined by the Regional Office no later than close of the next business day following the day in which the hospital knows of the patient's death. The report must include basic identifying information related to the hospital, the patient's name, date of birth, date of death, name of attending physician/practitioner, primary diagnosis(es), cause of death (preliminary, in case a final,

official cause of death is not yet available), and type(s) of restraint or seclusion used. CMS makes a standard form available for hospitals to use in submitting the required reports.

Hospitals must document in the patient's medical record the date and time each reportable death associated with the use of restraint or seclusion was reported to the CMS Regional Office.

After reviewing the submitted information, the Regional Office will determine whether an on-site investigation of the circumstances surrounding the patient's death is warranted and will direct the State Survey Agency to conduct a survey if applicable.

Survey Procedures §482.13(g)(1) & (3)(i):

- Does the hospital have restraint/seclusion death reporting policies and procedures that address responsibilities and systems for identifying restraint/seclusion-associated deaths reportable to CMS and for implementing the reporting and recordkeeping requirements?

- Can the hospital provide examples of restraint/seclusion-associated deaths that were reported to CMS?

    - If yes, review the report and medical records to determine whether:

        - the reports met the criteria for reporting to CMS;
        - were submitted timely to CMS;
        - were complete; and
        - the date and time the death reported to CMS was entered into the patient's medical record.

    - If no:

        - Ask the hospital how it ensures that there were no reportable restraint/seclusion-associated deaths.

        - If the hospital's system relies upon staff identification of reportable deaths, interview several applicable staff members to determine whether they are aware of the hospital's policy and know when and where to report internally a restraint/seclusion-associated death. Ask if there have been any patient deaths that meet the reporting requirements.

- Interview staff in various types of inpatient units, including a psychiatric unit if applicable, to determine whether they are aware of any patients who died while in restraints or seclusion or within one day of restraint or seclusion discontinuation,

excluding cases involving only the use of two-point soft wrist restraints and no seclusion. If yes, check whether the hospital has any evidence that these cases were reported to CMS.

A-0214

(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

§482.13(g) Standard: Death Reporting Requirements: [- Hospitals must report deaths associated with the use of seclusion or restraint.]

(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:]

(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.

Interpretive Guidelines §482.13(g)(2), (3)(ii), & (4)

Hospitals must maintain an internal log or other type of tracking system for recording information on each death that occurs:

- While a patient is in only 2-point soft, cloth-like non-rigid wrist restraints and there is no use of seclusion; and

- Within 24 hours of the patient being removed from 2-point soft, cloth-like non-rigid wrist restraints where there was no use of any other type of restraint or seclusion.

Use of the log or tracking system is limited only to patient deaths meeting one of these two criteria. Examples of patient deaths associated with restraints that must still be reported to CMS include:

- Deaths occurring during or within 24 hours of discontinuation of 2-point soft, cloth-like non-rigid wrist restraints used in combination with any other restraint device or with seclusion; or

- Deaths associated with the use of other types of wrist restraints, such as 2-point rigid or leather wrist restraints.

These cases would not be included in this internal log or tracking system and would require reporting the death to CMS using telephone, fax, or electronically.

The two-point soft wrist restraint death report must be entered into the internal log or tracking system within 7 days of the patient's death.

The death report log or tracking system entry must include:

- The patient's name;
- Patient's date of birth;
- Patient's date of death;
- Name of the attending physician or other licensed independent practitioner who is responsible for the care or the patient;
- Patient's medical record number; and
- Primary diagnosis(es).

Depending on the size and nature of the patient population the hospital serves and the types of services it provides, there will likely be variations in the frequency of restraint use as well as in the incidence of patient deaths. Surveyors should adjust their expectations for the volume of log or tracking system entries accordingly. For example, hospitals with intensive care units might be more likely to use both soft, 2-point wrist restraints and to have seriously ill patients who die as a result of their disease while such restraints are being used or within 24 hours after their discontinuance. On the other hand, a rehabilitation hospital would be expected to use such restraints less frequently, and to have patients who die less frequently while hospitalized.

The log or tracking system must be available in written, i.e., hard copy, or electronic form immediately upon CMS's request. CMS will specify the form in which the information is

to be provided. Generally CMS would request access to the log or tracking system during an on-site survey by CMS staff or State surveyors acting on CMS's behalf when assessing compliance with restraint/seclusion requirements. However, CMS may also request that a copy of portions or the entire log or tracking system be provided, even though no survey is in progress. Accreditation organizations conducting hospital inspections in accordance with a CMS-approved Medicare hospital accreditation program are also entitled to immediate access to the log or tracking system.

The hospital is not required to make the contents of the log or tracking system available to any other outside parties, unless required to do so under other Federal or State law.

The hospital must document in the patient's medical record the date and time the death report entry was made into the log or tracking system.

Survey Procedures §482.13(g)(2), (3)(ii), & (4)

- Does the hospital have restraint/seclusion death reporting policies and procedures that address responsibilities and systems for identifying restraint/seclusion-associated deaths that must be recorded in an internal hospital log/tracking system, and for implementing the reporting and recordkeeping requirements?

- Ask the hospital how it ensures that each death that must be captured in the log/tracking system is identified and entered.

- Interview inpatient unit staff to determine whether they have had patients who die while 2-point soft wrist restraints are being used without seclusion or within 24 hours of their discontinuance. If yes, ask the hospital to demonstrate that it has recorded such deaths.

- If the hospital's log or tracking system relies upon staff identification of reportable deaths, interview several applicable staff members to determine whether they are aware of the hospital's policy and know when and where to report internally a restraint/seclusion-associated death.
- Review the log/tracking system for patient deaths associated with use of only 2-point soft wrist restraints to determine if:

    - Each entry was made within 7 days of the patient's death; and

    - Each entry contains all the information required under the regulation.

- Is the hospital able to make the log or tracking system available immediately on request?

- Review a sample of medical records of patients whose deaths were entered in the log or tracking system.

- Does the medical record indicate that only soft, 2-point wrist restraints were used?

- Is there documentation in the medical record of the entry into the log or tracking system?

A-0215

(Rev. 75, Issued: 12-02-11, Effective: 12-02-11, Implementation: 12-02-11)

§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

Interpretive Guidelines, §482.13(h)

Visitation plays an important role in the care of hospital patients. An article published in 2004 in the Journal of the American Medical Association (Berwick, D.M., and Kotagal, M.: "Restricted visiting hours in ICUs: time to change." JAMA. 2004; Vol. 292, pp. 736-737) discusses the health and safety benefits of open visitation for patients, families, and intensive care unit (ICU) staff and debunks some of the myths surrounding the issue (physiologic stress for the patient; barriers to provision of care; exhaustion of family and friends). The article ultimately concluded that "available evidence indicates that hazards and problems regarding open visitation are generally overstated and manageable," and that such visitation policies "do not harm patients but rather may help them by providing a support system and shaping a more familiar environment" as they "engender trust in families, creating a better working relationship between hospital staff and family members." Hospitals that unnecessarily restrict patient visitation often miss an opportunity to gain valuable patient information from those who may know the patient best with respect to the patient's medical history, conditions, medications, and allergies, particularly if the patient has difficulties with recall or articulation, or is totally unable to recall or articulate this vital personal information. Many times visitors who may know the patient best act as an intermediary for the patient, helping to communicate the patient's needs to hospital staff.

Although visitation policies are generally considered to relate to visitors of inpatients, "visitors" also play a role for outpatients who wish to have a support person present during their outpatient visit. For example, a same-day surgery patient may wish to have a support person present during the pre-operative patient preparation or post-operative recovery. Or an outpatient clinic patient may wish to have a support person present during his or her examination by a physician. Accordingly, hospital visitation policies must address both the inpatient and outpatient settings.