



Restraint and Seclusion Patient Safety Briefing Emergency Medicine Patient Safety Foundation

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March 2012
Revised July 16, 2012 and April 2, 2017

Introduction

Restraint and seclusion is a very important patient safety issue. Appropriately applied restraints can protect patients from harming themselves or others. Paradoxically, improperly applied restraints can result in patient injury and death. It is also an important regulatory issue for accreditation organizations such as the Joint Commission. Likewise, any hospital accredited by DNV Healthcare, CIHQ, or by the Healthcare Facility Accreditation Program must follow any specific standards they may have.

Hospitals must follow any specific state law requirements on restraint and seclusion (R&S). Many states have specific laws for hospitals that have a separate behavioral health unit. States can implement more stringent state laws but cannot have standards that conflict with federal regulations. This is based on the federal preemption doctrine.

Any hospital that accepts Medicare or Medicaid reimbursement must ensure they are in compliance with the CMS Hospital Conditions of

Participation (CoPs). The hospital must comply with the CMS regulations and interpretive guidelines for all patients and not just Medicare and Medicaid patients. Currently, CMS has about fifty pages of regulations in the current hospital CoP manual. Every emergency department nurse, physician, and other practitioner who works for a hospital that accepts Medicare and Medicaid reimbursement should be aware of the CMS hospital interpretive guidelines. This includes most hospitals in the country with the exception of VA hospitals.

www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCLetter06-31.pdf *Region IV*

HOSPITAL RESTRAINT/SECLUSION DEATH REPORT WORKSHEET

A. Regional Office (RO) Contact Information:
 RO Contact's Name: _____
 Date/Time of Report to RO: _____ (Date) RO Contact's Phone: _____
 _____ (Time) RO Fax Number: _____

B. Provider Information:
 Hospital Name: _____ CCN: _____ NPI Number: _____
 Address: _____ State: _____ Zip Code: _____
 Person Filing the Report:
 Filer's Phone Number: { _____

C. Patient Information:
 Name: _____ Date of Birth: _____
 Admitting Diagnoses: _____
 Date of Admission: _____ Date/Time of Death: _____
 Cause of Death: _____

38

CMS made one change to the restraint standards effective July 16, 2012. This was published in the federal register and is available at www.federalregister.gov/articles/2012/05/16. Previously, CMS required that a restraint work sheet be completed and sent to the CMS regional office if a patient died in a restraint, within 24 hours of being in a restraint, or within seven days if the restraint caused the death. Now the hospital can just enter the information on an internal log for any patient who dies in two soft wrist restraints. The log would include the patient's name, date of birth, date of death, attending physician, primary diagnosis, and medical record number

The restraint must not have caused the death and the patient must not have been in seclusion. The name of practitioner responsible for patient can be used in lieu of attending if under the care of a non-physician practitioner such as a PA or Nurse Practitioner. There must be information

in the medical record that the information was placed in the internal log. This must be documented as soon as possible and in no event more than seven days. The internal log does not have to be sent to CMS but the surveyors may ask to see it.

CMS has made a proposed change to the CMS hospital restraint standards in the Hospital Improvement Act that was published in the federal register on June 16, 2016. CMS would change the terminology from “licensed independent practitioners” to “licensed practitioners.” This would make it clear that physician assistants (PAs) can order restraint and seclusion.

Joint Commission Standards

Hospitals that are Joint Commission (TJC) accredited must follow their standards on restraint and seclusion. TJC has a set of standards for hospitals that use them for “Deemed Status”. If a hospital has Deemed Status, it means they do not have to go through a CMS survey by their state agency every three years. However, they may be subject to receive a complaint or a validation survey. The CMS restraint standards use to be different from those from the Joint Commission but now they are more closely cross walked. This occurred after TJC agreed to go through the Deemed Status process with CMS in 2008.

The Joint Commission made some changes in 2017 because of Project Refresh. TJC has ten Provision of Care standards (PC). These PC standards are as follows;

- 03.05.01 R&S must be clinically justified and warranted by the patient’s behavior that threatens the safety of patients or staff
- 03.05.03 R&S must be used safely
- 03.05.05 Need an order for R&S
- 03.05.07 Must monitor patients in R&S
- 03.05.09 Need written policies and procedures on R&S
- 03.05.11 Need to evaluate and reassess patients in R&S

- 03.05.13 Patients who are in restraint and seclusion must be continuously monitored
- 03.05.15 Must document the use of R&S
- 03.05.17 Staff must be trained to safety use R&S
- 03.05.19 Hospital must report any death with the use of R&S (deemed status)

The CMS Hospital CoPs on R&S

The CMS manual section on restraint and seclusion (R&S) starts at Tag Number 154. Some hospitals may be in a system with a critical access hospital. These are small hospitals that have 25 beds or less. They have a separate CMS manual which does not contain restraint standards except for one reference in the swing bed section. Critical Access Hospitals (CAH) have to have some standards and often adopt many or all of the restraint standards that the other hospitals use. A CAH can also have up to a ten bed separate rehab or behavioral health unit. If this occurs then the separate unit is required to follow these standards.

The following is a summary of the important sections from the CMS hospital conditions of participation requirements on R&S that every emergency department practitioner should know;

- Patients have a right to be free from unnecessary restraint and seclusion. Hospitals should make sure this is in the written patient rights standard that is given to all ED patients. R&S can only be used only when necessary and never as coercion, discipline, convenience, or retaliation.
- Hospital leadership is responsible for creating a culture that supports the right for the patient to be free from R&S. The ED manager and chief nursing officer can assess and monitor the use through the performance improvement process. CMS does recognize the use of protocols but the nurse is obligated to get an order from the ED physician or LIP when restraints are used. The order needs to be entered into the chart.
- CMS uses the terminology that the patient is either *violent* or/and *self destructive or non-violent and non-self destructive*. TJC uses the terminology that the patient is either *behavioral health* or *non-*

behavioral health. There are different standards to follow if the patient comes into the emergency department and is violent and/or self-destructive.

- Emergency department staff should also be familiar with the definition of what constitutes a restraint. The definition should be in the policy and procedure manual which staff should be educated on during orientation and periodically thereafter. CMS has interpreted this to mean that staff should be trained on an annual basis so this should be added to the yearly skills lab.
 - A **physical restraint** is any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely.
- Physical restraints includes things like soft limb restraints, a freedom splint or elbow immobilizer, restraint soft belt, restraint net, hard locking restraints and restraint jackets. Most hospitals report that they no longer use a restraint jacket because of safety concerns. Manually holding down a patient who is actively violent is a form of restraint. Also hospital do not generally use leather restraints because they are an infection control issue since they cannot be cleaned.
- CMS has a focus of when a drug is used as a restraint. 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 can also be a restraint. This issue should be addressed in the P&P. Medication can be a restraint if it is not a standard treatment or standard dosage for the patient's condition. If you give a double or triple dose or a medication off label, it may be considered by CMS to be a drug used as a restraint. Giving Ativan for a patient having alcohol withdrawal is not considered to be a restraint. It is part of the standard treatment and is with the pharmacy parameters set forth by the FDA and manufacturer. It is also a national practice standard.
- **Seclusion** is defined as 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. Recently, there has been the issue of overcrowding and boarding of behavioral health patients until a psych bed can be attained. Many emergency departments have started to have locked units to safely manage this population. CMS says that being on a locked unit is not seclusion.

- Restraints do not include forensic restraints such as those used by law enforcement. This may include shackles or handcuffs. However, staff should still monitor their use for patient safety reasons. Hospitals should also state in their policy and procedure that forensic restraints do not constitute restraint and seclusion and therefore are not subject to the CMS or TJC restraint and seclusion standards.
- Restraints do not include orthopedic devices like casts or double shantz dressings. It does not include the use of padded side rails if the patient has a history of seizures. The ED carts are so narrow that CMS allows both of the side rails to be up for patient safety. Patients who have all four side rails on a regular bed and who cannot lower them would be considered to be restrained. An exception is made for the special air mattress bed to prevent pressure ulcers.
- An exception from the definitions of restraints is made for staffs that physically hold down a child for medical reasons such as to give them an antibiotic shot or to start an IV or do a lumbar puncture. Mitts are not a restraint if they are not tied down and are not too bulky to allow a patient movement of their fingers.
- CMS does not consider the use of weapons on patients by hospital staff as being safe. Hospital security cannot use pepper spray, tazer, or a stun gun on a patient. (See tag 154) If a patient comes in to the emergency department and is out of control, the local police can be called and often the police will place the patient under arrest. CMS will permit law enforcement to use them as allowed by state and federal law. However, as a caution, emergency department staff still needs to provide oversight to ensure the safety of the patient.
- ED staff may want to have a preprinted order sheets and nursing assessment sheet for patients who need restraint and seclusion. The sheet can include all of the requirements on it such as documenting the reason for the restraint and seclusion. These would allow timely

intervention for the patient who is a danger to himself or others, or is attempting to remove medical devices such as nasogastric tubes or foleys.

- Restraints can only be used when less restrictive interventions have been determined to be ineffective to protect the patient or others from harm. For example, using a protective cover over the IV along with a sleeve covering can prevent the use of a restraint in some cases. If the patient only needs two limb restraints and not four then this is an example of least restrictive.
- Staff should consider alternatives. If two family members are staying with the patient and each can hold his hand then this may prevent applying two soft limb restraints. For example, hospital staff put a mattress on the floor protected by blankets as opposed to restraining the restless patient. ED with lower to the ground stretchers, low beds, and protective mats can prevent injuries from a patient who is a fall risk without restraining them.
- CMS requires a written or signed verbal order for any patient who is restrained or placed into seclusion. CMS will allow a licensed independent practitioner (LIP) to write the order. State law determines who is a LIP and not CMS. It is usually staff like a PA, NP, or licensed resident. Medical students are not allowed to write an order for a restraint.
- If a LIP writes the order, CMS requires that the attending physician must be notified. If a PA is working in the ED with an ED physician it is probably just easier to have the physician write the order. Otherwise the PA should document that the ED physician is aware the patient is in restraints. ED nurses who are caring for admitted patients who are staying in the ED because there is no bed available must make sure the attending physician is aware that the patient is in restraint and/or seclusion. Emergency departments that have patient

flow issues and who board admitted patients for long periods need to be aware of the restraint and seclusion interpretive guidelines.

- It was previously discussed that there must be an order written in the order sheet of the medical record. CMS does allow three types of PRN orders prior to physician evaluation. For example, if a patient has a repetitive self-mutilating behavior and keeps banging his head against the wall then CMS would allow the patient to be restrained. A physician could write an order to have all four side rails up when the patient is in bed. Remember if the patient can lower the rail then it is not a restraint. Therefore, nursing documentation should include this. A physician could write an order to place the patient in a “Geri Chair” when out of bed. If the patient is able to get out of the Geri chair when they want it is not a restraint. If they cannot get out of the chair then it is a restraint.
- CMS states that you must have a plan of care. If you use restraints then you need to amend the plan of care. This can be documented in the ED nurses notes.
- Restraints must be discontinued at the earliest possible time. When they are no longer needed they need to be removed.
- Patients must be assessed and monitored at regular intervals, usually not exceeding a few hours. Intervals are based on patient’s need, condition and type of restraint used. CMS and TJC do not specify time frame for assessment. TJC use to specify two hour assessments for nonbehavioral health patients and every 15 minutes for behavioral health patients.
 - i. Many hospitals still have it in their policy to do an assessment every two hours for patients who are non-violent or non-self-destructive. Hospitals who do select the two hour time frame might consider saying “at appropriate two hour intervals.” Some emergency

departments and hospitals have selected a longer interval such as four hours. Remember, the both CMS and TJC will hold you to your written policy and procedure.

- ii. Many hospital use 15 minute assessments for patient who are violent and or self-destructive. Again, the hospital is free to choose a time frame. Again, the surveyor will hold the hospital to the time frame selected in the policy.
- There are many documentation requirements when the patient is in restraints. Hospitals generally use a special documentation sheet to capture all of the required elements. It could include things like vital signs, fluids offered, toileting offered, mental status, circulation, skin integrity, level of distress or agitation, or attempts to reduce restraints.
 - Restraints and seclusion must be implemented in accordance with safe, appropriate restraining techniques. They must be used as directed. Staff should complete an incident report or use the incident reporting system if a patient is injured from a restraint. Risk Management should be notified and may need to make a report under a federal law known as the Safe Medical Devices Law.
 - If a patient is violent or self-destructive, then a face to face evaluation must be done within one hour of arrival to the ED. This can be done by the physician, PA, NP, or the nurse if allowed by the hospital policy and trained appropriately. CMS has specific criteria that must be documented in the medical record. Hospitals should consider having a form to capture all of the required elements. An assessment is done to look for the cause such as hypoglycemia, hypoxia, sepsis, drug interactions, or electrolyte imbalance. Consider having a standard form that contains all the elements. This assessment would include;
 - The patient's reaction to the intervention
 - The patient's medical and behavioral condition

- The need to continue or terminate the restraint or seclusion
 - Physical and behavioral assessment
 - A review of systems, behavioral assessment, as well as patient's history including drugs and medications and the most recent lab tests
- There must be time limited orders for the patient who is violent and or self-destructive. For example, an adult patient is four hours. The nurse needs to have the ED physician write the order every four hours until 24 hours. At the 24 hour mark, if the patient is still in the emergency department, the patient needs to be seen by a LIP or physician if the order is to be renewed. Children 9-17 are two hours and children under 9 is one hour.
- The hospital must have a policy on restraint and seclusion. Everything that has been discussed should be included in the policy. The policy must say that violent and or self-destructive patient must be seen and a new order written every 24 hours. However, for non-violent patients the hospital gets to set the policy and determine the time frame. Some hospitals say the non-violent or non-self destructive patient must be seen every 48 or 72 hours and a new order written.
- CMS has a long list of things that nursing staff must be educated about. CMS discusses that staff education and training should be ongoing so hospital should include education in their yearly skills lab. Emergency department physicians and mid level providers who order restraints, must at a minimum be educated on the hospital's policy.
- Staff should be aware of any specific state law on restraint and seclusion. As previously discussed, hospitals should be aware of any standards from their accreditation agency.
- Any patient who is in restraint and seclusion must be continuously monitored on a 1:1 basis. R&S can only be used for patients who are

violent and or self-destructive in which they present a danger to themselves or others. Hospitals with both audio and video in close proximity to the patient can use this instead.

- The hospital must report to CMS regional office (not a State Department of Health) each death that occurs while a patient is in restraint or in seclusion at the hospital. A report has to be made if the patient died while in restraints or within 24 hours of when a restraint was used. This is true even if the restraint did not cause the death. The hospital must also report any death that occurred within 7 days where it is due to the restraint. Hospitals should vigilantly monitor this requirement. An exception was made to this section on July 16, 2012 and was discussed above. The hospital does not have to complete the restraint worksheet and report it to CMS if the patient died in two soft limb restraints where the restraint did not cause the death. This must be entered instead into an internal log. It must also be documented in the medical record.

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Patient safety brief is available off the website at www.empsf.org

Resources and References

The CMS hospital CoP manual is located at

http://cms.hhs.gov/manuals/Downloads/som107ap_a_hospitals.pdf

Six Core Strategies to Reduce the Use of Seclusion and Restraints Planning Tool at

http://surveyortraining.cms.hhs.gov/data/1039/debriefing_p_and_p_5-28-05.doc

Learning from Each Other Success Stories and Ideas for Reducing R&S in Behavioral Health at www.naphs.org, www.apna.org, www.psych.org, or www.apna.org, <http://www.naphs.org/catalog/ClinicResources/index.html>

Restraint and Seclusion-A Risk Managers Guide, Stephan Haimowitz, Sept 2006 at [www.nasmhpd.org/general_files/publications/ntac_pubs/R-S%20RISK%20-10-06\(1\).pdf](http://www.nasmhpd.org/general_files/publications/ntac_pubs/R-S%20RISK%20-10-06(1).pdf)

GAO, Mental Health, Improper Restraint and Seclusion Places People at Risk, Sept 1999, 99-176.

GAO Testimony, Mental Health, Extend of Risk From Improper Restraint or Seclusion is Unknown, October 26, 1999, 00-26.