pennsylvania
DEPARTMENT OF HUMAN SERVICES

# Bureau of Human Services Licensing

## Use of Bedside Mobility Devices in Personal Care Homes and Assisted Living Residences

**Table of Contents:**



**Introduction:**

Bed rails, enablers, side rails, safety rails, and grab bars, hereinafter referred to as, "Bedside Mobility Devices" or "devices," are types of equipment that are positioned on the side of a bed to assist residents who may need additional support with safety and/or mobility. The potential benefits of these devices include:

- Aiding residents with turning and repositioning from within the bed
- Aiding residents to help pull themselves up while in bed
- Providing a handhold for getting into or out of bed
- Providing a feeling of comfort and security
- Reducing the risk of residents falling out of bed
- Providing easy access to bed controls and personal care items

**Personal Care Home (PCH) and Assisted Living Residence (ALR) providers must be aware that these devices have caused numerous deaths and serious injuries, despite the implementation of precautionary measures. The potential risks of such devices include:**

- **Entrapment**
- **Strangulation**
- **Suffocation**
- **More serious fall-related injuries if a resident "climbs" the device**
- **Increased agitation and anxiety, when used or perceived as a restraint**

**The Consumer Product Safety Commission has released numerous warnings on the dangers of such devices. One recent report can be found here.**



Issue Date: 06/26/2023

Bureau of Human Services Licensing
625 Forster Street, Room 631 | Harrisburg, PA 17120 | 717.783.3670 | F 717.783.5662 | www.dhs.pa.gov

These areas of risk are not exclusive to traditional beside rails; they are also present with all types of Bedside Mobility Devices. Areas where injuries occur most often are identified in the following diagram by the **Patient Safety Authority**:

ZONE 1 Within the rail

ZONE 2 Under the rail, between the rail supports or next to a single rail support

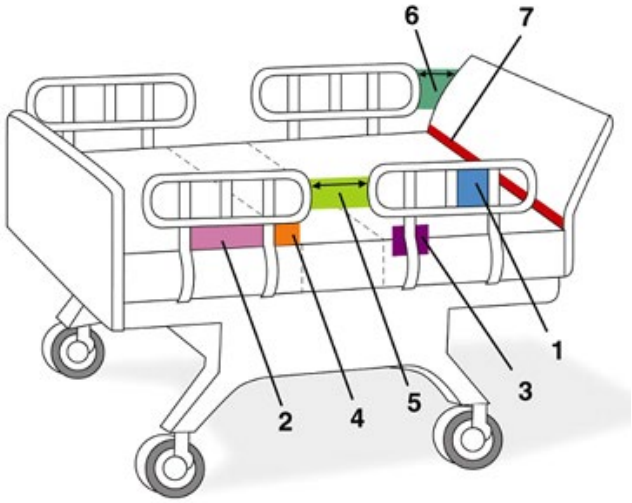
ZONE 3 Between the rail and the mattress

ZONE 4 Under the rail, at the ends of the rails

ZONE 5 Between split bed rails

ZONE 6 Between the end of the rail and the side edge of the head or foot board

ZONE 7 Between the head or foot board and the mattress end




The FDA has approved the use of the Cone and Cylinder tool, to the right, that providers may find helpful to measure the risk of entanglement. More information can be obtained in the FDA's Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment document.

Cone and cylinder tool.



Bureau of Human Services Licensing
625 Forster Street, Room 631 | Harrisburg, PA 17120 | 717.783.3670 | F 717.783.5662 | www.dhs.pa.gov

## Regulatory Requirements

The Bureau of Human Services Licensing strongly recommends that Personal Care Homes and Assisted Living Residences consider all available alternatives before implementing the use of Bedside Mobility Devices. When such devices are in use, **the following requirements apply:**

- The resident's support plan must reflect:
  - The specific need for the device
  - The intended use and any risks associated with the use
  - The resident's ability to use the device safely for the purpose it was intended
  - Identification of the specific device to be used and whether a cover is required to meet FDA guidelines
    - *Example: Ms. Smith has an unsteady gait and uses a Halo Safety Ring for stability as she gets out of bed. While PT evaluation supports that the device can be used for this purpose, any use of such device includes the risk of strangulation, suffocation, and entrapment. The Halo Safety Ring openings comply with FDA guidelines and the device does not require a cover.*
- Bedside Mobility Devices must be installed and maintained according to the manufacturer's instructions and be clean, in good repair, and free of hazards.
- The PCH/ALR must develop and implement procedures to ensure that all Bedside Mobility Devices are periodically assessed for proper installation and maintenance and that they remain appropriate for any residents that utilize them.
- Devices that raise and lower are only permitted if the resident is able to raise and lower the device independently.
- Bedside Mobility Devices must not restrict the resident's movement when in bed or prevent the resident from getting in and out of bed.
- To avoid entrapment, entanglement, or strangulation, the FDA guidelines below must be applied to all Bedside Mobility Devices. In a typical opening, these guidelines should be applied to either the vertical or horizontal axis. In other words, an opening that exceeds the dimensional guidance in one direction, only, may be compliant.
  - Within the device, the openings should be less than 120 mm (4 ¾ inches)
    - If any openings within the device exceed 120mm (4 ¾ inches), a cover that allows for safe gripping and use of the device for its intended purpose must be in place.
  - Under the device, between the device supports, or next to single device support, the openings must be less than 120 mm (4 ¾ inches)
    - Securely placed guards, wedges, or bumpers may be used to fill these openings, if necessary. These accessories must be securely installed so they cannot be accidentally displaced or damaged.
  - Between the device and mattress, the openings must be less than 120 mm (4 ¾ inches)



Bureau of Human Services Licensing
625 Forster Street, Room 631 | Harrisburg, PA 17120 | 717.783.3670 | F 717.783.5662 | www.dhs.pa.gov

    - Securely placed guards, wedges, or bumpers may be used to fill these openings, if necessary. These accessories must be securely installed so they cannot be accidentally displaced or damaged.
  - Under the device, at the ends of the device, openings between the mattress support platform and the lowest portion of the rail must be less than 60 mm (2 3/8 inches) and any V-shaped openings under the rail must be greater than a 60-degree angle.
  - *All openings between the device and any other part of the bed must be measured by taking maximum shifting and/or compression* into account.

- Bedside mobility devices that slide under the mattress and are not securely attached to the structure of the bed can move and create entrapment zones not always present upon inspection. These types of devices are not permitted under any circumstance.
- If a resident using one of these devices experiences a change in condition resulting in the device no longer serving the resident's needs, the device must be removed immediately to prevent injury and/or being perceived as a restraint.

**This guidance applies to both Personal Care Homes and Assisted Living Residences. In addition to this guidance, Assisted Living Residences must also comply with 55. PA Code §2800.203 (Bedside Rails).**

## Regulatory References

| | | | |
|---|---|---|---|
| *§2600.42* | *Resident Rights* | *§2800.42* | *Resident Rights* |
| *§2600.81* | *Physical Accommodations and Equipment* | *§2800.81* | *Physical Accommodations and Equipment* |
| *§2600.95* | *Furniture and Equipment* | *§2800.95* | *Furniture and Equipment* |
| *§2600.141* | *Resident Medical Evaluation* | *§2800.141* | *Resident Medical Evaluation* |
| *§2600.142* | *Assistance with Healthcare* | *§2800.142* | *Assistance with Healthcare* |
| *§2600.202* | *Prohibitions* | *§2800.202* | *Prohibitions* |
| *§2600.225* | *Initial and Annual Assessment* | *§2800.203* | *Bedside rails* |
| *§2600.227* | *Development of the Support Plan* | *§2800.224* | *Initial Assessment and Preliminary Support Plan* |
| | | *§2800.225* | *Additional Assessments* |
| | | *§2800.227* | *Development of the Final Support Plan* |

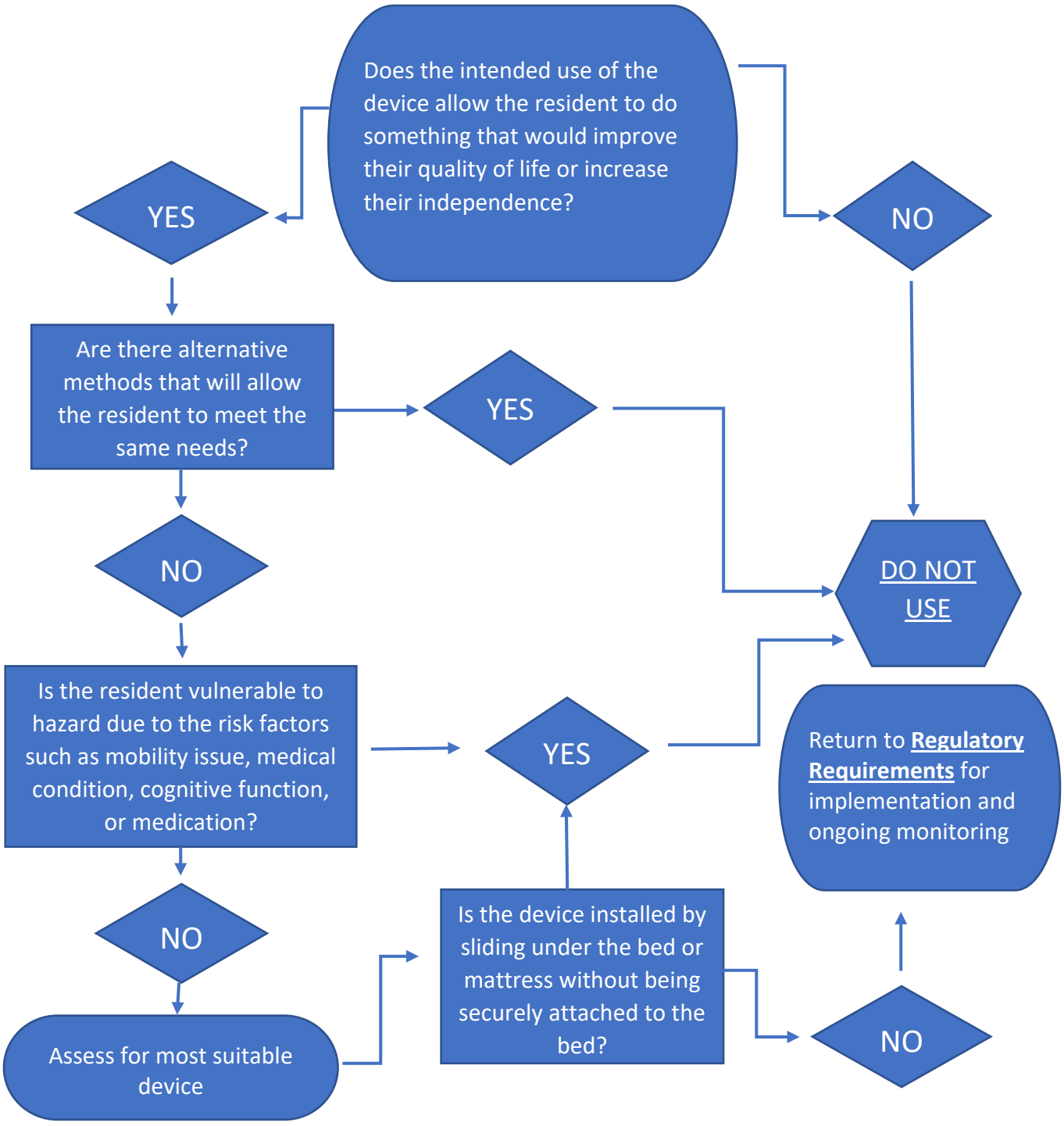
## External References

- https://www.fda.gov/media/88765/download
- https://www.fda.gov/media/71460/download
- https://www.fda.gov/medical-devices/bed-rail-safety/recommendations-health-care-providers-about-bed-rails
- https://theconsumervoice.org/uploads/files/issues/New_Standard_for_Portable_Adult_Bed_Rails.pdf
- https://www.fda.gov/files/medical%20devices/published/Hospital-Bed-System-Dimensional-and-Assessment-Guidance-to-Reduce-Entrapment---Guidance-for-Industry-and-FDA-Staff.pdf



Bureau of Human Services Licensing
625 Forster Street, Room 631 | Harrisburg, PA 17120 | 717.783.3670 | F 717.783.5662 | www.dhs.pa.gov

# BEDSIDE MOBILITY DEVICE DECISION GUIDE






Bureau of Human Services Licensing
625 Forster Street, Room 631 | Harrisburg, PA 17120 | 717.783.3670 | F 717.783.5662 | www.dhs.pa.gov

pennsylvania
DEPARTMENT OF HUMAN SERVICES

# Best Practices for the Use of Bedside Mobility Devices in Personal Care Homes and Assisted Living Residences

While providing many potential benefits related to turning and positioning, transferring, comfort, security, and/or accessibility Bedside Mobility Devices also carry serious risks of injury and death. The Bureau of Human Services Licensing strongly recommends that Personal Care Homes (PCH) and Assisted Living Residences (ALR) implement the following list of Best Practices if you are considering utilizing these types of devices in your facility.

- Alternative Solutions
  - There are many alternative means to provide the same benefits as Bedside Mobility Devices that should be considered before implementing the use of Bedside Mobility Devices, including:
    - Beds that can be raised or lowered to the floor
    - Securely placed fall-mats
    - Position wedges (specialized pillows for bed positioning), roll guards or foam bumpers
    - Alternative assistive devices, grip handles, transfer handles, and trapeze bars that are not installed at the side of the bed.

- Policies and Procedures
  - The facility should develop and implement policies and procedures that address and mitigate the risk of using Bedside Mobility Devices. These policies and procedures should include:
    - A determination in the home/residence rules, indicating whether residents may bring such devices into the facility with them, upon admission.
    - Education of the resident and the resident's designated person on the intended use and risks of using Bedside Mobility Devices.
    - Attempting to obtain a prescription, order, or documentation from the resident's Primary Care Physician indicating that the resident has a physical condition or diagnosis that causes the resident to require assistance with turning and positioning, transferring, comfort, security, and/or accessibility and that the benefit of utilizing this device outweighs the potential risks.
    - Assessing residents for risk factors, such as neurocognitive disorders and/or problems with memory, sleeping, pain, or decision making and obtaining a Physical Therapy or Occupational Therapy evaluation to assist in determining if the resident can use the device in accordance with the written recommendation and as intended by the manufacturer.
    - Checking the Consumer Product Safety Commission website for potential warnings and recalls related to specific devices intended for use in the PCH/ALR.
    - A process through which staff of the PCH/ALR will obtain the manufacturer's instructions for each type of device in use, maintain records of these instructions, and ensure that each device is installed, maintained, and utilized according to the manufacturer's instructions.
    - Utilizing the **BEDSIDE MOBILITY DEVICE USE DECISION GUIDE** before a Bedside Mobility Device is installed and periodically, during reviews of the resident's support plan.



Bureau of Human Services Licensing
625 Forster Street, Room 631 | Harrisburg, PA 17120 | 717.783.3670 | F 717.783.5662 | www.dhs.pa.gov