



Emergency Physicians Insurance eXchange

EPIX Patient Safety Briefs (Previously known as EPIX Email Alerts)

Restraint and Seclusion

Written by Sue Dill Calloway RN MSN JD

Restraint and seclusion (R&S) are both a patient safety and risk management issue. Appropriately applied restraints can protect patients from harming themselves or others; however, unnecessary restraints and improper monitoring have resulted in injuries and deaths.

The Center for Medicare and Medicaid (CMS) rewrote the hospital regulations on restraint in 1998 (and have amended them many times since) after the Hartford Courant investigative report documented 142 deaths from restraints used between 1988 and 1998. And of course, medical malpractice or wrongful death actions have been filed due to injury or death from the use of restraints or seclusion. Hospitals can also be fined in many states by the state agency for restraint deaths. Restraints also increase the risk of delirium by four fold. (1)

Restraint and seclusion are the most common reasons why hospitals are cited by CMS. The January 28, 2016 deficiency report shows that 1,634 hospitals were cited by CMS. (2) CMS has 50 pages of hospital restraint standards found in the CMS Hospital Conditions of Participation (CoPs) manual in tag numbers 154 to 214. (3)

There are basically 21 rules to understanding and complying with the CMS standards. The four accreditation organizations also have restraint and seclusion standards which are closely cross walked with the CMS restraint CoPs. Any hospital that accepts Medicare or Medicaid patients must follow the CMS restraint regulations and interpretive guidelines. Hospitals must follow any stricter state laws on restraint and seclusion. Every emergency department physician, provider, or nurse should be aware of their specific state laws and the CMS guidelines.

Patient's Right to be Free from Unnecessary Restraint and Seclusion

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 when necessary and never as coercion, discipline, convenience, or retaliation.

Know the CMS Terminology: Violent and/or Self-Destructive

CMS uses the terminology that the patient is either *violent and/or self-destructive* or *non-violent*

and/or non-self-destructive. The Joint Commission (TJC) uses the terminology that the patient is either a *behavioral health* or *non-behavioral health patient*. There are different standards to follow if the patient comes into the emergency department and is violent and/or self-destructive.

Know the Definition of Restraint

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 (P&P) which all staff should be educated on during orientation and periodically thereafter. CMS has interpreted this to mean that staff should be trained on an ongoing 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 include things like soft limb restraints, elbow immobilizers, freedom splint, restraint soft belt, restraint net, hard locking restraints and restraint jackets. Leather restraints should not be used for infection control reasons as they cannot be cleaned and disinfected. Most hospitals report that they no longer use a restraint jacket because of safety concerns including patient deaths. Manually holding down a patient who is actively violent is a form of restraint.

Leadership and a Culture of Safety

Hospital leadership is responsible for creating a culture that supports the right for the patient to be free from R&S. The ED manager, ED medical director, and the chief nursing officer can assess and monitor the use through the performance improvement process. CMS does recognize the use of protocols so the nurse is obligated to get an order from the ED physician or licensed independent practitioner (LIP) when restraints are used. The order needs to be entered into the emergency department chart.

Drug Used as a Restraint

Emergency department staff should know 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 is a restraint. This issue should be addressed in the P&P.

Medication can be a restraint if it is not a standard treatment, a standard dose for the patient's condition, or is an off label use. Giving Ativan for the patient having alcohol withdrawal is not considered to be a restraint. It is part of the standard treatment and is within the pharmacy parameters set forth by the FDA and manufacturer. It is also a national practice standard.

Know Seclusion Requirements

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 and/or self-destructive behavior. Recently, there has been the issue of overcrowding and boarding of behavioral health patients in the emergency department until a psych bed can be attained. Many emergency departments have locked units to safety manage this population. CMS says that being on a locked unit is not seclusion. However, being in a locked room or posting a security guard at the door that is preventing the patient from leaving is seclusion.

If seclusion is used, there are many other restraint standards that apply. The patient must have a face to face exam within one hour. There must be an order.

What is Not a Restraint?

Emergency department staff should know the exceptions to what is not a restraint. Restraints do not include forensic restraints such as those used by law enforcement. This may include shackles or handcuffs. The policy and procedure should include this.

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 staff 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.

Can't Tazer, Pepper Spray, or Use a Stun Gun on a Patient

CMS does not consider the use of weapons on patients by hospital staff as being safe. Hospital security cannot use pepper spray, a tazer, or a stun gun on a patient. (See tag 154.) Security could use these devices on criminals such as an active shooter or someone trying to break into the pharmacy.

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.

Preprinted Order Sheets, Electronic Order, and Assessment Forms

ED staff may want to have preprinted order sheets, electronic orders, and nursing assessment sheets 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 indwelling catheters.

Least Restrictive Interventions and Alternatives

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 an elastic arm 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 and only two should be used. A new order must be obtained if the patient goes from two soft restraints to four or vice versa.

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.

An Order is Required

CMS requires a written 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 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.

What about PRN Orders?

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.

Plan of Care

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.

Discontinue at Earliest Possible Time

Restraints must be discontinued at the earliest possible time. When they are no longer needed they need to be removed.

Assessment of Patients in R&S

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. In the past TJC specified two hour assessments for non-behavioral health patients and every 15 minutes for behavioral health patients.

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.

Many hospitals use 15 minute assessments for patients who are violent and or self-destructive. Again, the hospital is free to choose a time frame. Again, the TJC or CMS surveyor will hold the hospital to the time frame selected in the policy.

Any patient who is in both 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.

Documentation Requirements

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.

Use as Directed

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. A report will have to be filed with the CMS regional office.

One Hour Face-to-Face Evaluation

If a patient is violent and/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 emergency department 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. 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 or provider 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 so the order can be renewed. Children ages 9-17 are two hours and children under 9 are one hour.

Must have a R&S Policy and Procedure

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 the 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.

Required Education

CMS has a long list of things that nursing staff must be educated about. In fact, there are ten pages of educational requirements for nursing staff. CMS discusses that staff education and training should be ongoing so hospitals should include education in their yearly skills lab. Emergency department physicians must at a minimum be educated on the hospital's policy. Hospitals can decide if the physicians on the medical staff need any additional training.

Reporting Restraint Use and Injury to CMS

The hospital must report to the 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. An exception to this requirement is if the patient died in two soft limb wrist restraints where the restraint *did not* cause the death. This must be entered instead into an internal log. The internal log must include the patient's name, date of birth, date of death, name of attending, medical record number, and primary diagnosis. It must also be documented in the patient's medical record. The hospital must also report to CMS any death that occurred within 7 days of restraint where it is due to the restraint. Hospitals should vigilantly monitor this requirement. See also CMS Survey Memo on Hospital Restraint/Seclusion Deaths [here](#). (4)

Type In Information and Print Off

DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR MEDICARE & MEDICAID SERVICES		Form Approved OMB No. 0938-1210
REPORT OF A HOSPITAL DEATH ASSOCIATED WITH RESTRAINT OR SECLUSION		
A. Hospital Information:		
Hospital Name		CCN
Address		
City	State	Zip Code
Person Filing the Report		Filer's Phone Number
B. Patient Information:		
Name		Date of Birth
Primary Diagnosis(es)		
www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS10455.pdf		
Medical Record Number	Date of Admission	Date of Death
Cause of Death		

Summary

Every emergency department physician, midlevel provider, and nurse should be familiar with the CMS restraint interpretive guidelines and regulations. This includes following the hospital's policy and procedure and any specific state laws. Any questions can be emailed to hospitalscg@cms.hhs.gov.

Sources and Resources

1. JAMA March 20, 1996;275(11):852-857, *Precipitating Factors for Delirium in Hospitalized Elderly Patients*.
2. CMS deficiency report can be viewed on the CMS hospital website at <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/Hospitals.html>.
3. The Medicare State Operations Manual, Appendix A, Hospitals, at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107_Appendixtoc.pdf.
4. CMS Survey Memo, May 9, 2014, *Hospital Restraint/Seclusion Deaths to be Reported Using CMS Form 10455, Report of a Hospital Death Associated with R&S*, at <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions-Items/Survey-and-Cert-Letter-14-27-.html?DLPage=1&DLEntries=10&DLFilter=restraint&DLSort=3&DLSortDir=descending>.
5. *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, www.apna.org, or <http://www.aha.org/content/00-10/learningfromeachother.pdf>.
6. Haimowitz, JD, Stephan. *Restraint and Seclusion - A Risk Managers Guide*, Sept 2006 at <http://www.nasmhpd.org/sites/default/files/R-S%20RISK%20MGMT%2010-10-06%282%29.pdf>.
7. GAO, *Mental Health, Improper Restraint and Seclusion Places People at Risk*, Sept 1999, 99-176.
8. GAO *Testimony, Mental Health, Extend of Risk from Improper Restraint or Seclusion is Unknown*, October 26, 1999, 00-26.

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Emergency Physicians Insurance Exchange RRG
13620 Lincoln Way, Suite 230 | Auburn, CA 95603
(866) 374-2467 | www.epixrrg.com