

Seclusion and Restraint: New Rules and New Roles

*Opening
January 8, 2007*


The New Rules

- The Landscape
- The New Rule
- The Focus Points



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A Preview of the Changes

- Revised and combined medical and behavioral health standards
- Clarification of definitions
- Additional role and authority for RNs and PAs
- Staff and physician training requirements
- Flexibility for providers with specific roles for hospital policy 
- Expanded reporting requirements
- Documentation requirements

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Federal Regulatory Background

- Dec 1997- proposed patient rights CoP
 - 62 FR 66726
 - 42 CFR part 482
- July 1999 – interim final rule
 - 64 FR 36070
- December 2006 – final rule
 - 71 FR 71378
 - 42 C.F.R. § 482.13(e)



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Other Sources of Standards

■ JCAHO 

■ State law (allowed to be more restrictive than CoP)
(and WA laws are)

- Psychiatric hospitals (ch. 71.12 RCW)
 - WAC 246-322-180
- RTFs (ch. 246-337 WAC; ch. 71.12 RCW)
 - WAC 246-337-110
- E&Ts (ch. 71.05/71.34 RCW)
 - WAC 388-865-0545 (adults)
 - WAC 388-865-0546 (minors)
 - WAC 388-865-0580 (minors)
- Hospitals (ch. 70.02 RCW)
 - WAC 246-337-050

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Alternatives to S/R

■ APA Task Force

■ "Learning from Each Other--Success Stories and Ideas for Reducing Restraint/Seclusion in Behavioral Health." 2003

■ American Psychiatric Assn, American Psychiatric Nurses Assn, and the National Assn of Psychiatric Health Systems, with American Hospital Assn.

■ "Roadmap to Seclusion and Restraint Free Mental Health Services: Training Curriculum." 2006.

■ SAMHSA.

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Why All the Focus ?

- October 11, 1998 *Hartford Courant* report
- 142 deaths over a 10-year period related to seclusion or restraint, 59.6 percent occurred in the hospital setting (including psychiatric hospitals and psychiatric wards of general hospitals):
 - 47.2 percent of the 142 deaths involved physical restraints or therapeutic holds,
 - 44.1 percent involved mechanical restraint,
 - 3.1 percent involved a combination of the two
 - 5.5 percent were seclusion-related.

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Sentinel Event Alert

Preventing Restraint Deaths – November 18, 1998

- A 'must read' for anyone dealing with S/R issues
- JCAHO reviewed 2 years of sentinel event reports:
 - 20 deaths - Most occurred in psychiatric hospitals (12), followed by general hospitals (6) and long term care facilities (2);
 - In 40% of the cases, the cause of death was asphyxiation.
- JC reviewed RCAs and identified factors that may lead to increased risk of death
- JC suggested strategies to reduce risk and address the root causes

Available at:

http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_8.htm



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Sentinel Event Alert

Preventing Restraint Deaths – November 18, 1998

Suggested Strategies for Reducing Risk

- Redouble efforts to reduce the use of physical restraint and therapeutic hold.
- Revise procedures for assessing the medical condition of psychiatric patients.
- Enhance staff orientation/education regarding alternatives to physical restraints and proper application of restraints or therapeutic holding.
- Consider age, sex and gender of patients when setting therapeutic hold policies.
- Revise the staffing model.
- Develop structured procedures for consistent application of restraints.
- Continuously observe any patient that is restrained.
- If a patient must be restrained in the supine position, ensure that the head is free to rotate to the side and, when possible, the head of the bed is elevated to minimize the risk of aspiration.
- If a patient must be restrained in the prone position, ensure that the airway is unobstructed at all times (for example, do not cover or "bury" the patient's face). Also, ensure that expansion of the patient's lungs is not restricted by excessive pressure on the patient's back (special caution is required for children, elderly patients and very obese patients).
- Never place a towel, bag or other cover over a patient's face as part of the therapeutic holding process.
- Do not restrain a patient in a bed with unprotected split side rails.
- Discontinue use of certain types of restraints, such as high vests and waist restraints.
- Ensure that all smoking materials are removed from patient's access, including access from family and friends.

GAO Report

- *MENTAL HEALTH: Improper Restraint or Seclusion Use Places People at Risk*
- Completed at request of 10 House and Senate members (September 1999)
- 24 deaths associated with restraint or seclusion during fiscal year 1998
 - "Because reporting is so fragmentary, we believe many more deaths related to restraint or seclusion may occur."
 - "We also recommend that HCFA improve reporting of restraint and seclusion use and any related deaths or injuries and require staff training in safely applying restraint or seclusion as well as alternative methods for dealing with potentially violent situations."



OIG Report

- September 2006
- Hospitals failed to report to CMS 44 of 104 documented deaths related to restraint and seclusion between August 2, 1999 and December 31, 2004



National Examples

- \$3.7 million settlement (California 1998)
- \$2.5 million settlement (Texas 2003)
- \$2 million verdict (Ohio 2000)
- \$1.4 million settlement (Penn. 2006)
- \$1.25 million settlement (Conn. 2006)
(plus waiver of \$1m hospital costs = \$2.3m total cost)



National Examples, cont'd.

- Injury cases
 - fractures
 - reflex sympathetic disorder/neuropathy/brachial plexopathy
 - pressure ulcers
 - burns



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Local Examples



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Who Must Comply?

- **All Medicare- and Medicaid-participating hospitals**
 - (short-term, psychiatric, rehabilitation, long-term, children's, and alcohol-drug)
- **All patients**
 - regardless of age or diagnosis
- **All uses of restraint or seclusion**
 - regardless of the patient's location within a hospital

71 FR 71382, 84-5, 94

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Patient Rights

ALL PATIENTS HAVE THE RIGHT TO BE FREE FROM RESTRAINT OR SECLUSION, OF ANY FORM, IMPOSED AS A MEANS OF COERCION, DISCIPLINE, CONVENIENCE, OR RETALIATION BY STAFF. RESTRAINT OR SECLUSION MAY ONLY BE IMPOSED TO INSURE THE IMMEDIATE PHYSICAL SAFETY OF THE PATIENT, STAFF, OR OTHERS AND MUST BE DISCONTINUED AT THE EARLIEST POSSIBLE TIME.

42 C.F.R. § 482.13(e)

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Never Acceptable

Seclusion or restraint may never be imposed, in any form, as a means of coercion, discipline, retaliation, or for convenience.

42 C.F.R. § 482.13(e)

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What is Allowed?

- Restraint or seclusion
 - Can only be imposed to ensure the immediate physical safety of the patient, staff, or others,
 - Must be discontinued at the earliest possible time, and
 - Less restrictive interventions must have been determined to be ineffective.
- Seclusion may only be used to manage violent or self-destructive behavior of patients that jeopardizes the immediate physical safety of the patient, a staff member, or others.

42 C.F.R. § 482.13(e)(1)(ii), (2), (4)

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What is a Restraint?

- 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
- 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)

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A Drug is a Restraint When...

- The overall effect of a medication is to **reduce** the patient's ability to effectively or appropriately interact with the world around the patient, then the medication is not being used as a standard treatment for the patient's condition



- Avoid Problems: Document When Drug is Not a Restraint

PRN Ativan - e.g.
- to reduce anxiety/agitation and allow patient to better tolerate necessary care procedures/devices

- to decrease anxiety and agitation that is interfering with patient's ability to participate in the unit milieu

71 FR 71390-1

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Standard Treatment

- A standard treatment for a medication used to address a patient's condition would include all of the following:
 - The medication is used within the pharmaceutical parameters approved by the Food and Drug Administration (FDA) and the manufacturer for the indications it is manufactured and labeled to address (including listed dosage parameters).
 - The use of the medication follows national practice standards established or recognized by the medical community and/or professional medical association or organization.
 - Use of the medication to treat a specific patient's clinical condition is based on that patient's symptoms, overall clinical situation, and on the physician's or other LIP's knowledge of that patient's expected and actual response to the medication.
- What about children, adolescents, and the elderly?



71 FR 71390-91

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What is NOT a Restraint

- devices, such as orthopedically prescribed devices
- surgical dressings or bandages
- protective helmets
- other methods that involve the physical holding of a patient for the purpose of
 - conducting routine physical examinations or tests,
 - protecting the patient from falling out of bed,
 - permitting the patient to participate in activities without the risk of physical harm



42 C.F.R. § 482.13(e)(1)(i)(C)

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BUT –

Be sure to document your assessment and purpose in using any device.

These devices could conceivably be used as a restraint.

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Handcuffs

- Rules do not govern use of handcuffs or other devices by law enforcement officials who are not employees of the hospital.
 - Law enforcement responsible for using its restraining devices in accord with its federal and state law.
- Hospital still responsible for providing safe and appropriate care to patient.



71 FR 71389

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What is Seclusion ?

- Involuntarily confining the patient alone in a room or area where the patient is physically prevented from leaving.
 - Includes situation where patient is restricted to a room or area alone and staff are physically intervening to prevent the patient from leaving the room or area
- May only be used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others
- Does not include confinement on a locked unit, ward, or other area where the patient is with others.

42 C.F.R. § 482.13(e)(1)(ii)



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General Requirements for All Interventions

Use of restraint or seclusion must be:

- In accord with written modification to patient's plan of care
- Implemented in accord with safe and appropriate techniques
 - As determined by hospital policy (+ state law)

42 C.F.R. § 482.13(e)(4)

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More General Requirements for All Interventions


Use of restraint or seclusion :

- May only be used if less restrictive interventions have been determined to be ineffective to protect the patient, staff, or others from harm,
 - Providers must use the least restrictive type or technique of restraint or seclusion that will be effective to protect from harm.

42 C.F.R. § 482.13(e)(4)

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Individualized Assessments

- Every patient is entitled to an individualized assessment and treatment that takes into account the patient's individual strengths, weaknesses, choices, needs, and concerns:
 - An individualized assessment that considers the patient's characteristics, such as age, history, size, medical and mental condition, and preferences, should be the basis of any intervention,
-  What seems least restrictive for one patient may not be an appropriate option for another patient.

71 FR 71391

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Orders for Seclusion or Restraint

- Must be ordered by physician or other LIP responsible for care of patient
 - Authorized by hospital policy (+ state law)
- No PRN orders
- Attending physician must be consulted ASAP if ordered by LIP other than attending
 - Hospital policies and procedures should address the definition of "as soon as possible" (based on the needs of their particular patient population).

42 C.F.R. § 482.13(e)(5), (6), (7)

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Initiation Prior to Order

- RN may initiate restraint use prior to obtaining an order
 - If LIP not available to issue order
 - PC.11.40 – obtain verbal/written order w/in 12h +written order w/in 24h
 - CoP – does not prohibit this
- Must be consistent with hospital policies and procedures
 - And patient's needs and clinical condition

71 FR 71396

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Order Renewal (Med/Surg)

- JC: Orders must be renewed each day based on the examination of the patient by an LIP (PC.11.40 EP7)



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General Verbal Order Rule

NEW! 5 year trial (with automatic sunset)

- All orders, including verbal orders, must be dated, timed, and authenticated.
- If there is no State law that designates a specific timeframe for the authentication of verbal orders, verbal orders must be authenticated within 48 hours.
- Authentication by the practitioner or another practitioner who is responsible for the care of the patient and authorized to write orders by hospital policy in accordance with State law.

42 CFR § 482.24(c)(1)

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Protocols?

- Protocols (PC.11.60) are not prohibited by CoP as long as each initiation continues to be authorized by an order based on an individualized assessment of the patient.
 - No 'standing' orders
 - CMS will want to see evidence of medical staff involvement in developing, reviewing and QI monitoring of any protocol



71 FR 71395-6

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Monitoring and Assessment General Requirements

- Condition of patient must be monitored by physician, LIP, or other trained staff
 - Interval determined by hospital policy
 - "The hospital is responsible for providing the level of monitoring and frequency of reassessment that will ensure the patient's safety."
- R/S must be discontinued at earliest possible time, regardless of length of order

71 FR 71385 ; 42 C.F.R. § 482.13(e)(10)

42 C.F.R. § 482.13(e)(9)

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Determining What to Monitor and Assess

- Hospital policies should address frequency of assessment and monitoring components of monitoring (for example, vital signs, hydration and circulation, level of distress and agitation, mental status, cognitive functioning, skin integrity), nutritional needs, range of motion, elimination needs, and other care needs.
- Items to be monitored will vary with the type of intervention used and the patient's condition.
 - For example, the use of a restraint that keeps the patient immobilized would require a check of the patient's skin integrity and steps to prevent skin breakdown. Depending on the duration of the intervention, range of motion exercises might be necessary. The patient's mental status, as well as vital signs, should be assessed, particularly when the restraint is initiated to manage self-destructive or violent behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others. The patient should be provided the opportunity for toileting, hydration, and eating if the intervention used impedes these activities.

71 FR 71400

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Compare to JC

- PC.11.70 – Hospital policies and procedures establish frequency, nature, and extent of monitoring.
 - At least every 2 hours, or sooner according to patient need and hospital policy
- PC.12.130 – Trained staff assess the patient every 15 minutes.

 The Joint Commission

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“Behavioral Health Care” ?

- CoPs now address S/R to manage “violent or self-destructive behavior”
- Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others, and must be discontinued at the earliest possible time.
- This standard applies to all patient populations
 - not just patients on psychiatric units or those with behavioral/mental health care needs



71 FR 71382

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Remember:

JC Still = ‘Behavioral Health Care’

- “Behavioral health care’ = use of S/R primarily to protect patient against injury to self or others because of an emotional or behavioral disorder
- PC.12 standards apply to all behavioral health settings
 - Selected PC.12 standards apply to behavioral health uses of restraint or seclusion in non-behavioral health settings (acute medical/surgical) (see page PC-30)



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Med/Surg Examples- Violent or Self-destructive Behavior

- From CoP Final Rule:
 - A patient may experience a severe medication reaction that causes him or her to become violent.
 - A patient may be withdrawing from alcohol and having delirium tremors (DTs). The patient is agitated, combative, verbally abusive, and attempting to hit staff.



71 FR 71383

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Med/Surg Examples- Violent or Self-destructive Behavior

From **OLD** Interpretive Guidelines:

- “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.
 - 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 (§482.13(f)).
 - Example 2: A patient diagnosed with Alzheimer’s Disease has surgery for a fractured hip. Staff determines that it is necessary to immobilize the hip to prevent re-injury. The use of less restrictive alternatives has been evaluated or was unsuccessful. Restraint use in this situation is governed by the acute medical and surgical care standard (§482.13(e)). “

State Operations Manual Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals (Rev. 1, 05-21-04); A-0062

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Additional Monitoring and Assessment Violent or Self-destructive Behavior

- Patient must be seen face-to-face within 1 hour after the initiation of the intervention
 - Physician, LIP, or trained R.N. or P.A.
- Evaluate
 - Patient's immediate situation
 - Patient's reaction to the intervention
 - Medical and behavioral condition
 - Need to continue or terminate the intervention



42 C.F.R. § 482.13(e)(12)

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Additional Monitoring and Assessment Violent or Self-destructive Behavior

- If 1-hour face-to-face evaluation is conducted by R.N. or P.A., must consult attending ASAP after complete evaluation

Ending the intervention prior to the 1-hour point does not mean that the mandated assessment and consultation are no longer necessary.

These steps are still required, even if the intervention ends within one hour of initiation.



42 C.F.R. § 482.13(e)(14)

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JC or CoP ?



- PC.12.90 (CAMH Update 2, Sept. 2006 – effective January 2007)
 - Medicare-accredited facilities must comply with the 1999 Interim Final Rule that requires 1-hour face-to-face evaluation by an LIP (EP4)
 - Non-Medicare facilities – in-person evaluation within 4 hours of initiation of intervention (adults) (EP1)
 - Within 2 hours for patients age 17 and under
- 42 C.F.R. § 482.13(e)(12) (published December 2006 – effective January 2007)
 - 1-hour face-to-face may be conducted by LIP or by RN
 - must consult attending ASAP after complete evaluation

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Orders

Violent or Self-destructive Behavior

- May be renewed
 - As authorized by hospital policy
- Maximum renewal increments (below) until reach 24 hours:
 - Adults (18+): Every 4 hours
 - Adolescents (9 – 17): Every 2 hours
 - Children (under 9): Every 1 hour
- After 24 hours, LIP must see and assess patient before writing new order

42 C.F.R. § 482.13(e)(8)

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Orders – Compare to JC

Violent or Self-destructive Behavior

- PC 12.100 - Maximum order renewal increments
 - Same as CoP
- PC.12.110 - LIP in-person evaluation required (stricter than CoP):
 - Adults (18+): Every 8 hours
 - Minors (under 18): Every 4 hours

Documentation

Violent or Self-destructive Behavior

Documentation in record must include

- The 1-hour face-to-face evaluation
- Description of patient's behavior and intervention used
- Alternatives or other less restrictive interventions attempted (as applicable)
- Patient's response to the interventions
 - Including rationale for continued use of the intervention



Compare to JC

- PC.12.170 - Laundry list of documentation requirements for patient's medical record
 - Includes clinical details plus staff actions, such as informing patient of criteria for discontinuing S/R, assistance provided to patient to help him or her meet those criteria, and debriefing post-S/R (EP3)
- (behavioral health settings only)

Simultaneous S/R

Violent or Self-destructive Behavior

- Only permitted if patient is continuously monitored
 - Face-to-face by trained staff or
 - By trained staff in close proximity to patient using video and audio equipment



- Plan ahead for staff breaks, code team assignments, etc.

Simultaneous S/R

Violent or Self-destructive Behavior

Continual monitoring cannot happen solely from outside the seclusion room. Staff must enter the seclusion room in order to--(1) monitor a patient's vital signs, circulation, hydration needs, elimination needs, level of distress and agitation, mental status, cognitive functioning, etc., and assess and re-evaluate the patient; (2) provide for nutritional needs; range of motion, and elimination needs; and (3) provide other necessary therapeutic interventions and patient care.

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"Continual Monitoring"

- Not just restricted to simultaneous S/R
- "clinically indicated"



71 FR 71400-1

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Discontinuing Restraint/Seclusion

- Restraint or seclusion may only be employed while the unsafe situation continues. Once the unsafe situation ends, the use of restraint or seclusion must be discontinued, regardless of the length of time identified in the order



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Trial Period ?

- What about a trial period out of restraints, during which the patient would be closely observed?
 - If the patient again exhibited the symptoms that had prompted the prior use of restraints, the patient would be placed in restraint again and this episode would be considered as part of the original episode/order.
- Response: The approach suggested ... is equivalent to a PRN order, which is not permitted... If staff ends an ordered intervention, they have no authority to start it again without the initiation of a new order.
 - For example, a patient is released from restraint or seclusion. If this patient later exhibits violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others that can only be handled through the use of restraint or seclusion, a new order would be required.
 - Staff cannot discontinue an order and then restart it because that would constitute a PRN order. However, a temporary release that occurs for the purpose of caring for a patient's needs, for example, toileting, feeding, and range of motion, is not considered a discontinuation of the intervention.



Applies to trial release for 'medical' restraints as well.

71 FR 71399

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Physician Training

- Training requirements must be specified in hospital policy
- At a minimum must require working knowledge of hospital policy regarding use of seclusion or restraint
 - Any physician or LIP authorized to write order for seclusion or restraint



42 C.F.R. § 482.13(e)(11)

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Staff Training

- All clinical staff that have direct patient contact must have ongoing education and training in the proper and safe use of restraints
 - trained and able to demonstrate competency prior to applying restraints, implementing seclusion, or performing associated monitoring and assessment of, or providing care for a patient in restraint or seclusion.
 - based on the specific needs of the patient population
- Staff must demonstrate competencies initially, as part of orientation, and subsequently on a periodic basis.
- Individuals providing staff training must be qualified as evidenced by education, training, and experience in techniques used by hospitals to address patients' behaviors.
- Successful completion of training and demonstration of competency must be documented in staff personnel records.

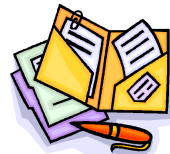


42 C.F.R. § 482.13(f)

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Compare to JC

- Staff training requirements are specific and more extensive than CoPs
 - PC.12.30 (behavioral health settings)



The Joint Commission

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Mental Health Advance Directives



"I would like the interventions below to be tried before use of seclusion or restraint is considered"

- "Talk me down" one-on-one
- More medication
- Time out/privacy
- Show of authority/force
- Shift my attention to something else
- Set firm limits on my behavior
- Help me to discuss/vent feelings
- Decrease stimulation
- Offer to have neutral person settle dispute
- Other, specify

"If it is determined that I am engaging in behavior that requires seclusion, physical restraint, and/or emergency use of medication, I prefer these interventions in the order I have chosen (choose "1" for first choice, "2" for second choice, and so on): "


- Seclusion
- Seclusion and physical restraint (combined)
- Medication by injection
- Medication in pill or liquid form

" I expect the choice of medication to reflect any preferences and instructions I have expressed in Part III C of this form. "

Chapter 71.32 RCW; 71 FR 71392

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Death Reporting



- Hospital must report to CMS (by COB of next business day) any death that occurs:
 - during restraint or seclusion
 - within 24h after removal from S/R
 - within 1 week after S/R where it is reasonable to assume that use of S/R directly or indirectly contributed to death (includes death related to restriction of movement, chest compression, restriction of breathing, or asphyxiation)
- Document date and time of report in patient record

42 C.F.R. § 482.13(g) 57

It May Be Used Against You...

- Consider standard form to use for documentation of report and inclusion in patient record.
- Use QI/peer review process for investigation and improvement.

PC.11.20 & PC.12.180

REPORT of Patient Death
As required by 42 C.F.R. § 482.13(g)

Patient Name: _____ MR Number: _____
 DOB: _____
 Date of Death: _____
 Date/Time of Telephone Report to CMS: _____
 CMS employee receiving report: _____

INDICATE THE CATEGORY OF REPORT (X):

_____ The death of this patient occurred at the same time that the patient was in (circle one) restraint or seclusion. No causal connection or assumed or implied.

_____ The death of this patient occurred within 24 hours after the time the patient was removed from (circle one) restraint or seclusion. No causal connection or assumed or implied.

_____ The death of this patient occurred within 1 week after the time the patient was removed from (circle one) restraint or seclusion. Pending further investigation, this death is being reported as required by law as being "reasonable to assume that use of restraint or placement in seclusion may have contributed directly or indirectly to a patient's death." No causal connection or assumed or implied.

On _____ (date), I reported the above information to CMS Region X at
 (206)xxx-xxxx.

 signature
 Chief Nursing Officer

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CMS Will Ask for More...


Current CMS Worksheet
S&C-06-31, Sept 29, 2006
New one in the works...

Restraint/Seclusion Death Report Worksheet

-2-

<p>Contact Information RO contact's name: _____ Date of RO contact: _____ RO Contact's phone number: _____ Facility contact: _____ Facility contact's phone number: _____</p> <p>Provider Information Hospital Name: _____ Provider Number: _____ Address: _____ Zip Code: _____</p> <p>Patient Information Name: _____ Date of Birth: Age: _____ Medicare/Medicaid Number: _____ Admitting Diagnosis: _____ Date of Admission: _____ Date/Time of Death: _____ Cause of Death: _____ Did the facility conduct a root cause analysis? yes _____ no _____ NOTE: Hospitals may provide the following information over the telephone, or to the SA during its investigation. Length of Time in Restraint/Seclusion: _____ Circumstances surrounding the death: _____</p> <p>Results of any facility investigation: _____</p> <p>Restraint/Seclusion Information Type: Physical Restraint _____ Seclusion _____ Drug Used as a Restraint _____ Restraint Standard: Acute Medical/Surgical Care _____ Behavioral Management _____ Restraint Method: _____ Reason(s) for seclusion/restraint use: _____ Less restrictive methods of behavior management considered: _____ Restraint/seclusion order date/time: _____ Quote actual restraint/seclusion orders: _____</p>	<p>Monitoring method(s), frequency, last date/time monitored: _____ Last date/time of assessment: _____ Were there previous instances of restraint/seclusion deaths since 8/2/97? yes _____ no _____ If there were prior deaths, were steps taken with previous deaths to prevent recurrence? _____</p> <p>Additional Information/Comments: _____</p> <p>Action Information Facility notifications Other agencies the provider notified: (SA, FDA, etc.) _____ Agency date/time: _____ Agency date/time: _____ Agency date/time: _____</p> <p>SA action(s) Date of receipt of restraint/seclusion death report from RO: _____ Date of Survey: _____ Date the completed Restraint/Seclusion Death Report forwarded to RO: _____</p> <p>RO action(s) Date sent as complaint to SA: _____ Date authorized SA complaint survey: _____ Date Method/Person notifying CO: _____</p> <p>CO action(s) Date of receipt of initial restraint/seclusion death report: _____ Date of receipt of initial restraint/seclusion death report worksheet: _____ Date of receipt of complete restraint/seclusion death report worksheet: _____ Person recording the information: _____</p>
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Other Reporting Obligations



- FDA:** suspected medical device related deaths
 - within 10 working days of the patient's death
 - MedWatch FDA Form 3500A
 - FDA forwards copy to CMS
- State:**
 - WAC 246-320-145 – DOH - unanticipated death or major permanent loss of function, not related to the natural course of a patient's illness or underlying condition
 - within two administrative business days of hospital leaders learning of the confirmed event
 - RCW 70.56.020 – DOH - patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility
 - initial report within forty-eight hours of confirmation
 - subsequent report must be submitted to the department within forty-five days
 - RCW 68.50.010/.020 – Medical Examiner/Coroner
 - where the circumstances of death indicate death was caused by unnatural or unlawful means
 - KOME - Unexpected deaths during, associated with, or as a result of, diagnostic or therapeutic procedures
 - RSNs – RSNs are required to monitor adverse events - WAC 388-865-02800.
 - Contracts with providers typically contain reporting requirements
- Patient:** RCW 70.41.380 - Notice of unanticipated outcomes
- JC** (if you report sentinel events) (But do your RCA even if you don't report !)

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What Does CMS Do With Reports?

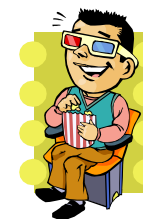
- State survey agency
- Data analysis
- P&As



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Stay Tuned ...

Interpretive Guidelines
WILL
be produced.



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Hospital & Health Law Seminar

University of Washington School of Law
Friday, April 27, 2007

- Federal Update
Speaker: Steve Brennan
- State Legislative Update
Speaker: Randy Revelle
- New DOH Licensing Rules
Speakers: Taya Briley, Kristen Petersen
- Update on the Washington Market
Speaker: Margaret Stanley
- Legal and Clinical Ethics: Human Subject Research
Speaker: David Forster
- Tax Update
Speakers: Susan Mathis, LaVerne Woods
- Malpractice Update
Speaker: Mary Spillane
- Credentialing Hot Topics: New and Emerging Technologies; Evidence-Based Credentialing
Speaker: Kristin Miles
- Stark Law Update
Speaker: Bob Homchick

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The preceding is the opinion of the author and should not be construed as the official opinion of the Washington State Attorney General.

The End

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