CMS HOSPITAL CONDITIONS OF PARTICIPATION (COPS) 2014

Patient Rights

Dianne McKissack
Senior Program Director
Johnson Regional Medical Center
Clarksville, AR
Objectives:

• Patients will be able to understand the basic patient rights standards and the patients’ rights to exercise each of them.

• Participants will be able to identify the patient’s right to a “Designation of a Representative."

• Participants will identify and discuss ways to protect patient's privacy, confidentiality, and ensure their rights to access their medical record, as well as to informed consent and to actively participate in their treatment.

• Participants will identify and discuss the Seclusion and Restraint standards of CMS.

• Participants will utilize information given to discuss new CMS visitation guidelines.
Patient Rights Standards

Delineates minimum protections and rights for patients

- Includes: Right to notification of rights and exercise of rights
  - Privacy and safety
  - Confidentiality of medical records
- Restraint issues
  - 50 pages of restraint standards
- Grievances
- Advance directives
- Visitation rights
## Deficiency Report Breakdown

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Notice of Patient Rights and Grievance Process

The hospital must ensure the notice of patient rights are met

• Must provide Patient Rights in a manner the patient will understand
  • Patients who do not speak English – or have limited English
  • Patients with low health literacy – “the ability to read, understand and act on health information” – is an emerging public health issue that affects all age, race, and income levels.
    • According to the National Patient Safety Foundation (NPSF), more than 66% of US adults age 60 and over have either inadequate or marginal literacy skills.
    • And, according to the NPSF, 1 out of 5 American adults reads at the 5th grade level or below
  • Must have P&P to ensure patients have information necessary to exercise their rights
A hospital must inform each patient of the patients’ rights in advance of furnishing or discontinuing care – includes IP and OP

- **Must take reasonable steps to determine the patients’ wishes on designation of a representative:**
  - If the patient *IS NOT* incapacitated and *has* an individual to be their representative, then the hospital must provide the representative with the notice of patient rights in addition to the patient.
  - If the patient *IS* incapacitated and *has* a representative who presents with an advanced directive, such as the DPOA, then the hospital must provide the representative with the notice of patient rights.
  - If the patient *IS* incapacitated and *has no* advance directive, then to the person who is the spouse, domestic partner, parent of minor child, or other family member is given the patient rights in addition to the patient.

- **Must give Medicare patients the Important Message from Medicare (IM) Notice within two days of admission and in advance of discharge, if more than two days—at least within 48 hours of discharge**
Designation of Representative  

- Hospitals **CANNOT** ask for supporting documentation from the patient representative, unless more than one individual claims to be their representative.
- If hospital refuses the request of an individual to be the patient’s representative, then this must be documented in the medical record.
- Some states have laws regarding representatives
- The hospital **must** adopt a P&P on this...this is new for most hospitals...
Grievance Process

The hospital must have a process for prompt resolution of patient grievances

- The hospital must inform each patient how and to whom to file a grievance
- Use the CMS definition of grievance
  - **Definition:** A patient grievance is a formal or informal written or verbal complaint (when the verbal complaint about patient care is not resolved at the time of the complaint by staff present) by a patient, or a patient’s representative, regarding the patient’s care, abuse, or neglect, issues related to the hospital’s compliance with the CMS CoP or a Medicare beneficiary billing complaint related to rights.
Grievances...

If someone other than the patient complains about care or treatment, contact the patient and ask if this person is their authorized representative.

- Obtain the patient’s permission to discuss protected health information with designated person because of HIPAA
- Document in the file that the patient’s permission was obtained
- Some facilities get a HIPAA compliant form signed
- Not a grievance if patient is satisfied with care, but family member is not

- Billing issues are **not** generally grievances, unless it is a quality of care issue.
- A written complaint is **always** a grievance whether inpatient or outpatient (e-mail and fax is considered written).
- If complaint is telephoned in after patient is dismissed, then this is also considered a grievance.
- All complaints on abuse, neglect, or patient harm will always be considered a grievance.
- If patient asks you to treat as grievance, it will always be a grievance.
Exercise of Rights

Patients have the right to participate in the development and implementation of their plan of care.

• Requires hospital to actively include the patient in developing their plan of care - including changes
Informed Consent

- CMS has 3 sections in the hospital CoP manual on Informed Consent: Informed decisions, medical records and surgical services.
  - The patient has the right to make informed decisions:
    - Right to be informed of health status and to be involved in care planning and treatment.
    - Informed decision on discharge planning to post acute care.
    - Right to request or refuse treatment.
    - Right to delegate the right to make informed decisions to another (DPOA, guardian)
The patient has the right to make and have the advance directives followed when incapacitated. Staff must provide care that is consistent with these directives.

• The P&P must include delegation of patient rights to the representative, if the patient incompetent.

• The patient may designate in the AD a support person to make a decision on visitation.
  • The visitation regulations are one of the newest patient rights

• You must provide written information to the patient on their rights under state law, at time of admission for inpatient and same notice required for ED, observation, or same day surgery

• Document whether or not they have an AD

• Provide and document advance directives education

• Includes Psychiatric or Behavioral Health AD
The patient has a right to have a family member or representative notified and their physician notified on admission, if they are not aware. Must now ask every patient on admission and document
• Must do so promptly when patient responds affirmatively
• If the patient is incapacitated must identify a family member or representative, to promptly notify
Standard: The patient has a right to personal privacy while within the hospital - Need consent for video/electronic monitoring:

Make sure the patient is aware and can see the camera

- Such as cameras in patient rooms (sleep lab, ED safe room, eICU)
- Include in your general admission consent form that all patients sign on admission or make sure patients are aware in unit specific areas
- May use to monitor patients who are violent or self-destructive - who are in both restraint and seclusion
- Must have clinical need to utilize
Privacy continued

• Must have P&P that restrict access to MR to those who need to know, such as nurse who takes care of the patient.
• Must utilize Special Confidentiality for Behavioral Health Patients.
• Discusses incidental uses and disclosures
  • Names on spine of chart
  • Names on outside of rooms
  • Whiteboards that list patient present in OR or Behavioral Health
• Take reasonable safeguards
  • Ask waiting patients to stand back a few feet from a counter used for patient registration
• Protect your computer password
• Limit access to areas with light-boards or whiteboards
Privacy and Safety

The right to receive care in a safe setting includes following standards of care and practice for environmental safety, infection control, and security such as preventing infant abductions, preventing patient falls, and medication errors.

• Very broad authority for patient safety issue
• Right to respect for dignity and comfort
• Includes washing hands between patients
• Review and analyze incident or accident reports to identify problems with a safe environment

The patient has the right to be free from all forms of abuse or harassment and neglect.
Confidentiality

Patients have a right to confidentiality of their medical records and to access of their medical records.

- MR are kept secure and only viewed when necessary by staff involved in care
- Minimal necessary standard such as abstract out information on child abuse and don’t give protective services the entire chart
- Do not post patient information, where it can viewed by visitors
- If white board visible to public, hospital may use first name and first initial of last name
- Must protect patient’s medical record information from unauthorized person - must have a policy and procedure on this...
- Obtain patient or patient representative written authorization to disclose medical record information
Access to records...

Patients have the right to access the information contained within their medical records

- Right to inspect their record or to get a copy
  - 30 day rule under HIPAA, unless state law or P&P more stringent
  - HIPAA changes Sept 23, 2013
- Limited exceptions such as psychotherapy notes, prisoners, if jeopardize health of themselves or others, information could cause harm to another, under promise of confidentiality, etc.
- Access to the medical record must be within a reasonable time frame and hospitals cannot frustrate efforts of patients to get records
- If patient is incompetent, then the personal representative should sign as the personal representative such as guardian, parent, or DPOA.
- Reasonable cost for copying, postage, or summary
- No retrieval fee allowed under federal law
Weapons

CMS does not consider the use of weapons by hospital staff on patients as safe in the application of restraint (154)

- Could use on criminal breaking into building
- Weapons include pepper spray, mace, nightsticks, tasers, stun guns, pistols, etc.
- Okay - if patient is arrested and used by law enforcement (police)
Patients have a right to be free from physical or mental abuse, and corporal punishment

- This includes that restraint and seclusion (RS) will only be used when necessary
  - Not as coercion, discipline, convenience, or retaliation
  - Only used for patient safety and discontinued at earliest possible time
- R&S guidelines from CMS apply to all hospital patients, even those in behavioral health
- Hospitals should consider adding it to their patient rights statement-if not already there
- If patient falls, do not use R&S as routine part of fall prevention (154)
Hospital Leadership’s Role in Seclusion & Restraint

• Leadership is responsible for creating a culture that supports the right to be free from R&S
  • Must make sure systems and processes are in place to eliminate inappropriate R&S and monitors use thru PI process
  • Must make sure only used for physical safety of patient or staff
• Must ensure hospital complies with all R&S requirements (154)
Restraints Protocols

• CMS previously did not recognize or allow the use of protocols like TJC does
  • Protocols are now **not** banned by the new regulations (168) but still need separate order for R&S so didn’t really help

• Must contain information for staff on how to monitor and apply like intubation protocol

• Must document individualized assessment, symptoms, and diagnosis that triggered protocol

• Need physician involvement in developing and review and quality monitoring of S&R use
Restraint Standards

The Joint Commission calls it behavioral health and non-behavioral health; whereas, CMS calls it violent and or self destructive (V/SD) and non-violent and non-self destructive

• Decision to use R&S is not driven from diagnosis but from assessment of the patient
  • If a patient becomes violent or has self destructive behavior (V/SD) in the ICU or ED, CMS has one set of standards that apply
  • CMS says it is not the department in which the patient is located but the behavior of the patient – so can have V/SD restraints on the medical floor
Definition of Restraint

- **Definition**: 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.
  - Mechanical restraints include belts, restraint jackets, cuffs, or ties.
  - Manual method of holding the patient is a restraint.
    - Therapeutic holds to manage V/SD patients are a form of 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 and is **not** a standard treatment or standard dosage for the patient's condition (160).
Definition of Seclusion

- Seclusion is the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving (162)
  - Seclusion may only be used for the management of violent or self-destructive behavior (V/SD behavior) that jeopardizes the immediate physical safety of the patient, a staff member, or others
  - It is **NOT** being on a locked unit with others or for time out, if the patient can leave the area (162)
  - It is when they are alone in a room and physically prevented from leaving
  - May only use seclusion for management of V/SD behavior
Restraints do not include:

- Forensic restraints such as handcuffs, shackles, or other restrictive devices applied by law enforcement or police (0154)
- Orthopedically prescribed devices, surgical dressings or bandages, or protective helmets (161)
- Methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests (161)
- Protecting the patient from falling out of bed
  - Striker beds or the narrow, stretcher carts and their use of side rails are not a restraint
- IV board unless tied down or attached to bed
- Postural support devices for positioning or securing (161)
Restraints do not include... continued

- Device used to position a patient during surgery or while taking an x-ray
- Recovery from anesthesia is part of surgical procedure and medically necessary (161)
- Mitts unless tied down or pinned down or unless so bulky or applied so tightly the patient can not use or bend their hand (161)
  - Mitts that look like boxing gloves are a restraint
- Padded side rails put up when on seizure precaution
- Giving a child a shot to protect them from injury (161)
Restraints do include...

- Physically holding a patient (adult or child) for forced medications is a physical restraint
- Tucking in a sheet so tight the patient could not move (159)
- Use of enclosed bed or net bed unless the patient can freely exit the bed such as zipper inside the bed
- Freedom splint that immobilizes limb
- Side rails to keep the patient from getting out of bed, when the patient cannot lower

- Remember that it is not the thing but what the thing does to the patient in which their movement is restricted
Is this a restraint?
Restraints...more information

- Devices with multiple purposes - such as side rails or Geri chairs, when they cannot be easily removed by the patient and restrict the patient’s movement constitute a restraint.
- If belt across patient in wheelchair, and he can unsnap belt or Velcro, then it is not a restraint (159).
- If patient can lower side rails, when he/she wants, then it is not a restraint - but document this.
- If a patient can remove a device, it is not a restraint.
- Stroller safety belts, swing safety belts, high chair lap belts, raised crib rails, and crib covers (161) are okay as long as age or developmentally appropriate.
  - Use of these safety intervention must be addressed in your policy.
- Holding an infant or toddler is not a restraint.
Less Restrictive

Restraints can only be used when less restrictive interventions have been determined to be ineffective to protect the patient or others from harm (154, 164, 165)

- You must train on what is least restrictive interventions
- Type or technique used must also be least restrictive
  - Is what the patient doing a hazard? Allowing sundowners to walk or wander at night (154)
- Request from patient or family member is not sufficient basis for using, if not indicated by condition of patient
- Must do an assessment of patient
- Must document that restraint is least restrictive intervention to protect patient safety based on assessment
  - What was the effect of least restrictive intervention?
Alternatives

Alternatives should be considered along with less restrictive interventions (186)

• What are other things you could do to prevent using R&S, such as sitter or family member staying with patient?
• Distractions such as watching video games or working on a laptop computer
• Try nonphysical intervention skills (200)
• Consider having a list of alternatives in the toolkit
Restraints: LIP Can Write Orders

• LIPs can write orders for restraints
  • Any individual permitted by both state law and hospital policy for patients independently, within the scope of their licensure, and consistent with granted privileges, to order restraint, seclusion
    • NP, licensed resident, but not a medical student
    • CMS says usually not a PA, but state law determines this
  • Remember must specify who in your P&P (168)
Restraints: Notify Doctor ASAP

Any established time frames must be consistent with ASAP (not in 1 or 3 hours)

- Hospital Medical Staff Policy determines who is the attending physician
- Hospital P&P should address the definition of ASAP (182, 170)
- RN or PA who does 1 hour face-to-face must notify attending physician and discuss findings (182)
- Be sure to document, if LIP or nurse notifies physician
Restraints: Plan of Care

Restraints must be used in accordance with a written modification to the patient's plan of care (166)

What was the goal of the plan of care?

• Use of restraint should be in modified plan of care
• Care plan should be reviewed and updated in writing within time frame specified in P&P (166)
• Plan reflects a loop of assessment, intervention, evaluation and reevaluation
• Orders are time limited and this is included in the plan of care
• For the patient who is V/SD may want to debrief as part of plan of care, but not mandated by CMS. Debriefing no longer mandated by TJC for behavioral patients (deemed status) TJC requires de-escalation under PC.01.01.01
Restraint: End at Earliest Time

Restraints must be discontinued at the earliest possible time (154, 174)

- Regardless of the time identified in the order
- If you discontinue and still time left on clock and behavior reoccurs, you **must** get a new order
- **Temporary release** for caring for patient is okay (feeding, ROM, toileting), but a **trial release** is seen as a PRN order and not permitted (169)

**Restraints only used while unsafe condition exists**

- The hospital policy should include who has authority to discontinue restraints (154, 174)
- Under what circumstances restraints are to be discontinued and who is allowed to take them off
- Based on determination that patients behavior is no longer a threat to self, staff, or others (put this in your P&P)
- Policy should also include procedures to follow when staff need to apply in an emergency
Assessment

Staff must assess and monitor patient’s condition on an ongoing basis (0154, 174, 175)

• Physician or LIP must provide ongoing monitoring and assessment also (175)

• One reason to determine - if R&S can be removed

• Took out word continually monitored except for V/SD patients, and says at an interval determined by hospital policy
  • Intervals are based on the patient’s need, condition, and type of restraint used (V/SD or not)

• CMS doesn’t specify time frame for assessment like TJC (TJC used to say every 2 hours for medical patients and every 15 minutes for behavioral health patients)
  • This must be in your hospital P&P frequency of evaluations and assessments (175) and document to show compliance
Restraint: One Hour Rule

One Hour Rule

- Standard for behavioral health patients or V/SD patients
- Time limits for R&S used to manage V/SD behavioral and drugs used as restraint to manage them (178)
- Must see (face to face visit) and evaluate the need for R&S within one hour after the initiation of this intervention
  - Can be done by physician, LIP or a RN or PA, trained under 482.13 (f)
- Physician does not have to come to the hospital to see patient now, telephone conference may be appropriate
Time Limited Orders/Renew Order

Time limits apply-written order is limited to (171)

- 4 hours for adults
- 2 hours for children (9-17)
- 1 hour for under age 9
  - Related to R&S for violent or self destructive behavior and for safety of patient or staff

The original order for both V/SD restraint & seclusion may be renewed up to 24 hours then the physician reevaluates

- Nurse evaluates the patient and shares the assessment with the practitioner when need order to renew (171, 172)
- Unless state law if more restrictive
- After the original order expires, the MD or LIP must see the patient and assess before issuing a new order
Monitoring...

For behavioral health (V/SD) patients

• Can’t use R&S together unless the patient is visually monitored in person face to face or by an audio and video equipment
• Person to monitor patient face to face or via audio and visual must be assigned and a trained staff member
• Must be in close proximity to the patient (183)
• There must be documentation of this in the medical record
Documentation

Most hospitals use a special documentation sheet for assessment parameters, including frequency of assessment, and hospital policy should address each of these (175, 184)

• If the doctor writes a new order or renews order need documentation that describes patients clinical needs and supports continued use (174)
  • Document: fluids offered (hydration needs), vital signs
  • Toileting offered (elimination needs)
  • Removal of restraint and ROM and repositioning
  • Mental status, circulation

Attempts to reduce restraints, skin integrity, and level of distress or agitation, et. al.
  • Document the patient’s behavior and interventions used

Behavior should be documented in descriptive terms to evaluate the appropriateness of the intervention (185)

Document clinical response to the intervention (188)

Symptoms and condition that warranted the restraint must be documented (187)
Log and QA/PI

Hospital take actions thru QI activities

- Hospital leadership should assess and monitor use to make sure medically necessary
- Have a log to record use-shift, date, time, staff who initiated, date and time of each episode was initiated, type of restraint used, whether any injuries of patient or staff, age, and gender of patient
Deaths

The hospital must report to CMS each death that occurs while a patient is in restraint or in seclusion at the hospital

• Remember, the SMDA (Safety Medical Devises Act) also requires reporting

• Sentinel event reporting to Joint Commission is voluntary, but need to do Root Cause Analysis (RCA) within 45 days

• Must report every death that occurs within 24 hours after the patient has been removed from R&S

Except - Changes June 7, 2013

• Do not need to report death if patient had on only 2 soft wrist restraints and deaths not due to the restraints
  • Instead complete Internal Log

  Be sure to document this in the medical record also

• Each death known to the hospital that occurs within 1 week after R&S, where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death
Staff Education

New staff training requirements
- All staff having direct patient contact must have ongoing education and training in the proper and safe use of restraints and able to demonstrate competency (175)
  - Yearly education of staff as when skills lab is done
  - Document competency and training
  - Hospital P&P should identify what categories of staff are responsible for assessing and monitoring the patient (RN, LPN, Nursing assistant, 175)
  - Patients have a right to safe implementation of RS by trained staff (194)
  - Training plays critical role in reducing use (194)
  - Staff, including agency nurses, must not only be trained but must be able to demonstrate competency in the following:
    - The application of restraints (how to put them on), monitoring, and how to provide care to patients in restraints

Physician and other LIP training requirements must be specified in hospital policy (176)
- At a minimum, physicians and other LIPs authorized to order R or S by hospital policy in accordance with state law must have a working knowledge of hospital policy regarding the use of restraint or seclusion
- Hospitals have flexibility to determine what other training physicians and LIPs need
Staff Education continued...

This must be done before performing any of these functions (196)

• Training must occur in orientation before new staff can use them on a patient
• Training must occur on a periodic basis consistent with hospital policy
• Have a form to document that each of the education requirements have been met

The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following

• Techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require RS
Staff Education includes...

- The use of non-physical intervention skills (200)
- Choosing the least restrictive intervention based on an individualized assessment of the patient's medical, or behavioral status or condition (201)
- The safe application and use of all types of R&S used in the hospital, including training in how to recognize and respond to signs of physical and psychological distress (for example, positional asphyxia) (202)
- Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary (204)
- Monitoring the physical and psychological well-being of the patient who is restrained or secluded, including but not limited to, respiratory and circulatory status, skin integrity, vital signs, and any special requirements specified by hospital policy associated with the 1-hour face-to-face evaluation (205)
Staff Education includes...

- Including respiratory and circulatory status, skin integrity, VS, and special requirements of 1 hour face to face
- The use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including required periodic recertification (206)
- Staff must be qualified as evidenced by education, training, and experience
- Hospital must document in personnel records that the training and competency were successfully completed (208)
- Security guards respond to V/SD patients would need to train
- Don’t want someone going into the room of a V/SD patient without training to prevent injury to staff and patient
Trainer/Cost and Time

Individuals doing training program must be qualified (207)

• Trainers must have high level of knowledge and need to document their qualifications
• Train the trainer programs are done by many facilities
• CMS said need to revise your training program every year which should take person 4 hours to do
  • Can have librarian do literature search for new articles on evidenced based restraint research
Visitation Rights Notice

**Hospital must have written P&P on visitation rights**

- Policy includes the restrictions
- Hospital must inform each patient of any restrictions to visitation and must document it was given
- Inform patient of the right to receive visitors they choose, and that they can change their mind
  - This includes spouse, same sex partner, friend, or family
  - Cannot discriminate based on sex, gender, sexual orientation, race, or disability
- Support person may be the same or different from the patient representative
- Any refusal to honor must be documented in the chart
- The hospital policy must ensure that all visitors enjoy full and equal visitation rights no matter who they are
- Hospital needs to educate the staff
- Consider in orientation and periodically - Should have a culturally competent training program