

## FACT SHEET

### CMS Finalizes Hospital Rules on Restraint and Seclusion

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On December 8, 2006, the Center for Medicaid and Medicare Services (CMS) issued its Final Rule on Hospital Conditions (Patients Rights). 42 C.F.R. § 482.13; 71 FR 71378. The Final Rule includes provisions on the use of restraint and seclusion and applies to all Medicare-and Medicaid-participating hospitals, including short-term, psychiatric, rehabilitation, long-term, children's, and alcohol-drug hospitals. This fact sheet provides background on the Final Rule and a summary of its main provisions.

#### **A. Background**

Below is a brief timeline concerning the federal statutes and regulations regarding restraint and seclusion, starting with the hospital conditions of participation in 1999:<sup>1</sup>

**1999 Interim Final Rule on Hospital Conditions of Participation.** The Health Care Finance Administration (HCFA), which later became the Center for Medicaid and Medicare Services (CMS), issued an Interim Rule on the Hospital Conditions of Participation (Patients Rights) on July 2, 1999. 64 FR 36070. CMS received 4200 comments on the Interim Rule within the comment period and held a Town Hall in 2002 to get comments on the so-called "One Hour Rule," which in the Interim Rule required a psychiatrist or licensed independent practitioner (LIIP) to conduct a face-to-face evaluation of an individual within one-hour of the initiation of restraint or seclusion.

**2000 Children's Health Act.** Congress passed the Children's Health Act of 2000 (CHA). P.L. 106-310. The CHA includes restrictions on the use of seclusion and restraint in federally-funded health care facilities (42 U.S.C. § 290ii *et seq.* [known as Part H]) and non-medical community-based residential facilities for children and youth (42 U.S.C. § 290jj *et seq.* [known as Part I]). According to CMS, the CHA establishes minimum standards for the use of restraint and seclusion. 71 FR 71378.

**2001 Interim Final Rule on Conditions of Participation for Psychiatric Residential Facilities for Individuals under the Age of 21 (PRTFs).** CMS issued an Interim Rule on the Conditions of Participation for PRTFs on January 22, 2001. 66 FR 7148. CMS

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<sup>1</sup> There are also Conditions of Participation for Intermediate Care Facilities for Individuals with Mental Retardation, 42 C.F.R. § 483.450, and Long-Term Care Facilities, 42 C.F.R. § 483.13. These were issued in the 1990's and need to be revised to comply with the Children's Health Act of 2000, 42 U.S.C. § 290ii *et seq.* and to reflect evidence-based practices.

published an additional Interim Final Rule with comment to amend and further clarify the 1/22/01 Interim Final Rule. 66 FR 28110. CMS has not yet issued a Final Rule for PRTFs.

**2006 Final Rule on Hospital Conditions of Participation (Patients Rights).** CMS issued the Final Rule on December 8, 2006 to comply with deadlines established in the Medicare Prescription Drug, Improvement and Modernization Act of 2003. 42 CFR § 482.13; 71 FR 71378. This Rule is the subject of this fact sheet.

**2007 CHA Regulations.** CMS has told NDRN that it plans to issue regulations implementing these minimum standards in 2007. The Center for Mental Health Services (CMHS) of the Substance Abuse and Mental Health Services Administration (SAMSHA) has informed NDRN that it plans to issue regulations regarding the non-medical community-based residential facilities for children and youth in 2007. CMS and CHMS have also indicated that they plan to issue conditions of participation for additional specific treatment settings in addition to regulations to implement the minimum standards of the CHA regulations.

## **B. Summary of Provisions of Final Rule - Hospital Conditions of Participation (Patient Rights)**

Below is a summary of the main provisions of the Final Hospital Rule regarding the use of restraint and seclusion. The summary notes the differences between the Final Hospital Rule, the previous Interim Final Hospital Rule, and the CHA, where appropriate.

- 1. Combined Standards.** The CHS has one set of rules that applies to seclusion and restraint in all federally-funded facilities. 42 U.S.C. § 290ii *et seq.* The Interim Final Rule for hospitals contained separate standards for 1) the use of restraint for acute medical/surgical care and 2) restraint and seclusion for behavior management. Commentators on the Interim Final Rule felt that it was unclear which requirements applied to which situations. 71 FR 71382. Based on these comments, CMS combined the two standards into one standard called “Restraint or Seclusion.” 42 C.F.R. § 482.13(e). Even though CMS has combined the standards, CMS still has some provisions that apply only to restraint or seclusion used for the “management of violent or self-destructive behavior.” These specific provisions will be noted where applicable.
- 2. Definitions:** The Final Rule has adopted a uniform definition of restraint and seclusion across all hospital care settings. 71 FR 71388.
  - a. Restraint.** The definition of “restraint” has not significantly changed between the Interim and Final Rule. 42 C.F.R. § 482(e)(1)(i). Under the Final Rule, a “restraint” is:

- (A) Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely; or
- (B) A drug or medication when it is 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. 42 C.F.R. § 482.13(e)(1)(i)(A) and(B).

The Final rule excludes the following devices, materials, equipment and methods from the definition of restraint:

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). 42 C.F.R. § 482.13(e)(i)(C).

With respect to the provisions on the definition of chemical restraint, 42 C.F.R. 482.13(e)(1)(i)(B), CMS explains that a medication constitutes a restraint and is not considered “standard treatment” if “the overall effect of a medication is to reduce the patient's ability to effectively or appropriately interact with the world around the patient.” 71 FR 713091.

- b. **Seclusion.** The Final Rule defines “seclusion” as the “involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving.” 42 CFR § 482.13(e)(1)(ii). This definition is broader than the definition of “seclusion” in the CHA, which narrowly defines “seclusion,” as a “behavior control technique involving locked isolation.” 42 USC § 290ii(d)(2) (emphasis added).

The preamble to the hospital regulations is helpful in distinguishing “seclusion” from “time out.” In response to commentators concerns about what constituted “seclusion” and “time out,” CMS explained that the key distinction between seclusion and time rested on whether an intervention was voluntary and whether the individual had any personal control over when seclusion starts and stops:

*The key distinction in deciding whether an intervention is*

*seclusion or a time out is whether the patient is physically prevented from leaving a room or area. Another distinction is the patient's level of personal control. In the case of seclusion, boundaries are placed on the patient's behavior based on the clinical determination that the patient's behavior poses a risk to the safety of the patient or others. In a time out, the patient is able to respond to staff direction encouraging a time out or to independently decide that such action is needed. In a time out, the staff and patient collaboratively determine when the patient has regained self-control and is able to return to the treatment milieu. In seclusion, this judgment is made by the clinicians-- that is, an agitated patient may feel that he or she should be released, even though the patient's behavior continues to be violent or self-destructive. 71 FR 71378, 71404.*

3. **Restrictions on Use.** The Final Rule provides that restraint or seclusion “may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others...” 42 C.F.R. § 482.13(e). The Final Rule also requires that the hospital first determine that less restrictive interventions are ineffective before using restraint and seclusion and that the type of restraint or seclusion used be the least restrictive. 42 C.F.R. § 482.13(e)(2) and (3).

In the Preamble to the Final Rule, CMS states that “it is not always appropriate for less restrictive alternatives to be attempted prior to the use of restraint. For example, when a patient physically attacks another patient, immediate action is needed.” 71 FR 71392. Instead, the less restrictive alternatives simply have to be considered and determined to be ineffective. *Id.* The Preamble also states that the “restrained patient should be afforded as much privacy as possible.” *Id.*

4. **Written Orders.** Restraint and Seclusion may be imposed only upon the written order of a physician or other licensed health care practitioner who is authorized to order restraint or seclusion by hospital policy in accordance with state law. 42 C.F.R. § 482.13(e)(5). The CHA has the same requirement regarding written orders. 42 U.S.C. § 290ii(b)(2).
5. **Plan of Care.** The Final Rule states that restraint and seclusion may only be used “in accordance with a written modification to the patient’s plan of care.” 42 C.F.R. § 482.13(e)(4)(i). This requirement has been carried over from the Interim Rule. In the Preamble, CMS states that “the use of restraint or seclusion constitutes a change in a patient’s plan of care.” 71 FR 71399.

6. **Duration of Order.** The CHA does not contain time limits for the use of restraint or seclusion. The Interim Final Rule, however, had time limits for restraint and seclusion when used for behavior management: for adults over 18 - four hours; for children and adolescents age 9 to 17 - two hours; and one hour for children under age 9. 42 C.F.R. § 482.13(e)(8)(i). The Interim Final rule also stated that the original order may only be renewed in accordance with these limits for up to a total of 24 hours. 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. The Interim Final Rule had no time limits on the use of restraint or seclusion for acute medical and surgical care.

The same time limits that were in the Interim Final Rule were included in the Final Rule if 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. 42 C.F.R. § 482.13(e)(8)(i). Restraint and seclusion must be discontinued “at the earliest possible time, regardless of the length of time identified in the order.” 42 C.F.R. § 482.13(e)(9).

7. **Monitoring.** The CHA does not contain any monitoring requirements for federally-funded health care facilities. The Interim Final Rule required that the “condition of the patient who is in a restraint or in seclusion must continually be assessed, monitored, and re-evaluated.” In the Preamble to the Final Rule, CMS stated that there was “much confusion over the meaning of ‘continually.’ 71 FR 71378,71399. As a result, CMS backed off on its requirement that there be continuous monitoring, and now, in the Final Rule, allows a physician, other licensed independent practitioner or trained staff that has completed training at an interval determined by hospital policy. 42 C.F.R. 482.13 (e)(10)(emphasis added).
8. **Face-to-Face One-Hour Assessments (the “One Hour Rule”).** The Interim Final Rule for Hospitals required that a physician or licensed independent practitioner see and evaluate all individuals in restraints or seclusion within one hour of the time these measures are instituted. In the Preamble to the Final rule, CMS stated that the One-Hour Rule was a “lightening rod for public comment.” 71 FR 71406. Hospitals and physicians vigorously opposed the One-Hour Rule, mainly on the grounds that it was too burdensome. In fact, CMS devotes two pages to the hospitals’ objections in the Preamble. 71 FR 71407-71408. In response to this pressure from the medical community, CMS expanded the list of persons who could perform the one-hour face-to-face assessments. The Final Rule now allows registered nurses and physician assistants, as well as physicians and licensed independent practitioners, to conduct the one-hour assessment. 42 C.F.R. § 482.13(e)(12).

- 9. Documentation in the Medical Record.** Neither the CHA nor the Interim Final Rule had any documentation requirements. The Final Rule has added a requirement that hospitals document the following in the patient's medical record:
- (i) The 1-hour face-to-face medical and behavioral evaluation if restraint or seclusion is used to manage violent or self-destructive behavior;
  - (ii) A description of the patient's behavior and the intervention used;
  - (iii) Alternatives or other less restrictive interventions attempted (as applicable);
  - (iv) The patient's condition or symptom(s) that warranted the use of the restraint or seclusion; and
  - (v) The patient's response to the intervention(s) used, including the rationale for continued use of the intervention. 42 C.F.R. § 482.13(e)(16).
- 10. Death Reporting.** The CHA requires hospitals to report to the "appropriate agency, as determined by the Secretary of HHS," all deaths occurring while an individual is secluded and each death occurring within 24 hours of individual being released from seclusion, and deaths where it is reasonable to assume that the death resulted from seclusion. 42 U.S.C. § 290ii-1(a). The Final Rule mirrors this requirement, but requires hospitals to report deaths only to CMS. 42 C.F.R. § 482.13(g).
- 11. Training.** The CHA requires federally-funded health care facilities to have an adequate number of qualified professional and supportive staff to evaluate patients, formulate written individualized, comprehensive treatment plans and to provide active treatment measures, in conformance with regulations promulgated by the Secretary of Health and Human Services. 42 U.S.C. § 290ii-2(a)[CHA]. The Final rule requires staff to have training at orientation, on a periodic basis, and before placing an individual in restraint or seclusion on 1) techniques to identify trigger behaviors, 2) the use of non-physical interventions and less restrictive alternatives, 3) the safe use of seclusion 4) clinical identification of behavior changes indicating that seclusion is no longer needed, 5) monitoring the physical and psychological well being of the individual being restrained, and 6) first aid techniques. 42 C.F.R. § 482.13 (f).
- 12. Enforcement.** The only enforcement mechanism for non-compliance with the CHA and CMS conditions of participation is termination of federal funding. 42 U.S.C. § 290-2(c). Unfortunately, there is no private right of action under the CHA to enforce its seclusion and restraint requirements.