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NEW/REVISED MATERIAL--EFFECTIVE DATE: JUNE 18, 2000

Section 482.13 Condition of Participation: Patient's Rights, provides interpretive guidance for hospital surveyors in the implementation of 42 CFR, Part 482 Medicare and Medicaid Programs; Hospital Conditions of Participation Patients' Rights; Interim Final Rule.

Appendix A

Interpretive Guidelines and Survey Procedures - Hospitals

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A 750	**§482.13 Condition of participation: Patients' rights.** A hospital must protect and promote each patient's rights.	Interpretive Guidelines: §482.13. These requirements apply to all Medicare or Medicaid-participating hospitals including short-term, psychiatric, rehabilitation, long-term, children's and alcohol-drug, whether or not they are accredited. This rule does not apply to psychiatric facilities for individuals under age 21, to residential treatment centers (unless these services are provided in a hospital setting); nor to Critical Access Hospitals (See Social Security Act (the Act) §1861(e)).
A 751	**(a) Standard: Notice of rights.** (1) A hospital must inform each patient, or when appropriate, the patient's representative (as allowed under State law), of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible.	This regulation requires that whenever possible, the hospital informs each patient of his or her rights in language that the patient understands. The hospital has the responsibility to establish policies and procedures that effectively ensure that patients and/or their representatives have the information necessary to exercise their rights under the Act. This responsibility includes and is not limited to providing all notices required by statute and regulation regarding patients' rights. For example, the patient must be given notice of the rights afforded to him/her by the provider agreement, including the right to an advance directive and notice of non-coverage (see 42 CFR part 489), as well as the rights listed in this CoP. Depending on other factors, the hospital may have existing mechanisms for notifying patients of their rights. The hospital may decide it is most effective to bundle the patients' rights and advance directives notice with these existing notices. In providing this information, the hospital must be sensitive to the communication needs of its patients. As part of its provider agreement, the hospital agrees to comply with Civil Rights laws that assure that it will provide interpretation for certain individuals who speak languages other than English, use alternative communication techniques or aides for those who are deaf or blind, or take other steps as needed to effectively communicate with the patient. These civil rights laws and regulations also apply to the provision of this information. The hospital's obligation to inform requires that the hospital presents information in a manner and form that can be understood, e.g., the use of large print materials, specialized programs to inform individuals who are deaf or blind, use of interpreters. The regulation does not require documentation in the patient's record that this information has been provided. For example, as part of its admission procedure, the hospital may routinely provide this information with each admission packet. The method for achieving notification of patients rights and whether this is documented is determined by the hospital.

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A 751 Cont.		Procedures: §482.13(a)(1) 1. Determine the hospital's policy for notifying patients of their rights. 2. Review records and interview staff to examine how the hospital meets the needs of diverse patients. 3. Individuals who need assistive devices (e.g., magnifying glass, braille, sign language), or have a communications challenge, such as deafness, low vision, blindness, or not being proficient in English, are at risk of not being informed of their rights. Include in the patient sample current patients who use assistive devices. Interview these patients, and/or their representatives to determine how the hospital assures that patients with these needs have been informed of their rights in a language and manner they understand. Probes: §482.13(a)(1) 1. Does the hospital have alternative means, such as written materials, signs, or interpreters, to communicate patients' rights, when necessary? 2. Do staff know what steps to take to inform a patient, if a patient has special needs?
A 752	(2) The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance.	Interpretive Guidelines: §482.13(a)(2) A "patient grievance" is a formal, written or verbal grievance that is filed by a patient, when a patient issue cannot be resolved promptly by staff present. The patient should have reasonable expectations of care and services and the facility should address those expectations in a timely, reasonable, and consistent manner. Although §482.13(a)(2)(ii) and (iii), A756 and A 757, address documentation of facility time frames for a response, the expectation is that the facility will have a process to implement a relatively minor change in a more timely manner than a written response. For example, a change in bedding, housekeeping of a room, and serving preferred food and beverages may be made relatively quickly without a written facility response. The hospital must inform the patient of the grievance process; including whom to contact to file a grievance. The hospital must inform the patient that he/she may lodge a grievance with the State agency directly, regardless of whether he/she has first used the hospital's grievance process. The hospital must further provide the patient a phone number and address for lodging a grievance with the State agency.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A 752 Cont.		Procedures: §482.13(a)(2) 1. Review the hospital's policies and procedures to assure that its grievance process encourages all personnel to alert appropriate staff concerning any patient grievance. 2. Interview patients or the patient's legal representative to determine compliance. Probes: §482.13(a)(2) 1. Is the hospital following its grievance policies and procedures? 2. Does the hospital's process assure that grievances involving situations or practices that place the patient in immediate danger, are resolved in a timely manner? 3. Does the patient know that he/she has the right to file a complaint with the State agency as well as or instead of utilizing the hospital's grievance process?
A 753	The hospital's governing body must approve and be responsible for the effective operation of the grievance process, and must review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee.	Procedures: §482.13(a)(2) 1. Determine how effectively the grievance process works. Are patient concerns addressed in a timely manner? Are patients informed of any resolution to their grievances? Does the hospital apply what it learns from the grievance as part of its continuous quality improvement activities? Probes: §482.213 (a)(2) 1. Is the governing body responsible for this function, or has the governing body delegated the responsibility in writing to a grievance committee? 2. Is the grievance process reviewed and analyzed through the hospital's quality assurance process or some other mechanism that provides oversight of the grievance process?
A 754	The grievance process must include a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control Peer Review Organization. At a minimum:	Interpretive Guidelines: §482.13(a)(2) This regulation requires coordination between the hospital's existing mechanisms for utilization review notice and referral to peer review organizations (PROs) for Medicare beneficiary concerns (see 42 CFR part 489.27). This requirement does not mandate that the hospital automatically refer each Medicare beneficiary's grievance to the PRO; however, the hospital must inform the beneficiary of this right and comply with his or her request if the beneficiary asks for PRO review.
A 755	(i) The hospital must establish a clearly explained procedure for the submission of a patient's written or verbal grievance to the hospital.	Interpretive Guidelines: §482.13(a)(2)(i) A grievance may be filed verbally or in writing. Probe: §482.13(a)(2)(i) 1. Does the patient, or (if he/she is incapacitated) his/her representative, know about the grievance process and how to use it?

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A 756	(ii) The grievance process must specify time frames for review of the grievance and the provision of a response.	Interpretive Guidelines: §482.13(a)(2)(ii) The hospital must review, investigate, and resolve each patient's grievance within a reasonable time frame. For example, grievances about situations that endanger the patient, such as neglect or abuse, should be reviewed immediately, given the seriousness of the allegations and the potential for harm to the patient(s). However, regardless of the nature of the grievance, the hospital should make sure that it is responding to the substance of each grievance while identifying, investigating, and resolving any deeper, systemic problems indicated by the grievance.
A 757	(iii) In its resolution of the grievance, the hospital must provide the patient with written notice of its decision that contains the name of the hospital contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.	Interpretive Guidelines: §482.13(a)(2)(iii) The written notice of the hospital's determination regarding the grievance must be communicated to the patient or the patient's representative in a language and manner the patient or the patient's legal representative, when necessary, understands. The hospital may use additional tools to resolve a grievance, such as meeting with the patient and his family, or other methods it finds effective. The regulatory requirements for the grievance process are minimum standards, and do not inhibit the use of additional effective approaches in handling patient grievances.
A 758	**(b) Standard: Exercise of rights.** (1) The patient has the right to participate in the development and implementation of his or her plan of care.	Interpretive Guidelines: §482.13(b)(1) This regulation requires the hospital to actively include the patient in the development, implementation and revision of his/her plan of care. It requires the hospital to plan the patient's care, with patient participation, to meet the patient's psychological and medical needs. Procedures: §482.13(b)(1). 1. Determine the extent to which the hospital initiates activities that involve the patient or the patient's legal representative in the patient's care. 2. If the patient refused to participate, interview the patient to verify his/her refusal. Probes: §482.13(b)(1) 1. What do you observe about the interactions between staff and patients? 2. Is there evidence that the patient or the patient's legal respresentative was included or proactively involved in the development of the patient's plan of care? 3. Were revisions in the plan of care explained to the patient?
A 759	(2) The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care.	Interpretive Guidelines: §482.13(b)(2) A patient may wish to delegate decision-making to specific persons, or the patient and family may have agreed among themselves on a decision-making process. To the degree permitted by State law, and to the maximum extent practicable, the hospital must respect the

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A 759 Cont.		patient's wishes and follow that process. In some cases, the patient may be unconscious or otherwise incapacitated. If the patient is unable to make a decision, the hospital should consult the patient's advance directives (see discussion at A 761). In the advance directive, the patient may provide guidance as to his/her wishes in certain situations, or may delegate decision-making to another individual as permitted by State law. If such an individual has been selected by the patient, relevant information should be provided to him/her so that informed health care decisions can be made for the patient. However, as soon as the patient is able to be informed of his/her rights, the hospital should provide that information to the patient. This regulation stresses, however, that the patient's right to make decisions about health care is not equivalent to an ability to demand treatment or services that are deemed medically inappropriate or unnecessary. Procedure: §482.13(b)(2) 1. Review records to determine what happens when staff and a patient disagree regarding the patient's plan of care. Probes: §482.13(b)(2) 1. Does evidence indicate the hospital respected a patient's request for or refusal of certain treatments?
A 760	The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.	Probes: §482.13(b)(2): 1. Has the patient been notified of his/her right to: a. Be informed of his/her health status; b. Be informed of his/her prognosis; c. Be involved in care planning and treatment, including pain management; and d. Request or refuse treatment? 2. Does evidence indicate that a patient's request for treatment was denied? If so, what was the reason for that denial?
A 761	(3) The patient has the right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these directives, in accordance with §489.100 of this part (Definition), §489.102 of this part (Requirements for providers), and §489.104 of this part (Effective dates).	Interpretive Guidelines: §482.13(b)(3) 42 CFR part 489.102 specifies the rights of a patient (as permitted by State law) to make medical care decisions (e.g., pain managment) and to formulate an advance directive and requires the hospital to do the following: # Disseminate its policies regarding the implementation of advance directives, including a clear and precise statement of limitation if the hospital cannot implement an advance directive on the basis of conscience. At a minimum, a statement of limitation should:

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A 761 Cont.		o Clarify any differences between institution-wide conscience objections and those that may be raised by individual physicians; o Identify the State legal authority permitting such an objection; and o Describe the range of medical conditions or procedures affected by the conscience objection. # The hospital must: o Document in the patient's medical record whether or not the patient has executed an advance directive; o Not condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive; o Ensure compliance with requirements of State law concerning advance directives and inform individuals that complaints concerning the advance directive requirements may be filed with the State survey and certification agency; and o Provide for the education of staff concerning its policies and procedures on advance directives. Procedures: §482.13(b)(3) 1. Review the records of a random sampling of patients for evidence of hospital compliance with advance directive notice requirements. 2. Interview staff to determine their knowledge of the advance directives of the patients in their care. 3. Determine to what extent the hospital educates its staff regarding advance directives. 4. Determine to what extent the hospital provides education for the patient population regarding one's rights under State law to formulate advance directives.
A 762	(4) The patient has the right to have a family member or representative of his or her choice and his or her own physician notified promptly of his or her admission to the hospital.	Probes: §482.13(b)(4) 1. Is there evidence that the hospital has a system in place to assure that a patient's family and physician are contacted as soon as can be reasonably expected after the patient is admitted (unless the patient requests that this not be done)?
A 763	**(c) Standard: Privacy and safety.** (1) The patient has the right to personal privacy.	Interpretive Guidelines: §482.13(c)(1) The underlying principle of this requirement is the patient's basic right to respect, dignity, and comfort. "The right to personal privacy" means that patients have privacy during personal hygiene activities (e.g., toileting, bathing, dressing), during medical/nursing treatments, and when requested as appropriate.

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A 763 Cont.		People not involved in the care of the patient should not be present without his/her consent while he/she is being examined or treated, nor should video or other electronic monitoring/recording methods be used while he/she is being examined without his/her consent. If an individual requires assistance during toileting, bathing, and other personal hygiene activities, staff should assist, giving utmost attention to the individual's need for privacy. Privacy should be afforded when the physician or other staff visit the patient to discuss clinical care issues. A patient's right to privacy may be limited in situations where a person must be continuously observed, such as when restrained or in seclusion when immediate and serious risk to harm self (such as when the patient is under suicide precautions) or others exists.
A 764	(2) The patient has the right to receive care in a safe setting.	Interpretive Guidelines: §482.13(c)(2) The intention of this requirement is to specify that each patient receives care in an environment that a reasonable person would consider to be safe. For example, hospital staff should follow current standards of practice for patient environmental safety, infection control, and security. (In situations related to harassment and/or abuse see A765). Additionally, this standard is intended to provide protection for the patient's emotional health and safety as well as his/her physical safety. Respect, dignity and comfort would be components of an emotionally safe environment. Procedures: §482.13(c)(2) 1. Review and analyze patient and staff incident and accident reports prior to the survey to identify any incidents or patterns of incidents concerning a safe environment. Expand your review if you suspect a problem with safe environment in the hospital. 2. Review QA/QI, safety, infection control and security (or the committee that deals with security issues) committee minutes and reports to determine if the hospital is identifying problems, evaluating those problems and taking steps to ensure a safe patient environment. 3. Observe the environment where care and treatment are provided. 4. Review policy and procedures on what the facility does to curtail unwanted visitors or contraband materials.
A 765	(3) The patient has the right to be free from all forms of abuse or harassment.	Interpretive Guidelines: §482.13(c)(3) The intent of this requirement is to prohibit all forms of abuse, neglect (as a form of abuse) and harassment whether from staff, other patients or visitors. Abuse is defined as the willful infliction of injury, unreasonable confinement, intimidation, or punishment, with resulting physical harm, pain, or mental anguish. This includes staff neglect or indifference to infliction of injury or intimidation of one patient by another.

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A 765 Cont.		For the purpose of this requirement, neglect is considered a form of abuse and is defined as the failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness. Procedures: §482.13(c)(3) Examine the extent to which the hospital has a system in place to protect patients from abuse, neglect and harassment of all forms, whether from staff, other patients, or visitors. In particular, determine the extent to which the hospital includes the following components that are suggested as necessary for effective abuse protection: (1) Prevent. A critical part of this system is that there are sufficient staff on duty, especially during the evening, nighttime, weekends and holiday shifts, to take care of the individual needs of all patients. (2) Screen. Persons with a record of abuse or neglect should not be hired or retained as employees. (3) Identify. The hospital creates and maintains a proactive approach to identify events and occurrences that may constitute or contribute to abuse and neglect. (4) Train. The hospital, during its orientation program, and through an ongoing training program, provides all employees with information regarding abuse and neglect, and related reporting requirements, including prevention, intervention, and detection. (5) Protect. The hospital must protect patients from abuse during investigation of any allegations of abuse or neglect or harassment. (6) Investigate. The hospital ensures, in a timely and thorough manner, objective investigation of all allegations of abuse, neglect or mistreatment. (7) Report/Respond. The hospital must assure that any incidents of abuse, neglect or harassment are reported and analyzed, and the appropriate corrective, remedial, or disciplinary action occurs, in accordance with applicable local, State, or Federal law. As a result of the implementation of this system, changes to the hospital's policies and procedures are made accordingly. Probes: §482.13(c)(3) 1. Are staffing levels across all shifts sufficient to care for individual patient's needs? 2. Does the hospital have a written procedure for investigating allegations of abuse and neglect including methods to protect patients from abuse during investigations of allegations? 3. How does the hospital substantiate allegations of abuse and neglect? 4. Do incidents of substantiated abuse and neglect result in appropriate action? 5. Are appropriate agencies notified in accordance with State and Federal laws regarding incidents of substantiated abuse and neglect? 6. Do staff members know what to do if they witness abuse and neglect?

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A 765 Cont.		7. What evidence is there that allegations of abuse and neglect are thoroughly investigated? If substantiated, has the hospital taken corrective action to lower the risk of recurrence? 8. Does the hospital conduct criminal background checks as allowed by State law for all potential new hires? 9. Is there evidence the hospital employs people with a history of abuse, neglect or harassment?
A 766	**(d) Standard: Confidentiality of patient records.** (1) The patient has the right to the confidentiality of his or her clinical records.	Interpretive Guidelines: §482.13(d) The hospital has sufficient safeguards to ensure that access to all information regarding patients is limited to those individuals designated by law, regulation, policy; or duly authorized as having a need to know. No unauthorized access or dissemination of clinical records is permitted. The right to confidentiality means safeguarding the content of information, including patient paper records, video, audio, and/or computer stored information from unauthorized disclosure without the specific informed consent of the individual, parent of a minor child, or legal guardian. Hospital staff and consultants, hired to provide services to the individual, should have access to only that portion of information that is necessary to provide effective responsive services to that individual. Confidentiality applies to both central records and clinical record information that may be kept at dispersed locations.
A 767	(2) The patient has the right to access information contained in his or her clinical records within a reasonable time frame.	Interpretive Guidelines: §482.13(d)(2) The general position of the Department of Health and Human Services with regard to the confidentiality rights of individuals is set forth in "Confidentiality of Individually-Identifiable Health Information, recommendations of the Secretary of Health and Human Services, pursuant to §264 of the Health Insurance Portability and Accountability Act of 1996." That policy specifies that patients should be allowed to inspect and obtain a copy of health information about themselves that is held by providers; and that providers may not withhold information except under limited circumstances. These circumstances include: o The information is about another person (other than a health care provider) and the hospital determines that patient inspection would cause sufficient harm to another individual to warrant withholding. o Inspection could be reasonably likely to endanger the life or physical safety of the patient or anyone else. o The information contains data obtained under a promise of confidentiality (from someone other than a health care provider), and inspection could reasonably reveal the source.

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A 767 Cont.		o The information is held by an oversight agency and access by the patient could be reasonably likely to impede an ongoing oversight or law enforcement activity. o The information is collected in the course of a clinical trial, the trial is in progress, an institutional review board has approved the denial of access, and the patient has agreed to the denial of access when consenting to participate. o The information is compiled principally in anticipation of, or for use in, a legal proceeding. o The information is used solely for internal management purposes and is not used in treating the patient or making any administrative determination about the patient, or if it duplicates information available for inspection by the patient. Probes: §482.13(d)(2) 1. Does the hospital have a procedure for providing records to patients within a reasonable timeframe? 2. Does the procedure include the method to identify what documents were not provided and the reason?
A 768	The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its record keeping system permits.	Interpretive Guidelines: §482.13(d)(2) In general, each patient should be able to see and obtain a copy of his/her records. Record holders may not deny access except to a portion of the record that meets criteria specified in A767. In these cases, the record holder may decide to withhold portions of the record; however, to the extent possible, the patient should be given as much information as possible. If the patient is incompetent, the patient record should be made available to his or her representative (as allowed under State law). Upon the patient's request, other designated individuals may access the patient's records. The patient has the right to easily access his/her medical records. The cost of duplicating a patient's medical record must not create a barrier to the individual's receiving his or her medical records. Records should be supplied at a cost not to exceed the community standard. If State law establishes a rate for the provision of records, then State law should be followed. However, in the absence of State law, the rate charged by organizations such as the local library, post office, or a local commercial copy center that would be selected by a prudent buyer can be used as a comparative standard.
	The following guidelines apply to both standard "e" and standard "f".	

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		Standards (e) and (f) concern the use of restraints in two situations: respectively, standard (e), use of restraints in medical and post-surgical care; and standard (f), **emergency use** of restraints in behavior management. For both situations, it is important to note that these requirements are not specific to any treatment setting, but to the situation the restraint is being used to address. Further, the decision to use a restraint is driven not by diagnosis, but by comprehensive individual assessment that concludes that for this patient at this time, the use of less intrusive measures poses a greater risk than the risk of using a restraint or seclusion. In the case of a patient with cognitive impairment, such as Alzheimer's Disease, which restraint standard (e) or (f) would apply? Two examples are offered for the sake of clarification. o Example 1: A patient with Alzheimer's Disease has a catastrophic reaction where he/she becomes so agitated and aggressive that he/she physically attacks a staff member. He/she cannot be calmed by other mechanisms, and his/her behavior presents a danger to himself, and to staff and other patients. The use of restraint or seclusion in this situation is governed by the behavior management standard. o Example 2: A patient diagnosed with Alzheimer's Disease has surgery for a fractured hip. Staff determine that it is necessary to immobilize the hip to prevent re-injury. The use of less restrictive alternatives have been evaluated or were unsuccessful. Restraint use in this situation is governed by the acute medical and surgical care standard (§482.13(e)). Comprehensive assessment is critical in coming to an effective intervention decision of what would be the greater benefit to a patient. In the case of a patient with dementia who wanders and there is concern about the patient falling, part of the hospital's assessment process should address these questions: o Is there a way to enable the patient to ambulate safely? o Is there some assistive device that will improve the patient's ability to safely self ambulate? o Is a medication or a reversible condition causing a problem with safely self ambulating? o Would the patient be content to walk with a staff person for a while? o Could he/she be brought closer to the nurse's station where he/she could be supervised? o Does he/she have a history of falling that indicates that for him/her, a fall is likely if he/she is allowed to walk about? o Could the patient's environment be altered to improve the patient's ability to self ambulate and reduce the risk of falling/injury?

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		Licensed Independent Practitioner (LIP) For the purpose of this rule, a LIP is any practitioner permitted by both law and the hospital as having the authority under his/her license to independently order restraints, seclulsion or medications for patients. This provision is not to be construed to limit the authority of a doctor of medicine or ostepathy to delegate tasks to other qualified healthcare personnel (i.e., Physician Assistants and Nurse Practioners) to the extent recognized under State law or a State's regulatory mechanism. Exceptions: The use of handcuffs or other restrictive devices applied by law enforcement officials is for custody, detention, and public safety reasons, and is not involved in the provision of health care. Therefore, the use of restrictive devices applied and monitored by law enforcement are not governed by standards (e) or (f) of the regulation. A voluntary 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. A positioning or securing device used to maintain the position, limit mobility or temporarily immobilize during medical, dental, diagnostic, or surgical procedures is not considered a restraint. Devices Which Serve Multiple Purposes Devices which serve multiple purposes such as a gerichair or side rails, when they have the effect of restricting a patient's movement and cannot be easily removed by the patient, constitute a restraint. Use of these restraints are not typically used to address violence or aggression, therefore their use would be governed by standard (e). The hospital should base its assessment for device use on what constitutes the least risk for the patient: the risk of what might happen if the device is not used versus the risk it poses as a restraint. Evaluation of whether devices should be used as restraints must include how they benefit the patient, and whether a less restrictive device/intervention could offer the same benefit at less risk. In any case, a thorough evaluation of the patient and his/her needs is essential. It is important to note that side rails present an inherent safety risk, particularly when the patient is elderly or disoriented. Even when a side rail is not intentionally used as a restraint, patients may become trapped between the mattress or bedframe and the side rail.

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		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. 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 he/she had fallen from the height of a lowered bed without raised siderails. <u>Drugs Used as a Restraint</u> Both standards (e) and (f) specify that a drug used as a restraint is a medication used to restrict the patient's freedom of movement in medical-post surgical situations (standard (e)) or for the emergency control of behavior (standard (f)), and is not a standard treatment for the patient's medical or psychiatric condition. A fundamental right that appears in both standards (e) and (f) is that the patient has the right to be free from restraints of any form that are imposed for coercion, discipline, convenience, or retaliation by staff – including drugs that are used as restraints. Three examples serve to clarify the distinction between standards (e) and (f). o Example 1: A patient has Sundowner's Syndrome. She gets out of bed in the evening and walks around the unit. The unit's staff find the patient's behavior bothersome, and ask the physician to order a high dose of a sedative to "knock out" the patient and keep her in bed. The patient has no medical symptoms or conditions that indicate that she needs a sedative. In this case, for this patient, the drug is being used inappropriately as a restraint. o Example 2: A patient is on an acute medical and surgical unit for a routine surgical procedure. He has no history of a psychiatric condition and is on no medications (aside from those he is being given before, during, and after surgery). One afternoon during his recovery period, the patient becomes increasingly agitated and aggressive. Attempts to divert and calm him are ineffective. He begins shouting that his roommate is spying on him, and physically attacks the roommate. In this case, the use of a drug as a restraint to calm and protect the patient and his roommate from harm is governed by standard (f) – seclusion and restraint for behavior management. This patient needs to be seen and assessed by a physician or LIP within one hour of the initiation of the drug used as a restraint. o Example 3: A patient is in a detoxification program. He becomes violent and aggressive one afternoon. Staff administer a PRN medication ordered by the patient's physician or LIP to address this outburst of specific behaviors. In this case, the medication used for this patient is not considered a "drug used as a

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		restraint." The availability of a PRN medication to manage outbursts of specific behaviors, such as, of 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 for his medical or psychiatric condition." The use of this medication for this patient is not affected by standard (e) or (f). Drugs used as restraints are medications used in addition to or in replacement of the patient's regular drug regimen to control extreme behavior during an emergency. The medications that comprise the patient's regular medical regimen (including PRN medications) are not considered drug restraints, even if their purpose is to control ongoing behavior. The use of this medication should be addressed in the patient's plan of care and medical record. <u>Physical Restraint</u> The definition of physical restraint is any manual method or physical or mechanical device that restricts freedom of movement or normal access to one's body, material, or equipment, attached or adjacent to the patient's body that he or she cannot easily remove. Holding a patient in a manner that restricts his/her movement constitutes restraint for that patient. An object may be a restraint by functional definition; that is, when an object restricts the patient's movement or access to his or her body, it is a restraint. Under this definition, all sorts of more commonly used hospital devices and practices could meet the definition of a restraint, such as: -- Tucking a patient's sheets in so tightly that he or she cannot move; or -- Using a side rail to prevent a patient from voluntarily getting out of bed. The following questions need to be considered when defining an intervention as a physical restraint. -- Does the patient have the ability/skill to easily remove the intervention? AND -- Is the patient's freedom to move when the intervention is in place less than their freedom to move without the intervention, or is the patient's access to their body when the intervention is in place less than their access to their body without the intervention? A functional definition does not name each device and situation that can be used to inhibit an individual's movement, and promotes looking at situations on a case-by-case basis. Therefore, if the effect of using an object fits the definition of restraint for that patient at that time, then for that patient at that time, the device is a restraint.

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A 768 Cont.		Who is Authorized to Remove a Restraint? The hospital should address in its policies and procedures, at a minimum: o who has the authority to discontinue restraints (based on state law and hospital policies); and o under what circumstances restraints are to be discontinued.
A 769	**(e) Standard: Restraint for acute medical and surgical care**	Interpretive Guidelines: §482.13(e) In acute medical and post surgical care, a restraint may be necessary to ensure that (for example) an intravenous (IV) or feeding tube will not be removed, or that a patient who is temporarily or permanently incapacitated with a broken hip will not attempt to walk before it is medically appropriate. That is, medical restraint may be used to limit mobility, temporarily immobilize a patient related to a medical, post-surgical or dental procedure. If the intervention is undertaken because of an unanticipated outburst of severely aggressive or destructive behavior that poses an imminent danger to the patient or others, standard (f) applies. Other uses of restraint for acute medical and post-surgical care should be considered under standard (e). Risks associated with any intervention must be considered in the context of an ongoing loop of assessment, intervention, evaluation, and reintervention. A corollary principle is that the greater the risks associated with an intervention, the more careful and thorough the assessment must be. The rationale that the patient should be restrained because he/she "might" fall is an inadequate basis for using a restraint. When assessing and care planning for the patient, the hospital should consider whether he/she has a history of falling or a medical condition or symptom that indicates a need for a protective intervention. It is important to note that the regulation specifically states that convenience is not an acceptable reason to restrain a patient. A restraint must not serve as a substitute for adequate staffing to monitor patients. Procedures: §482.13(e) 1. Obtain a random sampling of restrained patients. Are inordinate numbers of patients restrained given the hospital's patient composition at that time? 2. What evidence is there that hospital staff identified the reason for the restraint, and eliminated other less invasive measures before applying the restraint? 3. Determine if there is a pattern of increased restraint use related to staff coverage. 4. Are there patterns of applying the same type of restraint regardless of the medical condition of patients? 5. Review patient incident/accident reports to determine the frequency (percent) of injuried patients who were also restrained at the time of their injury.

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A 769 Cont.		6. If record review indicates that restrained patients sustained injuries, determine what the hospital did to prevent additional injury while it investigated possible changes to its restraint protocol. 7. Were the reasons for the use of a restraint in relation to the medical condition explained to the patient in understandable terms? Could the patient articulate his/her understanding?
A 770	(1) The patient has the right to be free from restraints of any form that are not medically necessary or are used as a means of coercion, discipline, convenience, or retaliation by staff. The term "restraint" includes either a physical restraint or a drug that is being used as a restraint. A physical restraint is any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient's body that he or she cannot easily remove that restricts freedom of movement or normal access to one's body. A drug used as a restraint is a medication used to control behavior or to restrict the patient's freedom of movement, and is not a standard treatment for the patient's medical or psychiatric condition. (2) A restraint can only be used if needed to improve the patient's well being and less restrictive interventions have been determined to be ineffective. (3) The use of a restraint must be-- (i) Selected only when other less restrictive measures have been found to be ineffective to protect the patient 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 are outweighed by the risk of not using it. Alternative interventions do not always need to be tried, but should be considered prior to the use of a restraint. Probes: §482.13(e)(2)(3)(i) 1. Is there documentation in the medical record to explain the rationale for the use of restraints? 2. Were less intrusive measures considered first?

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A 771 Cont	(ii) In accordance with the order of a physician or other licensed independent practitioner permitted by the State and hospital to order a restraint. This order must--	Interpretive Guidelines: §482.13(e)(3)(ii) The hospital should have a written policy, conforming to state law, indicating which LIP are permitted to order restraint in that facility. Procedure: §482.13(e)(2)(3)(ii) 1. Review hospital policy and medical by-laws to ascertain clinical practice guidelines which describe the responsibilities of medical staff and clinicians who are privileged in this area. 2. Know who the State recognizes as a LIP or as having the right to order restraints or seclusion
A 772	(A) Never be written as a standing or on an as needed basis (that is, PRN); and	Interpretive Guidelines: §482.13(e)(3)(ii)(A) This regulation prohibits the use of PRN orders for restraint use. Procedures: §482.13(e)(3)(ii)(A) 1. Verify in the patient's medical record, and/or the physician's order, that the intent of the order is for the specific reason, and for the specified time period. 2. Review the medical record including the progress notes, flow charts and nursing notes to evaluate any patterns of use and if orders were obtained. Probes: §482.13(e)(3)(ii)(A) 1. Is there evidence of restraints being implemented on a PRN basis?
A 773	(B) Be followed by consultation with the patient's treating physician, as soon as possible, if the restraint is not ordered by the patient's treating physician;	Interpretive Guidelines: §482.13 (e)(3)(ii)(B) The "treating" physician is the physician who is responsible for the management and care of the patient. It is important to consult with the treating physician, as soon as possible, because information regarding the patient's history may have a significant impact on selection of restraint intervention. Procedure: §482.13(e)(3)(ii)(B) 1. Check the patient's medical record for documentation of contact with the treating physician if he/she did not order the restraint.
A 774	(iii) In accordance with a written modification to the patient's plan of care;	Interpretive Guidelines: §482.13(e)(3)(B)(iii) The use of restraints (including drugs used as restraints and physical restraints) should be referred to in the patient's "modified" plan of care or treatment plan. Procedures: §482.13(e)(3)(B)(iii) 1. Determine whether the hospital's procedure followed the expectations of restraint requirements. Does the plan of care reflect a loop of assessment, intervention, evaluation, and re-intervention.

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A 774 Cont.		Probes: §482.13 (e)(3)(B)(iii) 1. Is there evidence of assessment of the identified problem or of individual patient assessment? 2. Does the patient's plan of care reflect that assessment? 3. What was the goal? Was it outcome oriented? 4. What was the described intervention? 5. Who is responsible for implementation? 6. Did the physician orders, which included a time-limit, get incorporated into the plan of care? 7. After the discontinuation of the restraint intervention, was this information documented in the update of the plan of care?
A 775	(iv) Implemented in the least restrictive manner possible.	See A 770 for guidance. The least restrictive intervention is based on an individual assessment of the patient.
A 776	(v) In accordance with safe and appropriate restraining techniques, and	Interpretive Guidelines: §482.13(e)(3)(B)(v) Determine if the hospital's procedures reflect current standards of practice regarding appropriate restraining technique in that environment. Restraint use should not cause harm or pain to the patient. Procedure: §482.13(e)(3)(B)(v) 1. Examine medical records of patients for whom restraints are used in the sample. Probes: §482.13(e)(3)(B)(v) 1. After restraints were applied, was an assessment immediately made to ensure that restraints were properly and safetly applied? 2. Was nursing procedure and policy followed? 3. What was the patient's response? If negative, were timely changes made? 4. Was there any evidence of injury to the patient?
A 777	(vi) Ended at the earliest possible time.	Interpretive Guidelines: §482.13(e)(3)(B)(vi) The use of restraints should be frequently evaluated and ended at the earliest possible time based on the assessment and reevaluation of the patient's condition. Probes: §482.13(e)(3)(B)(vi) 1. If the time of restraint use is lengthy, look for evidence that the symptoms necessitating the restraint use have persisted. Is there evidence to indicate that the staff have evaluated if the restraint can be safely removed? 2. What are the hospital's policies and procedures for ending restraint use for medical and post surgical care?

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A 778 Cont.	(4) The condition of the restrained patient must be continually assessed, monitored, and reevaluated.	Interpretive Guidelines: §482.13(e)(4) The determination of frequency of monitoring should be made on an individual basis which includes a rationale that reflects consideration of the individual patient's medical needs and health status. Hospital policies and/or nursing policies should address: frequencies of assessment; assessment content (e.g., vital signs, circulation, hydration needs, elimination needs, level of distress and agitation, mental status, cognitive functioning, skin integrity); and provide for nutritional needs, range of motion, and elimination needs. Probes: §482.13(e)(4) 1. Was there a valid rationale for the decision regarding the frequency of assessment/monitoring documented in the medical record? 2. Was documentation consistent, relevant, and reflective of the patient's condition? 3. If the patient's mental status, coordination, or gait improved, what actions were taken by the staff? 4. What evidence do you find the hospital's/nursing assessment/monitoring policies are put into practice on all restrained patients? 5. Do the patient's care needs dictate how frequently the reassessment is made, and is there documented evidence of the reassessment?
A 779	(5) All staff who have direct patient contact must have ongoing education and training in the proper and safe use of restraints.	Interpretive Guidelines: §482.13(e)(5) Ongoing restraint and seclusion education and training must be provided both as a part of the initial orientation of all new and contract staff and as a part of ongoing inservice training for all staff who have direct patient care responsibilities. Probes: §482.13(e)(5) 1. Does the facility have a documented educational, instructional training program for the use of all restraint techniques used? 2. Are all levels of staff who have direct patient care responsibilities trained in the proper and safe application and use of restraints? Is this documented? 3. Does the training require staff to demonstrate knowledge of the assessment loop and the safe application of restraints before they are allowed to apply restraints? 4. Does the training review alternatives to the use of restraints? 5. Do all contract/agency personnel with direct patient care responsibilities have documented training in the hospital's restraint/seclusion policies?
A 780	**(f) Standard: Seclusion and restraint for behavior management.** (1) The patient has the right to be free from seclusion and restraints, of any form,	Interpretive Guidelines: §482.13(f)(1) "Seclusion" does not include confinement on a locked unit or ward where the patient is with others. Seclusion is not just confining an individual to an area but involuntarily confining him/her alone in a room or area where he/she is physically prevented from leaving. Seclusion

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A 780 Cont.	imposed as a means of coercion, discipline, convenience, or retaliation by staff. The term "restraint" includes either a physical restraint or a drug that is being used as a restraint. A physical restraint is any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient's body that he or she cannot easily remove that restricts freedom of movement or normal access to one's body. A drug used as a restraint is a medication used to control the behavior or to restrict the patient's freedom of movement and is not a standard treatment for the patient's medical or psychiatric condition. Seclusion is the involuntary confinement of a person in a room or an area where the person is physically prevented from leaving.	is different from timeout which means the restriction of a patient for any period of time to a designated area from which the patient is not physically prevented from leaving and for the purpose of providing the patient an opportunity to regain self-control. The behavior management standard for restraints and seclusion should be followed in emergency or crisis situations if a patient's behavior becomes aggressive or violent, presenting an immediate, serious danger to his/her safety or that of others. The behavior management standard governs the use of a restraint or seclusion in this type of a crisis situation whether it occurs on acute medical and surgical units, psychiatric units, Alzheimer's units, or in general, psychiatric, alcohol-drug, children's, rehabilitation, short-term, or long-term care hospitals. A restraint or seclusion for behavior management is used only as an emergency measure and is reserved for those occasions when severely aggressive or destructive behavior places the patient or others in imminent danger. While different factors may precipitate this type of psychiatric, behavioral, and physical outburst for an individual patient, the need for rapid assessment and continuous monitoring is applicable in each case. The behavior management standard (Standard (f)) does not apply to situations where the hospital wishes to restrain a patient to address the risk of a fall or to control wandering. The use of restraint for a non-violent or non-aggressive, otherwise cooperative patient may be governed by the Restraint of acute medical and surgical care (standard (e)). It is important to note that the regulation specifically states that convenience is not an acceptable reason to restrain a patient nor can restraint use serve as a substitute for adequate staffing to monitor a patient.
A 781	(2) Seclusion or restraint can only be used in emergency situations if needed to ensure the patient's physical safety and less restrictive interventions have been determined to be ineffective.	Interpretive Guidelines: §482.13(f)(2) Emergency is defined as a situation where the patient's behavior is violent or aggressive and where the behavior presents an immediate and serious danger to the safety of the patient, other patients, staff, or others. Documentation in the patient's medial record should include: - The patient's behavior and the intervention used; - The rationale for the use of the physical restraint or seclusion; and - The patient's response to the use of physical restraint or seclusion. Documentation in the patient's record should indicate a clear progression in how techniques are implemented with less intrusive restrictive interventions attempted (or considered prior to the introduction of more restrictive measures).

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A 781 Cont.		Procedures: §482.13(f)(2) 1. Review hospital procedures for emergency use of restraints and seclusion. 2. Look at incident and accident reports to determine if incidents and accidents are greater with restrained or secluded patients. 3. Examine patterns of restraints or seclusion use that may indicate that the intervention is not based on the patient's need, but on issues such as inadequate staffing or lack of training. Probes: §482.13(f)(2) 1. 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? 2. Do physician orders specify the reason for seclusion/restraint, the type of restraint and the duration? 3. 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? 4. 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)? 5. Does the clinical record reflect assessment and/or development of a plan of care?
A 782	(3) The use of a restraint or seclusion must be- (i) Selected only when less restrictive measures have been found to be ineffective to protect the patient or others from harm.	Probes: §482.13 (f)(3)(i) 1. Does the clinical record reflect changes in behavior and staff concerns regarding potential danger on the unit/ward prompting use of seclusion or restraints? 2. Did the patient's behavior place others/self at risk of harm? 3. Were other behavior interventions tried and documented?
A 783	(f)(3) The use of a restraint or seclusion must be-- (ii) In accordance with the order of a physician or other licensed independent practitioner permitted by the State and hospital to order seclusion or restraint.	Interpretive Guidelines: §482.13(f)(3)(ii) Hospitals should have policies and procedures for the initiation of restraint or seclusion to manage violent, aggressive behavior that places the patient or others in danger. This protocol should specify who can initiate restraints or seclusion in an emergency prior to obtaining a physician's or LIP's order. The use of verbal orders should be addressed. Probes: §482.13(f)(3)(ii) 1. Does the hospital have written policy indicating which practitioners are permitted to order seclusion or restraints in the facility? 2. Do the hospital's written policies conform with State law? 3. Does the hospital have written policies on the use of verbal orders? 4. Does the hospital have established policies for who can initiate restraint and seclusion? 5. Are the staff members who are able to initiate restraint and seclusion trained in the safe use of restraint and seclusion and able to demonstrate competency?

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	The following requirements will be superseded by existing State laws that are more restrictive:	
A 784	(A) Orders for the use of seclusion or a restraint must never be written as a standing order or on an as needed basis (that is, PRN).	Interpretive Guidelines: §482.13(f)(3)(ii)(A) Ongoing authorization of restrictive techniques is not permitted. The absence of evidence to justify such usage constitutes a "PRN order" to control inappropriate behavior, and is prohibited. Probe: §482.13(f)(3)(ii)(A) 1. Is there evidence of restraints or seclusion being implemented on a PRN basis?
A 785	(B) The treating physician must be consulted as soon as possible, if the restraint or seclusion is not ordered by the patient's treating physician.	Procedures: §482.13(f)(3)(B) 1. Determine the hospital's policies and procedures for prompt notification of treating physician when seclusion or restraint is ordered by someone other than the treating physician. 2. Determine if medical records reflect hospital's policies and procedures.
A 786	(C) A physician or other licensed independent practitioner must see and evaluate the need for restraint or seclusion within 1 hour after the initiation of this intervention.	Interpretive Guidelines: §482.13(f)(3)(ii)(C) A physician or LIP (as recognized by State law and hospital policy) evaluation of a patient must be face-to-face. A telephone call is not adequate. If a patient who is restrained for aggressiveness or violence quickly recovers and is released before the physician or LIP arrives to perform the assessment, the physician or LIP must still see the patient face-to-face to perform the assessment 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 assessment of the incident/situation that led to the intervention, as well as the physiological and psychological condition of the patient at the time of the assessment.
A 787	(D) Each written order for a physical restraint or seclusion is limited to 4 hours for adults; 2 hours for children and adolescents ages 9 to 17; or 1 hour for patients under 9.	Interpretive Guidelines: §482.13(f)(ii)(D) The use of physical restraint or seclusion must be limited to the duration of the emergency safety situation regardless of the length of the order. The time frames specified in these requirements are maximums. The physician or LIP has the discretion to decide that the order should be written for a shorter period of time; and in the meantime, staff should be assessing, monitoring, and re-evaluating the patient so that he or she is released from the restraint or seclusion at the earliest possible time. If restraints or seclusion are discontinued prior to the expiration of the original order, a new order must be obtained prior to reinitiating seclusion or reapplying the restraints and the requirements restart.

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A 787 Cont.		The physician is not required to perform another face-to-face assessment of the patient after 4 hours (or 2 hours or 1 hour for younger patients). While we encourage physician or LIP participation in the delivery of care and treatment, when the original order is about to expire, a nurse can telephone the physician or LIP, report the results of his/her most recent assessment, and request that the original order be renewed for another period of time (not to exceed the time limits established in the regulation).
A 788	The original order may only be renewed in accordance with these limits for up to a total of 24 hours.	Interpretive Guidelines: §482.13(f)(ii)(D)(i) Orders for restraints must be renewed on a daily basis. Probe: §482.13(f)(ii)(D)(i) 1. Does the renewal for seclusion/restraint provide a rationale that is based on an individual assessment of the patient?
A 789	After the original order expires, a physician or licensed independent practitioner (if allowed under State law) must see and assess the patient before issuing a new order.	At a minimum, if the patient has been in a restraint or in seclusion for 24 hours, the physician or LIP will at that point return to complete a face-to-face reevaluation. Twenty-four hours of restraint or seclusion is an extreme measure with the potential for serious harm to the patient. Probe: §482.13(f)(3)(ii)(D)(ii) If patients are in seclusion or restraints for longer than 24 hours, is there evidence of a new written order and assessment documentation in the medical record that provides a reasonable rationale supporting the decision to continue with that intervention?
A 790	(iii) In accordance with a written modification to the patient's plan of care;	The interpretive guidance, procedures, and probes at A 774 should be used to evaluate the use of seclusion or restraint for this requirement.
A 791	(iv) Implemented in the least restrictive manner possible;	Interpretive Guidelines: §482.13(f)(3)(ii)(D)(iv) A comprehensive assessment of the patient must determine that the risks associated with the use of the restraint are outweighed by the risk of not using it. Alternative interventions do not always need to be tried, but should be considered prior to the use of a restraint/seclusion. Probes: §482.13(f)(3)(ii)(D)(iv) 1. Is there clear documentation in the patient's medical record describing the steps or interventions used prior to the use of the needed restraint? That is, what documentation is in the medical record to explain the rationale for the use of restraints? 2. Were less intrusive measures tried or considered first? 3. Are those measures documented? 4. Is there evidence of consideration of the patient's health needs/problems prior to implementation of the intervention?

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A 792	(v) In accordance with safe appropriate restraining techniques; and	Interpretive Guidelines: §482.13(f)(3)(ii)(D)(v) Restraint/seclusion use should not cause harm or pain to patient. Procedure: §482.13(f)(3)(ii)(D)(v) 1. Examine and include patients for whom restraint is used in the sample. 2. Determine if the hospital's procedures reflect current standards of practice regarding appropriate restraining techniques. Probes: §482.13(f)(3)(ii)(D)(v) 1. Is there a clear description of the physical intervention utilized? 2. Did staff do an immediate assessment of the patient to ensure that the restraints were safely and correctly applied? 3. Was nursing procedure and policy followed? 4. What was the patient's response? If negative, were changes made? 5. Was there any evidence of injury to the patient?
A 793	(vi) Ended at the earliest possible time.	Interpretive Guidelines: §482.13(f)(3)(ii)(D)(vi) The use of restraints/seclusion should be frequently evaluated and ended at the earliest possible time based on the assessment and reevaluation of the patient's condition. Probes: §482.13(f)(3)(ii)(D)(vi) 1. If the time of restraint use is lengthy, is there evidence that the symptoms necessitating the restraint use have persisted. 2. What are the hospital's policies and procedures for ending restraint use for behavior management? 3. Does the evidence indicate that the staff have evaluated the patient's behavior so that the restraint can safely be removed?
A 794	(4) A restraint and seclusion may not be used simultaneously unless the patient is-- (i) Continually monitored face-to-face by an assigned staff member; or	Interpretive Guidelines: §482.13(f)(4) When using both seclusion and restraints at the same time, continual monitoring is defined as uninterrupted monitoring. Probes: §482.13(f)(4)(i) 1. Does the clinical record reflect uninterrupted monitoring?
A 795	(ii) Continually monitored by staff using both video and audio equipment. This monitoring must be in close proximity to the patient.	Interpretive Guidelines: §482.13(f)(4)(ii) The use of video and audio equipment does not eliminate the need for frequent assessment of the patients needs and status.

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A 795 Cont.		The hospital should ensure that staff who are assigned monitoring duties are competent to assess physical and psychological signs of distress. Probe §482.13(f)(4)(ii) 1. Is the staff person monitoring the patient in close proximity to the patient so as to allow emergency intervention if a problem arises? 2. Does the video equipment cover all areas of the room or location where the patient is restrained or secluded?
A 796	(5) The condition of the patient who is in a restraint or in seclusion must continually be assessed, monitored, and reevaluated.	Interpretive Guidelines: §482.13(f)(5) The frequency of monitoring will vary according to the type and design of the device or intervention as well as the emotional, psychological and physical condition, needs, and symptoms of the patient. Procedures: §482.13(f)(5) 1. Review the hospital's policy on restraints and seclusion to determine how the facility is assessing and monitoring patient medical and behavioral status. Obtain a sample of the patient population in restraints. 2. Look for a cycle of removing restraints, then reapplying them without evaluating the patient. Probes: §482.13(f)(5) 1. Does hospital policy describe which staff members are responsible for assessing and monitoring the patient? 2. Are time frames described for how often a patient is monitored for vital signs, respiratory and cardiac status, skin integrity checks? 3. Does the policy include frequent opportunities for offering fluids and nourishment, toileting/elimination, range of motion, exercise of limbs and systematic release of restrained limbs? Is this documented in the record? 4. Is the mental status assessed? Is this documented in the record? 5. Is the patient assessed regarding continued need for use of seclusion or restraint? Is there adequate justification for continued use and is this documented? 6. Is there documentation of ongoing patient assessment (e.g., skin integrity, circulation, respiration, intake and output, weight, hygiene, injury, etc)? 7. Did the patients understand the reasons for the use of restraints or seclusion?

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A 797	(6) All staff who have direct patient contact must have ongoing education and training in the proper and safe use of seclusion and restraint application and techniques and	Probe: §482.13 (f)(6) 1. Does the hospital have evidence that all staff who have direct patient care responsibilities and any other individuals who may be involved in the application of restraints (e.g., security guards, EMTs on the promises) have been trained and are able to demonstrate competency in the safe use of seclusion and the safe application and use of restraints?
A 798	alternative methods for handling behavior, symptoms, and situations that traditionally have been treated through the use of restraints or seclusion.	Probes: §482.13(f)(6) 1. Is there evidence that staff are updated and trained on alternative interventions other than restraint/seclusion techniques?
A 799	(7) The hospital must report to HCFA any death that occurs while a patient is restrained or in seclusion, or where it is reasonable to assume that a patient's death is a result of restraint or seclusion.	Interpretive Guidelines: §482.13(f)(7) The hospital must report to HCFA any death that occurs while a patient is in seclusion, or where it is reasonable to assume that the patient's death is a result of being in seclusion. The hospital must report to HCFA any death that occurs while a patient is in restraints for behavioral management reasons or where it is reasonable to assume that the patient's death is a result of restraint use for behavioral management reasons. The hospital should report these deaths to their HCFA regional office by the next business day following the patient's death. Procedures: §482.13(f)(7) 1. Review the written hospital policy on reporting deaths that occur while a patient is restrained or in seclusion, or where it is reasonable to assume that a patient's death is a result of restraint or seclusion. 2. Interview patient care staff to determine their knowledge of the hospital's policy or protocol regarding the determination whether a death reasonably may have resulted from seclusion or restraint, and their knowledge of HCFA reporting requirements. Probes: §482.13(f)(7) 1. Is there evidence of deaths, associated with restraints or seclusion, not reported to HCFA? 2. If there have been deaths associated with seclusions or restraints, were they reported to HCFA in a timely manner? Was this documented in the medical record? 3. Does the hospital have a written policy on reporting deaths associated with seclusion or restraints to HCFA in a timely manner? 4. Do patient care staff know the HCFA death reporting requirements?