OBJECTIVES

1) Defining restraints
2) Identifying physical risks and psychosocial impacts of restraint use
3) Determining if the use of position change alarms are restraints
4) Identifying key elements of non-compliance
F604: Defined

- F604 §483.10(e) Respect and Dignity. The resident has a right to be treated with respect and dignity, including:
  - §483.10(e)(1) The right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms, consistent with §483.12(a)(2).
  - §483.12 The resident has the right to be free from abuse, neglect, misappropriation of resident property, and exploitation as defined in this subpart. This includes but is not limited to freedom from corporal punishment, involuntary seclusion and any physical or chemical restraint not required to treat the resident's medical symptoms.

§483.12(a) The Facility Must...

- §483.12(a)(2) Ensure that the resident is free from physical or chemical restraints imposed for purposes of discipline or convenience and that are not required to treat the resident’s medical symptoms. When the use of restraints is indicated, the facility must use the least restrictive alternative for the least amount of time and document ongoing re-evaluation of the need for restraints.
**INTENT**

• The intent of this requirement is for each resident to attain and maintain his/her highest practicable well-being in an environment that:
  - Prohibits the use of physical restraints for discipline or convenience;
  - Prohibits the use of physical restraints to unnecessarily inhibit a resident’s freedom of movement or activity; and
  - Limits physical restraint use to circumstances in which the resident has medical symptoms that may warrant the use of restraints.

**NOT PROHIBITED, BUT RULES APPLY**

• When a physical restraint is used, the facility must:
  - Use the least restrictive restraint for the least amount of time; and
  - Provide ongoing re-evaluation of the need for the physical restraint.
**DEFINITIONS**

- “Convenience” is defined as the result of any action that has the effect of altering a resident's behavior such that the resident requires a lesser amount of effort or care, and is not in the resident's best interest.
- “Discipline” is defined as any action taken by the facility for the purpose of punishing or penalizing residents.
- “Freedom of movement” means any change in place or position for the body or any part of the body that the person is physically able to control.
- “Manual method” means to hold or limit a resident's voluntary movement by using body contact as a method of physical restraint.
- Medical symptom” is defined as an indication or characteristic of a physical or psychological condition.
- “Position change alarms” are alerting devices intended to monitor a resident's movement. The devices emit an audible signal when the resident moves in certain ways.
- “Physical restraint” is defined as any manual method, physical or mechanical device, equipment, or material that meets all of the following criteria:
  - Is attached or adjacent to the resident’s body;
  - Cannot be removed easily by the resident; and Effective November 28, 2017
  - Restricts the resident's freedom of movement or normal access to his/her body.
- “Removes easily” means that the manual method, physical or mechanical device, equipment, or material, can be removed intentionally by the resident in the same manner as it was applied by the staff.

**GUIDANCE**

- As described under Definitions, a physical restraint is any manual method, physical or mechanical device/equipment or material that limits a resident's freedom of movement and cannot be removed by the resident in the same manner as it was applied by staff. The resident's physical condition and his/her cognitive status may be contributing factors in determining whether the resident has the ability to remove it.
- For example, a bed rail is considered to be a restraint if the resident is not able to put the side rail down in the same manner as the staff. Similarly, a lap belt is considered to be a restraint if the resident cannot intentionally release the belt buckle.
EXAMPLES

Examples of facility practices that meet the definition of a physical restraint include, but are not limited to:

• Using bed rails that keep a resident from voluntarily getting out of bed;
• Placing a chair or bed close enough to a wall that the resident is prevented from rising out of the chair or voluntarily getting out of bed;
• Placing a resident on a concave mattress so that the resident cannot independently get out of bed;
• Tucking in a sheet tightly so that the resident cannot get out of bed, or fastening fabric or clothing so that a resident’s freedom of movement is restricted;
• Placing a resident in a chair, such as a beanbag or recliner, that prevents a resident from rising independently;
• Using devices in conjunction with a chair, such as trays, tables, cushions, bars or belts, that the resident cannot remove and prevents the resident from rising;
• Applying leg or arm restraints, hand mitts, soft ties or vests that the resident cannot remove;
• Holding down a resident in response to a behavioral symptom or during the provision of care if the resident is resistive or refusing the care;
• Placing a resident in an enclosed framed wheeled walker, in which the resident cannot open the front gate or if the device has been altered to prevent the resident from exiting the device; and
• Using a position change alarm to monitor resident movement, and the resident is afraid to move to avoid setting off the alarm.

PHYSICAL RISKS

• Physical Risks and Psychosocial Impacts Related to Use of Restraints Research and standards of practice show that physical restraints have many negative side effects and risks that far outweigh any benefit from their use. Physical restraints may increase the risk of one or more of the following
  – Decline in physical functioning including an increased dependence in activities of daily living (e.g., ability to walk), impaired muscle strength and balance, decline in range of motion, and risk for development of contractures;
  – Respiratory complications;
  – Skin breakdown around the area where the restraint was applied or skin integrity issues related to the use of the restraint (i.e., pressure ulcers/injuries);
  – Urinary/bowel incontinence or constipation;
  – Injury from attempts to free him/herself from the restraint; and
  – Accidents such as falls, strangulation, or entrapment.
**Psycho-Social Impact**

- Psychosocial impact related to the use of physical restraints may include one or more of the following:
  - Agitation, aggression, anxiety, or development of delirium;
  - Social withdrawal, depression, or reduced social contact due to the loss of autonomy;
  - Feelings of shame;
  - Loss of dignity, self-respect, and identity;
  - Dehumanization;
  - Panic, feeling threatened or fearful; and
  - Feelings of imprisonment or restriction of freedom of movement.

**Assessment, Care Planning, and Documentation for the Use of a Physical Restraint**

- The regulation limits the use of any physical restraint to circumstances in which the resident has medical symptoms that warrant the use of restraints.
- There must be documentation identifying the medical symptom being treated and an order for the use of the specific type of restraint. **However, the practitioner's order alone (without supporting clinical documentation) is not sufficient to warrant the use of the restraint.** The facility is accountable for the process to meet the minimum requirements of the regulation including appropriate assessment, care planning by the interdisciplinary team, and documentation of the medical symptoms and use of the physical restraint for the least amount of time possible and provide ongoing re-evaluation.
**But... The Family INSISTS!**

- The resident or resident representative may request the use of a physical restraint; however, the nursing home is **responsible** for evaluating the appropriateness of the request, and **must** determine if the resident has a medical symptom that must be treated and **must** include the practitioner in the review and discussion. **If there are no medical symptoms identified that require treatment, the use of the restraint is prohibited.** Also, a resident, or the resident representative, has the right to **refuse** treatment; however, he/she **does not have the right to demand a restraint be used when it is not necessary to treat a medical symptom.**

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**But... We Didn’t Know?**

- Facilities are responsible for knowing the effects devices have on its residents.
- If a device has a restraining effect on a resident, and is not administered to treat a medical symptom, the device is acting as a physical restraint.
- The restraining effects to the resident may have been caused intentionally or unintentionally by staff, and would indicate an action of discipline or convenience.
- In the case of an unintentional physical restraint, the facility did not intend to restrain a resident, but a device is being used that has that same effect, and is not being used to treat a medical symptom.
- These effects may result in convenience for the staff, as the resident may require less effort than previously required.
Use must be Individualized and Based on Condition and Medical Symptoms

• If a resident is identified with a physical restraint, the facility must be able to provide evidence that ensures:
  – The resident’s medical symptom that requires the use of a physical restraint has been identified;
  – A practitioner’s order is in place for the use of the specific physical restraint based upon the identified medical symptom;

NOTE: If a resident is recently admitted to the facility and a restraint was used in a previous health care setting, the facility must still conduct an assessment to determine the existence of medical symptoms that warrant the continued use of the restraint.
  – Interventions, including less restrictive alternatives were attempted to treat the medical symptom but were ineffective;
  – The resident/representative was informed of potential risks and benefits of all options under consideration including using a restraint, not using a restraint, and alternatives to restraint use;

NOTE: The resident, or resident representative (if applicable), has the right to refuse the use of a restraint and may withdraw consent to use of the restraint at any time. If so, the refusal must be documented in the resident’s record. The facility is expected to assess the resident and determine how resident’s needs will be met if the resident refuses/declines treatment.

Use must be Individualized and Based on Condition and Medical Symptoms, cont.

– The length of time the restraint is anticipated to be used to treat the medical symptom, the identification of who may apply the restraint, where and how the restraint is to be applied and used, the time and frequency the restraint should be released, and who may determine when the medical symptom has resolved in order to discontinue use of the restraint;
– The type of specific direct monitoring and supervision provided during the use of the restraint, including documentation of the monitoring; • The identification of how the resident may request staff assistance and how needs will be met during use of the restraint, such as for re-positioning, hydration, meals, using the bathroom and hygiene;
– The resident’s record includes ongoing re-evaluation for the need for a restraint and is effective in treating the medical symptom; and
– The development and implementation of interventions to prevent and address any risks related to the use of the restraint (See also the Long-Term Care Facility Resident Assessment Instrument User’s Manual, Version 3.0, Chapter 3, Section P-Restraints for further guidance and 42 CFR 483.25(d) [F689] for concerns related to ensuring the resident receives adequate supervision to prevent accidents).
NOTE:

- Falls do NOT constitute self-injurious behavior or a medical symptom that warrants the use of a physical restraint. Although restraints have been traditionally used as a falls prevention approach, they have major, serious drawbacks and can contribute to serious injuries.
- There is no evidence that the use of physical restraints, including, but not limited to, bed rails and position change alarms, will prevent or reduce falls. Additionally, falls that occur while a person is physically restrained often result in more severe injuries (e.g., strangulation, entrapment).

CONVENIENCE AND/OR DISCIPLINE

- A facility must not impose physical restraints for purposes of discipline or convenience. The facility is prohibited from obtaining permission from the resident, or resident representative, for the use of restraints when the restraint is not necessary to treat the resident's medical symptoms.

Anecdotally, it has been reported that staff will inform a resident, or the resident representative, that a restraint will be beneficial to the resident to prevent a fall or to safeguard the resident who may be wandering into other resident's rooms. However, in these instances, the surveyor should consider whether the restraint was used for the sake of staff convenience.
Convenience and/or Discipline, cont.

Reasons for using restraints for staff convenience or discipline may include:

• Staff state that a resident was placed in a restraint because staff are too busy to monitor the resident, and their workload includes too many residents to provide monitoring;
• Staff believe that the resident does not exercise good judgment, including that he/she forgets about his/her physical limitations in standing, walking, or using the bathroom alone and will not wait for staff assistance;
• Staff state that family have requested that the resident be restrained, as they are concerned about the resident falling especially during high activity times, such as during meals, when the staff are busy with other residents;
• Staff have identified to management that there is not enough staff on a particular shift or during the weekend and staffing levels were not changed;
• Staff state that new staff and/or temporary staff do not know the resident, how to approach, and/or how to address behavioral symptoms or care needs so they apply physical restraints;
• Lack of staff education regarding the alternatives to the use of restraints as a method for preventing falls and accidents;
• Staff have negative feelings or a lack of respect towards the resident, and restrain the resident to teach him/her a lesson;
• In response to a resident’s wandering behavior, staff become frustrated and restrain a resident to a wheelchair; and
• When a resident is confused and becomes combative when care is provided and staff hold the resident’s arms and legs down to complete the care (NOTE: This example differs from an emergency situation where staff briefly hold a resident for the sole purpose of providing necessary immediate medical care ordered by a practitioner).

Determination of Use of Restraints for a Period of Imminent Danger to the Safety and Well-Being of the Resident

• Some facilities have identified that a situation occurred in which the resident(s) is in “imminent danger” and there was fear for the safety and well-being of the resident(s) due to violent behavior, such as physically attacking others. In these situations, the order from the practitioner and supporting documentation for the use of a restraint must be obtained either:
  − during the application of the restraint, or
  − immediately after the restraint has been applied.
• The failure to immediately obtain an order is viewed as the application of restraint without an order and supporting documentation.
• Facilities may have a policy specifying who can initiate the application of restraint prior to obtaining an order from the practitioner.
**If Application of a Restraint Occurs...**

The facility must:
- Determine that a physical restraint is a measure of last resort to protect the safety of the resident or others;
- Provide ongoing direct monitoring and assessment of the resident's condition during use of the restraint;
- Provide assessment by the staff and practitioner to address other interventions that may address the symptoms or cause of the situation (e.g., identification of an infection process or delirium, presence of pain);
- Ensure that the resident and other residents are protected until the resident's behavioral symptoms have subsided, or until the resident is transferred to another setting;
- Discontinue the use of the restraint as soon as the imminent danger ends; and
- Immediately notify the resident representative of the symptoms and temporary intervention implemented.

Documentation must reflect:
- what the resident was doing and
- what happened that presented the imminent danger,
- interventions that were attempted,
- response to those interventions,
- whether the resident was transferred to another setting for evaluation,
- whether the use of a physical restraint was ordered by the practitioner, and
- the medical symptom(s) and cause(s) that were identified.

**Determination of Use of Bed Rails as a Restraint**

Facilities must use a **person-centered** approach when determining the use of bed rails, which would include conducting a comprehensive assessment, and identifying the medical symptom being treated by using bed rails. Bed rails may have the effect of restraining one individual but not another, depending on the **individual** resident’s conditions and circumstances.
Bedrails

• Residents who are cognitively impaired are at a higher risk of entrapment and injury or death caused by restraints.
• Residents in a bed with bed rails have attempted to exit through, between, under, over, or around bed rails or have attempted to crawl over the foot board, which places them at risk of serious injury or death.
• Serious injury from a fall is more likely from a bed with raised bed rails than from a bed where bed rails are not used.
• In many cases, the risk of using the bed rails may be greater than the risk of not using them as the risk of restraint-related injury and death is significant.

For example, a resident who has no voluntary movement may still exhibit involuntary movements. Involuntary movements, resident weight, and gravity's effects may lead to the resident's body shifting toward the edge of the bed, increasing the risk for entrapment, when bed rails are used.

Bedrails

• The use of partial bed rails may assist an independent resident to enter and exit the bed independently and would not be considered a physical restraint.
• To determine if a bed rail is being used as a restraint, the resident must be able to easily and voluntarily get in and out of bed when the equipment is in use.
• If the resident cannot easily and voluntarily release the bed rails, the use of the bed rails may be considered a restraint.
• Also refer to 42 CFR 483.25(n) – Bed Rails (tag F700).
DETERMINATION OF THE USE OF POSITION CHANGE ALARMS AS RESTRAINTS

• Position change alarms are any physical or electronic device that monitors resident movement and alerts the staff when movement is detected.

• Types of position change alarms include:
  – chair and bed sensor pads,
  – bedside alarmed mats,
  – alarms clipped to a resident’s clothing,
  – seatbelt alarms, and
  – infrared beam motion detectors.

Position change alarms do not include alarms intended to monitor for unsafe wandering such as door or elevator alarms.

SCARED TO MOVE?

• While position change alarms may be implemented to monitor a resident’s movements, for some residents, the use of position change alarms that are audible to the resident(s) may have the unintended consequence of inhibiting freedom of movement.

For example, a resident may be afraid to move to avoid setting off the alarm and creating noise that is a nuisance to the resident(s) and staff, or is embarrassing to the resident. For this resident, a position change alarm may have the potential effect of a physical restraint.
NEGATIVE OUTCOMES

Examples of negative potential or actual outcomes which may result from the use of position change alarms as a physical restraint, include:

- Loss of dignity;
- Decreased mobility;
- Bowel and bladder incontinence;
- Sleep disturbances due to the sound of the alarm or because the resident is afraid to move in bed thereby setting off the alarm; and
- Confusion, fear, agitation, anxiety, or irritation in response to the sound of the alarm as residents may mistake the alarm as a warning or as something they need to get away from.

PROCEDURES §483.12 AND (a)(2)- PHYSICAL RESTRAINTS

- The process to review concerns are outlined in the Physical Restraints Critical Element Pathway (Form CMS-20077)
**NOTE:**

A resident may have a device in place that the facility has stated can be removed by the resident. For safety reasons, do not request that the resident remove the restraint, but rather, request that staff ask the resident to demonstrate how he/she releases the device without staff providing specific instructions for the removal.

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**SURVEY PROCESS**

Use observations, interviews, and record review to gather and corroborate information related to:

- The use of the physical restraint, including whether the facility identified a device as a restraint, why it is used, how long it has been used, duration of use, alternatives attempted;
- What information was provided to the resident regarding the use of the restraint and whether the use of the restraint reflects the resident’s preferences and choices;
- Whether the physical restraint is used for, or has the effect of, staff convenience or discipline; or
- Physical and psychosocial outcomes from the use of the restraint.
**Survey Process, cont.**

- Use the Physical Restraints Critical Element (CE) Pathway, along with the above Guidance:
- When a resident’s clinical record reflects the use of a physical restraint;
- If the survey team observes a position change alarm, or other device or practice that restricts or potentially restricts a resident’s freedom of movement (physically or psychologically);
- If the resident or other individuals report that a restraint is being used on the resident; or
- If an allegation of inappropriate use of a physical restraint is received.

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**Potential Tags for Additional Investigation**

- During the investigation, the surveyor may have determined that concerns may also be present with related outcome, process and/or structure requirements. The surveyor is cautioned to investigate these related requirements before determining whether non-compliance may be present. Some examples of related requirements that should be considered include the following:
Potential Tags for Additional Investigation

- 42 CFR 483.10, 483.10(a)(1)-(2), 483.10(b)(1)-(2), F550 - Resident Rights and Dignity
- 42 CFR 483.10(c)(2)-(3), F553 - Right to Participate Planning Care
- 42 CFR 483.21(b)(1), F656 - Develop/Implement Comprehensive Care Plan
- 42 CFR 483.24, F675 - Quality of Life
- 42 CFR 483.25(d), F689 - Accidents
- 42 CFR 483.25(n)(1)-(4), F700 - Special Care: Bedrails
- 42 CFR 483.35, 483.35(a), and 483.35(c) - F725 and F726 – Sufficient and Competent Staff
- 42 CFR 483.40(b)-(b)(1), F742 - Treatment/Svc for Mental/Psychosocial Concerns
- 42 CFR 483.70(h), F841 - Responsibilities of Medical Director
- 42 CFR 483.75 (g)(2)(ii) - F867 - QAA Activities

Critical Element Pathway

- Physical Restraints Critical Element Pathway
- Form CMS 20077 (5/2017) Page 1
- Use this pathway:
  - When a resident's clinical record reflects the use of a physical restraint;
  - If the survey team observes a position change alarm or device or practice that restricts or potentially restricts a resident's freedom of movement;
  - If the resident or other individuals report that a restraint is being used on the resident; or
  - If an allegation of inappropriate use of a physical restraint is received.
- NOTE: For concerns related to involuntary seclusion, see the Investigative Protocol under Tag F603.
CRITICAL ELEMENT PATHWAY

Review the following in Advance to Guide Observations and Interviews:

• Review the most current comprehensive and most recent quarterly (if the comprehensive isn’t the most recent) MDS/CAAs for Sections C – Cognitive Patterns, E – Behavior, G – Functional Status, J – Health Conditions (falls), and P – Restraints and Alarms.

• Practitioner’s orders (e.g., medical symptom being treated, type of restraint, frequency of releasing the restraint).

• Care plan (e.g., medical symptoms justifying use of restraint, type of restraint used, frequency, duration, circumstances for when it is to be used, interventions to address potential or actual complications from restraint use such as increased incontinence, decline in ADLs or ROM, increased confusion, agitation, or depression).

• If use of a device is indicated in the care plan, how are care-planned interventions implemented?

• Is the resident’s movement restricted? If so, describe.

• When was the method used, by whom, and how did staff communicate or respond to the resident during the time of observations? Examples include:
  – Placing a chair or bed close enough to a wall that the resident is prevented from rising out of the chair or voluntarily getting out of bed;
  – Tucking in or fastening a sheet, fabric, or clothing tightly so that a resident’s freedom of movement is restricted;
  – Placing a resident in a chair, such as a beanbag or recliner, that prevents a resident from rising independently;
  – Using devices in conjunction with a chair, such as trays, tables, cushions, bars or belts, that the resident cannot remove and/or that prevent the resident from rising; or
  – Holding down a resident in response to a behavioral symptom or during the provision of care.
**Critical Element Pathway - Observations:**

- How does the resident request staff assistance (e.g., access to the call light, calling out to staff for help, grabbing at staff walking by)?
- How does staff respond to the resident?
- How often are staff monitoring the resident?
- How often is the resident taken to the bathroom, ambulated, or provided exercises or range of motion?
- When the restraint is released, who released the restraint, for how long, and how often?
- Is there a position change alarm in use? If so, why? What is the impact to the resident? For example, is the resident hesitant or afraid to move to avoid setting off the alarm?

**Critical Element Pathway - Observations:**

- Is the restraint used for discipline or results in convenience for staff?
- Examples include:
  - In response to a resident’s wandering behavior, staff become frustrated and restrain a resident to a wheelchair;
  - When a resident is confused and becomes combative when care is provided and staff hold the resident’s arms and legs down to complete the care (NOTE: This example differs from an emergency situation where staff briefly hold a resident for the sole purpose of providing necessary immediate medical care ordered by a practitioner); or
  - Staff place a resident in a bean bag chair, in the absence of a medical symptom, and the resident is unable to get out of it, which is potentially more convenient for staff.
**CRITICAL ELEMENT PATHWAY - OBSERVATIONS:**

- Are there any physical or psychosocial reactions to the use of any devices/practices?
  - Examples include:
    - Attempts to release/remove a device (e.g., pulling, picking, twisting);
    - Verbalizing anger/anxiety due to restricted movement;
    - Calling out for help to take a device off; or
    - Fear of moving since it could trigger the sound of a position change alarm; or
    - Attempting to stand up out of a chair (e.g., bean bag, recliner)?

**CRITICAL ELEMENT PATHWAY - OBSERVATIONS:**

- If staff said the resident can remove the restraint, request that staff ask the resident to demonstrate how he/she releases the restraint without staff providing specific instructions for the removal.
- During high activity times in the facility (e.g., getting ready in the morning, meal times, bathing), how do staff respond to residents who are wandering or confused?
RESIDENT/FAMILY INTERVIEWS

Resident, Resident Representative, or Family Interview: When conducting interviews, describe the device/practice instead of using the term "restraint" since the interviewee may not recognize that a restraint was/is being used. Note: A resident may have a restraint in place that the facility has stated can be removed by the resident. For safety reasons, do not request that the resident remove the restraint, but rather, request that staff ask the resident to demonstrate how he/she releases the restraint without staff providing specific instructions for the removal.

- Can you explain why you have the device?
- Who requested the device and why?
- Prior to the use of the device, did staff provide you with information regarding:
  - Why the device would be used;
  - The risks and benefits;
  - The effects of the device on your mobility, other activities of daily living, involvement in activities and meals, and
  - When and for how long the device would be used?
- What was tried before the device was used (e.g., less restrictive alternatives)?
- How were you involved in the development of the care plan for the use of the device? Does the care plan reflect your choices and preferences?
- How do you contact staff when you need assistance when the device is used? How does staff respond to requests?
- If there is a position change alarm in use, can you explain why the alarm is in use? How does it make you feel? Does the use of the alarm change how you move? If so, describe.
- Have you had any problems with the device being used? If so, please describe.
- For the resident representative, if a physical restraint was used when imminent danger was present, when did staff notify you? What did staff tell you about the use of the restraint (e.g., type, method)? Did staff explain when the restraint would be discontinued? If not, did staff explain why the restraint continues to be used?

TEAM INTERVIEWS

Staff Interviews (Nursing Aides, Nurses, DON, as appropriate): When conducting interviews, describe the device/practice instead of using the term "restraint" since the interviewee may not recognize that a restraint was/is being used.

- Why is this device being used for this resident?
- Have you had any training on the use of devices?
- How has the use of this device impacted how you provide care to this resident?
- When did the use of the device begin?
- What is the rationale (i.e., medical symptoms) for selecting this device?
- What are the risks and benefits of using the device for this resident?
- What measures were attempted before the device was started?
- How often is the device applied, for how long, and under what circumstances is it to be used?
- How often is the device removed?
- How do you respond to the resident’s request to remove the device?
- If you observe the resident trying to remove the device, verbalizing anger/anxiety, calling out for help to take the device off, pulling, picking, or twisting at the device, ask staff: How often does this occur? Has this been reported and to whom? Were care plan changes made and implemented?
- How do you monitor the resident when the device is used?
- What is the resident’s functional ability (e.g., bed mobility and transfer ability to and from bed or chair, and to stand and toilet)?
- Has the resident had any physical or psychosocial changes related to the use of the device? If so, describe.
- Are you assigned to provide care for other residents that use devices/restraints? Describe how you manage your time to meet the residents’ needs. Describe any training you’ve received in how to provide care for a resident with behavioral concerns?
- What are the facility’s protocols for the use of the restraint/device (e.g., restraint policy)?
- If there is a personal alarm or position change alarm in use, why is the alarm used? What is the impact to the resident? For example, is the resident hesitant or afraid to move to avoid setting off the alarm?

For licensed staff, ask:

- How do you supervise staff to ensure that the device is applied correctly and released, as ordered?
- If the resident had any physical or psychosocial changes related to the use of the device, how were care-planned interventions revised to address the changes? Was the attending practitioner notified of changes? What was the response?
- How often do you evaluate and assess the resident to determine the ongoing need for the use of the restraint for the treatment of the medical symptoms?
- What is the plan for reducing the use of the device, including ongoing assessment of the resident, revising the plan as necessary, and attempting other interventions to minimize or eliminate the use of the restraint? What was the resident’s response to other interventions?
- How are staff assigned to monitor, care for, and be familiar with residents’ behaviors (e.g., the number, location, and consistent staff assigned across different shifts/units)?
RECORD REVIEW

☐ What is the specific medical symptom justifying the use of the restraint or device that restricts the resident’s movement (physically or psychosocially).
☐ If the assessment identified whether the medical symptom could be eliminated or reduced, without the use of the device.
☐ What interventions, including less restrictive alternatives, were attempted and whether the interventions were successful in meeting the resident’s assessed needs.
☐ What information was provided and when to the resident or representative regarding the identification of a medical symptom requiring the use of the device, the risks and/or benefits, the least restrictive interventions, and when and for how long the device was going to be used.
☐ Whether the resident/resident representative was involved in the development of the care plan related to the use of the device in accordance with his/her preferences and choices.
☐ What is the resident’s current functional ability including strength and balance such as bed mobility, ability to transfer between bed or chair, and to stand or go to the bathroom.
☐ Whether there was a decline in physical or psychosocial functioning that may be related to the use of device (e.g., decline in ROM, pain, hydration, weight loss, continence status, muscle strength or balance, confusion, withdrawal, agitation, or depression) and if so, whether the care planned interventions were revised and implemented to address the decline.

☐ Whether the resident had any injuries, or potential injuries, that occurred during the use of the device and if so, the facility’s response.
☐ Whether there was a “significant change” in the resident’s condition (i.e., will not resolve itself without intervention by staff or by implementing standard disease-related clinical interventions) impacts more than one area of health; requires IDT review or revision of the care plan) and if so, if and when the MDS significant change comprehensive assessment was conducted.
☐ Who provides monitoring for the use of the device and how monitoring is provided for the implementation of interventions, such as when and how often the device is released and assistance provided for going to the bathroom, ambulation, and ROM.
☐ What ongoing assessment and evaluation for the treatment of the medical symptom was conducted related to the use of the device.
☐ What interventions have been attempted and evaluated to minimize/eliminate the use of the device and address the medical symptom/underlying problems causing the medical symptom.
☐ Whether there is any indication that the device is used for the purpose of discipline or staff convenience.
☐ If concerns are identified, review the facility policy related to the use of restraints or the device.
☐ If a position change alarm is in use, what is the rationale for its use, and impact on the resident.

CRITICAL ELEMENT DECISIONS

1) Did the facility ensure all of the following:
   • Ensure that the resident is free from physical restraints imposed for discipline or staff convenience;
   • Identify the medical symptom being treated when using a device or a facility practice that meets the definition of physical restraint;
   • Define and implement interventions according to standards of practice during the use of a physical restraint that is used for treatment of a medical symptom;
   • Provide the least restrictive restraint for the least time possible;
   • Provide ongoing monitoring and evaluation for the continued use of a physical restraint to treat a medical symptom; and
   • Develop and implement interventions for reducing or eventually discontinuing the use of the restraint when no longer required to treat a resident’s medical symptoms?

If No, cite F604
CRITICAL ELEMENT DECISIONS

2) For newly admitted residents and if applicable based on the concern under investigation, did the facility develop and implement a baseline care plan within 48 hours of admission that included the minimum healthcare information necessary to properly care for the immediate needs of the resident? Did the resident and resident representative receive a written summary of the baseline care plan that he/she was able to understand?

If No, cite F655

NA, the resident did not have an admission since the previous survey OR the care or service was not necessary to be included in a baseline care plan.

3) If the condition or risks were present at the time of the required comprehensive assessment, did the facility comprehensively assess the resident's physical, mental, and psychosocial needs to identify the risks and/or to determine underlying causes, to the extent possible, and the impact upon the resident's function, mood, and cognition?

If No, cite F636

NA, condition/risks were identified after completion of the required comprehensive assessment and did not meet the criteria for a significant change MDS OR the resident was recently admitted and the comprehensive assessment was not yet required.

CRITICAL ELEMENTS DECISIONS

4) If there was a significant change in the resident's status, did the facility complete a significant change assessment within 14 days of determining the status change was significant?

If No, cite F637;

NA, the initial comprehensive assessment had not yet been completed therefore a significant change in status assessment is not required OR the resident did not have a significant change in status.

5) Did staff who have the skills and qualifications to assess relevant care areas and who are knowledgeable about the resident's status, needs, strengths and areas of decline, accurately complete the resident assessment (i.e., comprehensive, quarterly, significant change in status)?

If No, cite F641

6) Did the facility develop and implement a comprehensive person-centered care plan that includes measurable objectives and timeframes to meet a resident's medical, nursing, mental, and psychosocial needs and includes the resident's goals, desired outcomes, and preferences?

If No, cite F656

NA, the comprehensive assessment was not completed.
CRITICAL ELEMENTS DECISIONS

7) Did the facility reassess the effectiveness of the interventions and review and revise the resident’s care plan (with input from the resident or resident representative, to the extent possible), if necessary, to meet the resident’s needs?

If No, cite F657

NA, the comprehensive assessment was not completed OR the care plan was not developed OR the care plan did not have to be revised.

ADDITIONAL POSSIBLE TAGS, CARE AREAS AND TASKS TO CONSIDER:

- Dignity (CA)
- Right to be Informed F552
- Right to Participate In Care F553,
- Accident Hazards (CA),
- Bed Rails F700,
- Behavioral-Emotional Status (CA),
- Unnecessary/Psychotropic Medications (CA),
- Sufficient and Competent Staffing, Medical Director F841,
- Resident Records F842,
- QAA/QAPI (Task).
KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F604, the surveyor’s investigation will generally show that the facility has failed, in one or more areas, to do any one or more of the following:

• Ensure that the resident is free from physical restraints imposed for discipline or staff convenience;
• Identify the medical symptom being treated when using a device or a facility practice that meets the definition of physical restraint;
• Define and implement interventions according to standards of practice during the use of a physical restraint that is used for treatment of a medical symptom;
• Provide the least restrictive restraint for the least time possible;
• Providing ongoing monitoring and evaluation for the continued use of a physical restraint to treat a medical symptom; or
• Develop and implement interventions for reducing or eventually discontinuing the use of the restraint when no longer required to treat a resident’s medical symptoms.

QUESTIONS?
REFERENCES

- https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Nursing-Homes.html