Assistive devices to maintain hearing include, but are not limited to, hearing aids, and amplifiers.

INTERPRETIVE GUIDANCE
This requirement does not mean that the facility must provide refraction, glasses, contact lenses or other assistive devices, conduct comprehensive audiological evaluations (other than the screening that is a part of the required assessment in §483.20(b)) or provide hearing aids or other devices.

The facility's responsibility is to assist residents and their representatives in locating and utilizing any available resources (e.g., Medicare or Medicaid program payment, local health organizations offering items and services which are available free to the community) for the provision of the services the resident needs. This includes making appointments and arranging transportation to obtain needed services.

In situations where the resident has lost their device, facilities must assist residents and their representative in locating resources, as well as in making appointments, and arranging for transportation to replace the lost devices.

Investigative Summary:
Use the Activities of Daily Living and Communication-Sensory Critical Element (CE) Pathways along with the above interpretive guidelines when determining if the facility meets requirements to ensure that residents receive proper treatment and assistive devices to maintain vision and hearing abilities.

Summary of Vision and Hearing Investigative Procedure
Briefly review the most recent comprehensive assessments, comprehensive care plan, and physician orders to determine if the facility assists residents in gaining access to vision and hearing services by making appointments, and arranging for transportation. Observations, interviews, and record reviews should be utilized to corroborate concerns identified. If the resident has been in the facility for less than 14 days (before completion of all the Resident Assessment Instrument (RAI) is required), review the baseline care plan which must be completed within 48 hours to determine if the facility is providing appropriate care and services based on information available at the time of admission.

F686
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§483.25(b) Skin Integrity

§483.25(b)(1) Pressure ulcers.

Based on the comprehensive assessment of a resident, the facility must ensure that—

(i) A resident receives care, consistent with professional standards of practice, to prevent pressure ulcers and does not develop pressure ulcers unless the individual's clinical condition demonstrates that they were unavoidable; and
(ii) A resident with pressure ulcers receives necessary treatment and services, consistent with professional standards of practice, to promote healing, prevent infection and prevent new ulcers from developing.

INTENT

The intent of this requirement is that the resident does not develop pressure ulcers/injuries (PU/PIs) unless clinically unavoidable and that the facility provides care and services consistent with professional standards of practice to:

- Promote the prevention of pressure ulcer/injury development;
- Promote the healing of existing pressure ulcers/injuries (including prevention of infection to the extent possible); and
- Prevent development of additional pressure ulcer/injury**.**

NOTE: CMS is aware of the array of terms used to describe alterations in skin integrity due to pressure. Some of these terms include: pressure ulcer, pressure injury, pressure sore, decubitus ulcer and bed sore. Clinicians may use and the medical record may reflect any of these terms, as long as the primary cause of the skin alteration is related to pressure. For example, the medical record could reflect the presence of a Stage 2 pressure injury, while the same area would be coded as a Stage 2 pressure ulcer on the MDS.

CMS often refers to the National Pressure Ulcer Advisory Panel's (NPUAP) terms and definitions, which it has adapted, within its patient and resident assessment instruments and corresponding assessment manuals, which includes the Minimum Data Set (MDS). We intend to continue our adaptation of NPUAP terminology for coding the resident assessment instrument while retaining current holistic assessment instructions definitions and terminology. The adapted terminology was used in the development of this guidance.

Additional information can be found on the NPUAP website at https://www.npuap.org/resources/educational-and-clinical-resources.

NOTE: References to non-CMS/HHS sources or sites on the Internet included above or later in this document are provided as a service and do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services. CMS is not responsible for the content of pages found at these sites. URL addresses were current at the date of this publication.

DEFINITIONS

Definitions are provided to clarify clinical terms related to pressure injuries and their evaluation and treatment.

"Pressure Ulcer/Injury (PU/PI)" refers to localized damage to the skin and/or underlying soft tissue usually over a bony prominence or related to a medical or other device. A pressure injury will present as intact skin and may be painful. A pressure ulcer will present as an open ulcer, the appearance of which will vary depending on the stage and may be painful. The injury occurs as a result of intense and/or prolonged pressure or pressure in combination with shear. Soft tissue damage related to pressure and shear may also be affected by skin temperature and moisture, nutrition, perfusion, co-morbidities and condition of the soft tissue.

Avoidable/Unavoidable

- "Avoidable" means that the resident developed a pressure ulcer/injury and that the facility did not do one or more of the following: evaluate the resident's clinical condition and risk factors; define and implement interventions that are consistent with resident needs, resident goals, and professional standards of practice; monitor and evaluate the impact of the interventions; or revise the interventions as appropriate.

- "Unavoidable" means that the resident developed a pressure ulcer/injury even though the facility had evaluated the resident's clinical condition and risk factors; defined and implemented interventions that are consistent with resident needs, goals, and professional standards of practice; monitored and evaluated the impact of the interventions; and revised the approaches as appropriate.

Colonized/Infected

- "Colonized" refers to the presence of micro-organisms on the surface or in the tissue of a wound without the signs and symptoms of an infection.

- "Infected" refers to the presence of micro-organisms in sufficient quantity to overwhelm the defenses of viable tissues and produce the signs and symptoms of infection.

Debridement- Debridement is the removal of devitalized/necrotic tissue and foreign matter from a wound to improve or facilitate the healing process. Debridement methods may include a range of treatments such as the use of enzymatic dressings to surgical debridement in order to remove tissue or matter from a wound to promote healing.

Eschar/Slough

- "Eschar" is dead or devitalized tissue that is hard or soft in texture; usually black, brown, or tan in color, and may appear scab-like. Necrotic tissue and eschar are

usually firmly adherent to the base of the wound and often the sides/ edges of the wound.

- "Slough" is non-viable yellow, tan, gray, green or brown tissue; usually moist, can be soft, stringy and mucinous in texture. Slough may be adherent to the base of the wound or present in clumps throughout the wound bed.

Exudate

- "Exudate" is any fluid that has been forced out of the tissues or its capillaries because of inflammation or injury. It may contain serum, cellular debris, bacteria and leukocytes.

- "Purulent exudate/drainage/discharge" is any product of inflammation that contains pus (e.g., leukocytes, bacteria, and liquefied necrotic debris).

- "Serous drainage or exudate" is watery, clear, or slightly yellow/tan/pink fluid that has separated from the blood and presents as drainage.

Friction/Shearing

- "Friction" is the mechanical force exerted on skin that is dragged across any surface.

- "Shearing" occurs when layers of skin rub against each other or when the skin remains stationary and the underlying tissue moves and stretches and angulates or tears the underlying capillaries and blood vessels causing tissue damage.

Granulation Tissue - "Granulation tissue" is the pink-red moist tissue that fills an open wound, when it starts to heal. It contains new blood vessels, collagen, fibroblasts, and inflammatory cells.

Tunnel/Sinus Tract/Undermining - The terms tunnel and sinus tract are often used interchangeably.

- A "tunnel" is a passageway of tissue destruction under the skin surface that has an opening at the skin level from the edge of the wound.

- A "sinus tract" is a cavity or channel underlying a wound that involves an area larger than the visible surface of the wound.

- "Undermining" is the destruction of tissue or ulceration extending under the skin edges (margins) so that the pressure ulcer is larger at its base than at the skin surface. Undermining often develops from shearing forces and is differentiated from tunneling by the larger extent of the wound edge involved and the absence

of a channel or tract extending from the pressure ulcer under the adjacent intact skin.

GUIDANCE STAGING

Staging of a PU/PI is performed to indicate the characteristics and extent of tissue injury, and should be conducted according to professional standards of practice. Determining whether damage to the skin and underlying tissue is a PI or PU depends on the staging of the damaged tissue. See stages below.

NOTE: Regardless of the staging system or wound definitions used by the facility, the facility is responsible for completing the MDS utilizing the staging guidelines found in the RAI Manual.

Stage 1 Pressure Injury: Non-blanchable erythema of intact skin

Intact skin with a localized area of non-blanchable erythema (redness). In darker skin tones, the PI may appear with persistent red, blue, or purple hues. The presence of blanchable erythema or changes in sensation, temperature, or firmness may precede visual changes. Color changes of intact skin may also indicate a deep tissue PI (see below).

Stage 2 Pressure Ulcer: Partial-thickness skin loss with exposed dermis

Partial-thickness loss of skin with exposed dermis, presenting as a shallow open ulcer. The wound bed is viable, pink or red, moist, and may also present as an intact or open/ruptured blister. Adipose (fat) is not visible and deeper tissues are not visible. Granulation tissue, slough and eschar are not present. This stage should not be used to describe moisture associated skin damage including incontinence associated dermatitis, intertriginous dermatitis (inflammation of skin folds), medical adhesive related skin injury, or traumatic wounds (skin tears, burns, abrasions).

Stage 3 Pressure Ulcer: Full-thickness skin loss

Full-thickness loss of skin, in which subcutaneous fat may be visible in the ulcer and granulation tissue and epibole (rolled wound edges) are often present. Slough and/or eschar may be visible but does not obscure the depth of tissue loss. The depth of tissue damage varies by anatomical location; areas of significant adiposity can develop deep wounds. Undermining and tunneling may occur. Fascia, muscle, tendon, ligament, cartilage and/or bone are not exposed. If slough or eschar obscures the wound bed, it is an Unstageable PU/PI.

Stage 4 Pressure Ulcer: Full-thickness skin and tissue loss

Full-thickness skin and tissue loss with exposed or directly palpable fascia, muscle, tendon, ligament, cartilage or bone in the ulcer. Slough and/or eschar may be visible on

some parts of the wound bed. Epibole (rolled edges), undermining and/or tunneling often occur. Depth varies by anatomical location. If slough or eschar obscures the wound bed, it is an unstageable PU/PI.

Unstageable Pressure Ulcer: Obscured full-thickness skin and tissue loss

Full-thickness skin and tissue loss in which the extent of tissue damage within the ulcer cannot be confirmed because the wound bed is obscured by slough or eschar. Stable eschar (i.e. dry, adherent, intact without erythema or fluctuance) should only be removed after careful clinical consideration and consultation with the resident's physician, or nurse practitioner, physician assistant, or clinical nurse specialist if allowable under state licensure laws. If the slough or eschar is removed, a Stage 3 or Stage 4 pressure ulcer will be revealed. If the anatomical depth of the tissue damage involved can be determined, then the reclassified stage should be assigned. The pressure ulcer does not have to be completely debrided or free of all slough or eschar for reclassification of stage to occur.

Other staging considerations include:

- **Deep Tissue Pressure Injury (DTPI): Persistent non-blanchable deep red, maroon or purple discoloration**

  Intact skin with localized area of persistent non-blanchable deep red, maroon, purple discoloration due to damage of underlying soft tissue. This area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue. These changes often precede skin color changes and discoloration may appear differently in darkly pigmented skin. This injury results from intense and/or prolonged pressure and shear forces at the bone-muscle interface. The wound may evolve rapidly to reveal the actual extent of tissue injury, or may resolve without tissue loss. If necrotic tissue, subcutaneous tissue, granulation tissue, fascia, muscle or other underlying structures are visible, this indicates a full thickness pressure ulcer. Once a deep tissue injury opens to an ulcer, reclassify the ulcer into the appropriate stage. Do not use DTPI to describe vascular, traumatic, neuropathic, or dermatologic conditions.

- **Medical Device Related Pressure Ulcer/Injury:** Medical device related PU/PIs result from the use of devices designed and applied for diagnostic or therapeutic purposes. The resultant pressure injury generally conforms to the pattern or shape of the device. The injury should be staged using the staging system.

- **Mucosal Membrane Pressure Ulcer/Injury:** Mucosal membrane PU/PIs are found on mucous membranes with a history of a medical device in use at the location of the injury. Due to the anatomy of the tissue, these ulcers cannot be staged.

PREVENTION OF PRESSURE ULCERS/NJURIES

A pressure ulcer/injury (PU/PI) can occur wherever pressure has impaired circulation to the tissue. A facility must:

- Identify whether the resident is at risk for developing or has a PU/PI upon admission and thereafter;

- Evaluate resident specific risk factors and changes in the resident's condition that may impact the development and/or healing of a PU/PI;

- Implement, monitor and modify interventions to attempt to stabilize, reduce or remove underlying risk factors; and

- If a PU/PI is present, provide treatment and services to heal it and to prevent infection and the development of additional PU/PIs.

The first step in the prevention of PU/PIs, is the identification of the resident at risk of developing PU/PIs. This is followed by implementation of appropriate individualized interventions and monitoring for the effectiveness of the interventions.

ASSESSMENT

An admission evaluation helps identify residents at risk of developing a PU/PI, and residents with existing PU/PIs. Because a resident at risk can develop a PU/PI within hours of the onset of pressure, the at-risk resident needs to be identified and have interventions implemented promptly to attempt to prevent PU/PI. The admission evaluation helps define those initial care approaches.

In addition, the admission evaluation may identify pre-existing signs suggesting that tissue damage has already occurred and additional tissue loss may occur. For example, a deep tissue pressure injury identified on admission could lead to the appearance of an unavoidable Stage 3 or 4 pressure ulcer. A Stage 1 PI can progress to an ulcer with eschar or exudate within days after admission. Some situations, which may have contributed to this tissue damage prior to admission, include pressure resulting from immobility during hospitalization or surgical procedures, during prolonged ambulance transport, or while waiting to be assisted after a debilitating event, such as a fall or a cerebral vascular accident.

It may be harder to identify erythema in a resident with darkly pigmented skin, putting those residents more at risk for developing PU/PIs. It may be necessary, in darker skinned residents to focus more on other evidence of PU/PI development such as changes in sensation, skin temperature or firmness.

Multiple factors, including pressure intensity, pressure duration, and tissue tolerance, significantly affect the potential for the development and healing of PUs/PIs. The comprehensive assessment, which includes the RAI, evaluates the resident's intrinsic risks, the resident's skin condition, and other factors (including causal factors) which

place the resident at risk for the development of or hinder the healing of PU/PIs. An individual may also have various intrinsic risks due to aging, such as decreased subcutaneous tissue and lean muscle mass, decreased skin elasticity, and impaired circulation or sensation.

The comprehensive assessment should address those factors that have been identified as having an impact on the development, treatment and/or healing of PU/PIs, including, at a minimum: risk factors, pressure points, under-nutrition and hydration deficits, and moisture and the impact of moisture on skin. The assessment also helps identify the resident who has multi-system organ failure or an end-of-life condition or who is refusing care and treatment. If the resident is refusing care, an evaluation of the basis for the refusal, and the identification and evaluation of potential alternatives is indicated.

Risk Factors

Not all risk factors are fully modifiable or can be completely addressed. Some risk factors, such as a permanent lack of sensation to an area, may not be modifiable. Some potentially modifiable risk factors, such as malnutrition or uncontrolled blood sugars, may take time to correct, despite prompt intervention. Other risk factors, such as pressure, can be modified promptly. Many studies and professional literature identify risk factors that increase a resident's susceptibility to develop or to not heal pressure PU/PIs.

Examples of these risk factors include, but are not limited to:

- Impaired/decreased mobility and decreased functional ability;
- Co-morbid conditions, such as end stage renal disease, thyroid disease or diabetes mellitus;
- Drugs such as steroids that may affect healing;
- Impaired diffuse or localized blood flow, for example, generalized atherosclerosis or lower extremity arterial insufficiency;
- Resident refusal of some aspects of care and treatment;
- Cognitive impairment;
- Exposure of skin to urinary and fecal incontinence;
- Under nutrition, malnutrition, and hydration deficits; and
- The presence of a previously healed PU/PI. The history of any healed PU/PI, its origin, treatment, its stages [if known] is important assessment information, since areas of healed Stage 3 or 4 PU/PIs are more likely to have recurrent breakdown.

Although the requirements do not mandate the use of any specific assessment tool (other than the RAI), many validated instruments are available to aid in assessing the risk for developing PU/PIs. It is important to keep in mind that research has shown that in a skilled nursing facility, 80 percent of PU/PIs develop within two weeks of admission and 96 percent develop within three weeks of admission. (Reference: Lyder CH, Ayello EA. Pressure Ulcers: A Patient Safety Issue. In: Hughes RG, editor. Patient Safety and Quality: An Evidence-Based Handbook for Nurses. Rockville (MD): Agency for Healthcare Research and Quality (US); 2008 Apr. Chapter 12. Available from: http://www.ncbi.nlm.nih.gov/books/NBK2650/)

Many clinicians utilize a standardized pressure ulcer/injury risk assessment tool to assess a resident's PU/PI risks upon admission, weekly for the first four weeks after admission, then quarterly or whenever there is a change in the resident's condition.

A resident's risk may increase due to an acute illness or condition change (e.g., upper respiratory infection, pneumonia, or exacerbation of underlying congestive heart failure) and may require additional evaluation. The frequency of assessment should be based upon each resident's specific needs.

Regardless of any resident's total risk score on an assessment tool, clinicians are responsible for evaluating each existing and potential risk factor for developing a pressure injury and determining the resident's overall risk. It is acceptable if the clinician's assessment places the resident at a higher risk level than the overall score of the assessment tool based on assessment factors that are not captured by the tool. Documentation of the clinician's decision should be placed in the medical record.

Pressure Points and Tissue Tolerance

Assessment of a resident's skin condition helps define prevention strategies. The skin assessment should include an evaluation of the skin integrity.

Tissue closest to the bone may be the first tissue to undergo changes related to pressure. PU/PIs are usually located over a bony prominence, such as the sacrum, heel, the greater trochanter, ischial tuberosity, fibular head, scapula, and ankle (malleolus).

An at-risk resident who sits too long in one position may be more prone to developing an ulcer/injury over the ischial tuberosity. Slouching in a chair may predispose an at-risk resident to pressure ulcers/injuries of the spine, scapula, or elbow. Elbow pressure injury is often related to arm rests or lap boards. Friction and shearing are also important factors in tissue ischemia, necrosis and PU/PI formation.

PU/PIs may develop at other sites where pressure has impaired the circulation to the tissue, such as pressure from positioning or use of medical devices applied for diagnostic or therapeutic purposes. The resultant PU/PI generally conforms to the pattern or shape of the device. Mucosal membrane PU/PIs are found on mucous membranes with a history of

a medical device in use at the location of the injury. Due to the anatomy of mucous membranes, these ulcers cannot be staged.

PU/PIs on the sacrum and heels are most common. PU/PIs may also develop from pressure on an ear lobe related to positioning of the head; on areas (for example, nares, urinary meatus, extremities) caused by tubes, casts, orthotics, braces, cervical collars, or other medical devices; pressure on the labia or scrotum related to positioning (for example, against a pommel type cushion); the foot related to ill-fitting shoes causing blistering; or on legs, arms and fingers due to contractures or deformity.

Nutrition and Hydration

Adequate nutrition and hydration are essential for overall functioning. Nutrition provides vital energy and building blocks for all of the body's structures and processes. Any organ or body system may require additional energy or structural materials for repair or function. The skin is the body's largest organ system. It may affect, and be affected by, other body processes and organs. Skin condition reflects overall body function therefore, the presence of skin breakdown may be the most visible evidence of a health issue.

Weight reflects a balance between intake and utilization of energy. Significant unintended weight loss may indicate under-nutrition or worsening health status. Weight stability (in the absence of fluid excess or loss) is a useful indicator of overall caloric balance. Severely impaired organs (heart, lungs, kidneys, liver, etc.) may be unable to use nutrients effectively. A resident with a PU/PI who continues to lose weight either needs additional caloric intake or correction (where possible) of conditions that are creating a hypermetabolic state. Continuing weight loss and failure of a PU/PI to heal despite reasonable efforts to improve caloric and nutrient intake may indicate the resident is in multi-system failure or an end-stage or end-of-life condition warranting an additional assessment of the resident's overall condition.

Before instituting a nutritional care plan, it helps to summarize resident specific evidence, including: severity of nutritional compromise, rate of weight loss or appetite decline, probable causes, the individual's prognosis and projected clinical course, and the resident's wishes and goals. Because there are no wound-specific nutritional measures, the interdisciplinary team should develop nutritional goals for the whole person and address nutritional status and needs in the care plan as appropriate.

NOTE: Although some laboratory tests may help clinicians evaluate nutritional issues in a resident with PU/PIs, no laboratory test is specific or sensitive enough to warrant serial/repeated testing. A practitioner may order test(s) that provide useful additional information or help with management of treatable conditions at their discretion

Water is essential to maintain adequate body functions. As a major component of blood, water dissolves vitamins, minerals, glucose, amino acids, etc.; transports nutrients into cells; removes waste from the cells; and helps maintain circulating blood volume as well

as fluid and electrolyte balance. It is critical that each resident at risk for hydration deficit or imbalance, including the resident who has or is at risk of developing a PU/PI, be identified and assessed to determine appropriate interventions.

NOTE: The surveyor should refer to the Guidance at 42 CFR 483.25(g), F692, Assisted Nutrition and Hydration, for investigation of potential non-compliance with the nutrition and hydration requirements. A low albumin level combined with the facility's lack of supplementation, for example, is not by itself sufficient to cite a nutrition related deficiency.

Moisture

Both urine and feces contain substances that may irritate the epidermis and may make the skin more susceptible to breakdown and moisture-related skin damage. Fecal incontinence may pose a greater threat to skin integrity, due to bile acids and enzymes in the feces. Irritation or maceration resulting from prolonged exposure to urine and feces may hasten skin breakdown, and moisture may make skin more susceptible to damage from friction and shear during repositioning.

It may be difficult to differentiate dermatitis related to incontinence from partial thickness PU/PI. This differentiation should be based on the clinical evidence and review of presenting risk factors. The dermatitis may occur in the area where the incontinence brief or underpad has been used.

Prevention and Treatment Strategies

The comprehensive assessment should provide the basis for defining approaches to address residents at risk of developing or already having a PU/PI. A determination that a resident is at risk for developing a PU/PI has significant implications for preventive and treatment strategies, but does not by itself indicate that development of a PU/PI was unavoidable. Effective prevention and treatment are based upon consistently providing routine and individualized interventions.

Based upon the assessment and the resident's clinical condition, choices and identified needs, basic or routine care could include, but is not limited to, interventions to:

- Redistribute pressure (such as repositioning, protecting and/or offloading heels, etc.);
- Minimize exposure to moisture and keep skin clean, especially of fecal contamination;
- Provide appropriate, pressure-redistributing, support surfaces;
- Provide non-irritating surfaces; and

- Maintain or improve nutrition and hydration status, where feasible. Adverse drug reactions related to the resident's drug regimen may worsen risk factors for development of, or for non-healing PU/PIs (for example, by causing lethargy or anorexia or creating/increasing confusion) and should be identified and addressed. These interventions should be incorporated into the plan of care and revised as the condition of the resident indicates.

Resident Choices

In the context of the resident's choices, clinical condition, and physician input, the resident's care plan should establish relevant goals and approaches to stabilize or improve co-morbidities, such as attempts to minimize clinically significant blood sugar fluctuations, and other interventions aimed at limiting the effects of risk factors associated with PU/PIs. Alternatively, facility staff and practitioners should document clinically valid reasons why such interventions were not appropriate or feasible.

In order for a resident to exercise his or her right appropriately to make informed choices about care and treatment or to decline treatment, the facility and the resident (or if applicable, the resident representative) must discuss the resident's condition, treatment options, expected outcomes, and consequences of refusing treatment. The facility is expected to address the resident's concerns and offer relevant alternatives, if the resident has declined specific treatments. (See §483.10(c), F552, Planning and implementing care.)

Pressure Injuries at End of Life

Residents at the end of life, in terminal stages of an illness or having multiple system failures may have written directions for his or her treatment goals (or a decision has been made by the resident's representative, in accordance with State law). The facility's care must reflect the resident's goals for care and wishes as expressed in a valid Advance Directive, if one was formulated, in accordance with State law. However, the presence of an Advance Directive does not absolve the facility from giving supportive and other pertinent care that is not prohibited by the resident's Advance Directive. It is important for surveyors to understand that when a facility has implemented individualized approaches for end-of-life care in accordance with the resident's wishes, the development, continuation, or worsening of a PU/PI may be considered unavoidable. If the facility has implemented appropriate efforts to stabilize the resident's condition (or indicted why the condition cannot or should not be stabilized) and has provided care to prevent or treat existing PU/PIs (including pertinent, routine, lesser aggressive approaches, such as, cleaning, turning, repositioning), the PU/PI may be considered unavoidable and consistent with regulatory requirements.

The Kennedy Terminal Ulcer (KTU)

The facility is responsible for accurately assessing and classifying an ulcer as a KTU or other type of PU/PI and demonstrate that appropriate preventative measures were in place to prevent non-KTU pressure ulcers.

KTUs have certain characteristics which differentiate them from pressure ulcers such as the following:

- KTUs appear suddenly and within hours;
- Usually appear on the sacrum and coccyx but can appear on the heels, posterior calf muscles, arms and elbows;
- Edges are usually irregular and are red, yellow, and black as the ulcer progresses, often described as pear, butterfly or horseshoe shaped; and
- Often appear as an abrasion, blister, or darkened area and may develop rapidly to a Stage 2, Stage 3, or Stage 4 injury.

Repositioning

Repositioning or relieving constant pressure is a common, effective intervention for an individual with a PU/PI or who is at risk of developing one. Assessment of a resident's skin integrity after pressure has been reduced or redistributed should guide the development and implementation of repositioning plans. Such plans should be addressed in the comprehensive care plan consistent with the resident's need and goals. Repositioning is critical for a resident who is immobile or dependent upon staff for repositioning, as the resident is unable to make small movements on their own that would help to relieve prolonged pressure to one area. The care plan for a resident at risk of friction or shearing during repositioning may require the use of lifting devices for repositioning. Positioning the resident on an existing PU/PI should be avoided since it puts additional pressure on tissue that is already compromised and may impede healing.

Determine repositioning frequency with consideration to the individual's:

- Level of activity and mobility,
- General medical condition,
- Overall treatment objectives,
- Skin condition, and
- Comfort.

The resident's skin condition and general comfort should be regularly assessed. The efficacy of repositioning must be monitored and revisions to the care plan considered, if the individual is not responding as expected to the repositioning interventions.

Facilities should consider the following repositioning issues:

1. The time an individual spends seated in a chair without pressure relief should be limited. Seated individuals should be repositioned so as to maintain stability and full range of activities. An acceptable seated posture minimizes the pressure and shear exerted on the skin and soft tissues, which may involve using pressure relieving devices/cushions or adjusting the seat tilt, foot rests, elevated leg rests and other support devices to prevent prolonged pressure to areas of the body that may be at particular risk for developing a PU/PI.

    1. If able, the resident should be taught to shift his or her weight while sitting in a chair. A resident who can change positions independently may need supportive devices to facilitate position changes. The resident also may need instruction about why repositioning is important and how to do it, encouragement to change positions regularly, and monitoring of frequency of repositioning.

    2. Many clinicians recommend a position change "off - loading" hourly for dependent residents who are sitting or who are in a bed or a reclining chair with the head of the bed or back of the chair raised 30 degrees or more. The resident may require more frequent position changes based on an assessment of their skin condition or their comfort. A "microshift," meaning a small change in the resident's position for a short period of time, may not be adequate since this approach does not allow sufficient capillary refill and tissue perfusion for a resident at risk of developing PU/PI's. Ongoing monitoring of the resident's skin integrity and tissue tolerance is critical to prevent development or deterioration of PU/PI's.

    3. Wheelchairs are often used for transporting residents, but they may severely limit repositioning options and increase the risk of PU/PI development. Therefore, wheelchairs with sling seats may not be optimal for prolonged sitting during activities or meals, etc. However, available modifications to the seating can provide a more stable surface and provide better pressure reduction.

    4. The care plan for a resident who is reclining and is dependent on staff for repositioning should address position changes to maintain the resident's skin integrity. This may include repositioning at least every 2 hours or more frequently depending upon the resident's condition and specific needs. Depending on the individualized assessment, more frequent repositioning may be warranted for individuals who are at higher risk for PU/PI development or who show evidence that repositioning at 2-hour intervals is inadequate. With rare exception (such as when both sacral and ischial PU/PI's are present) the resident should not be placed directly on the greater trochanter for more than momentary placement. Elevating the head of the bed or the back of a reclining chair to or above a 30 degree angle creates pressure comparable to that exerted

while sitting, and requires the same considerations regarding repositioning as those for a dependent resident who is seated.

Support Surfaces and Pressure Redistribution

Pressure redistribution refers to the function or ability to distribute a load over a surface or contact area. Redistribution results in shifting pressure from one area to another and requires attention to all affected areas. Pressure redistribution has incorporated the concepts of both pressure reduction and pressure relief.

Appropriate support surfaces or devices should be chosen by matching a device's potential therapeutic benefit with the resident's specific situation; such as multiple injuries, limited turning surfaces, ability to maintain position. The effectiveness of pressure redistribution devices (such as gel mattresses, air fluidized mattresses, and low loss air mattresses) is based on their potential to address the individual resident's risk, the resident's response to the product, and the characteristics and condition of the product. For example, an overinflated overlay product, or one that "bottoms out" (when the overlay is underinflated or loses inflation creating less than one inch between the resident and support material) is unlikely to effectively reduce the pressure risk. These products are more likely to reduce pressure effectively if they are used in accord with the manufacturer's instructions. The effectiveness of each product used needs to be evaluated on an ongoing basis. Surveyors should consider the following pressure redistribution issues:

- Static pressure redistribution devices (such as a gel mattress) may be indicated when a resident is at risk for PU/PI development or delayed healing. A specialized pressure redistribution cushion or surface, for example, might be used to extend the time a resident is sitting in a chair; however, the cushion does not eliminate the necessity for periodic repositioning and skin assessment.

- Dynamic pressure reduction surfaces may be helpful when:

    - The resident cannot assume a variety of positions without bearing weight on a PU/PI;

    - The resident completely compresses a static device that has retained its original integrity; or
    - The PU/PI is not healing as expected, and it is determined that pressure may be contributing to the delay in healing.

- Because the heels and elbows have relatively little surface area, it is difficult to redistribute pressure on these two surfaces. Therefore, it is important to pay particular attention to reducing the pressure on these areas for the resident at risk in accord with resident's overall goals and condition. Pillows used to support the entire lower leg may effectively raise the heel from contact with the bed, but use

of the pillows needs to take into account the resident's other conditions. The use of donut-type cushions is not recommended by the clinicians.

- A resident with severe flexion contractures also may require special attention to effectively reduce pressure on bony prominences or prevent breakdown from skin-to-skin contact.

Some products serve mainly to provide comfort and reduce friction and shearing forces, e.g., sheepskin, heel and elbow protectors. Although these products are not effective at redistributing pressure, they (in addition to pillows, foam wedges, or other measures) may be employed to prevent bony prominences from rubbing together or on other surfaces, such as armrests, the bed, or side rails.

Monitoring

Staff should remain alert to potential changes in the skin condition and should evaluate, report and document changes as soon as identified. For example, a resident's complaint about pain or burning at a site where there has been pressure or observation during the resident's bath that there is a change in skin condition should be reported so that the resident may be evaluated further.

After completing a thorough evaluation, the interdisciplinary team should develop a relevant care plan that includes measurable goals for prevention and management of PU/PIs with appropriate interventions. Many clinicians recommend evaluating skin condition (skin color, moisture, temperature, integrity, and turgor) at least weekly, or more often if indicated, such as when the resident is using a medical device that may cause pressure. Defined interventions should be implemented and monitored for effectiveness.

Assessment and Treatment of Pressure Ulcers/Injuries

It is important that each existing PU/PI be identified, whether present on admission or developed after admission, and that factors that influenced its development, the potential for development of additional PU/PIs or the deterioration of the PU/PIs be recognized, assessed and addressed. Any new PU/PI suggests a need to reevaluate the adequacy of prevention measures in the resident's care plan.

When assessing the PU/PI itself, it is important that documentation addresses:

- The type of injury (pressure-related versus non-pressure-related) because interventions may vary depending on the specific type of injury;

- The PU/PI's stage;

- A description of the PU/PI's characteristics;

- The progress toward healing and identification of potential complications;

- If infection is present;

- The presence of pain, what was done to address it, and the effectiveness of the intervention; and

- A description of dressings and treatments.

Types of Injuries

Three of the more common types of skin injuries are pressure, vascular insufficiency/ischemia (venous stasis and arterial ischemic ulcers) and neuropathic. See §483.25, F684, Quality of Care, for definition and description of injury types other than PU/PIs.

At the time of the assessment, clinicians (physicians, advance practice nurses, physician assistants, and certified wound care specialists, etc.) should document the clinical basis (for example, type of skin injury, location, shape, edges and wound bed, condition of surrounding tissues) for any determination that an injury is not pressure-related, especially if the injury has characteristics consistent with a pressure injury, but is determined not to be one.

Pressure Ulcer/Injury Characteristics

It is important that the facility have a system in place to assure that the protocols for daily monitoring and for periodic documentation of measurements, terminology, frequency of assessment, and documentation are implemented consistently throughout the facility.

When a PU/PI is present, daily monitoring, (with accompanying documentation, when a complication or change is identified), should include:

- An evaluation of the PU/PI, if no dressing is present;

- An evaluation of the status of the dressing, if present (whether it is intact and whether drainage, if present, is or is not leaking);

- The status of the area surrounding the PU/PI (that can be observed without removing the dressing);

- The presence of possible complications, such as signs of increasing area of ulceration or soft tissue infection (for example: increased redness or swelling around the wound or increased drainage from the wound); and

- Whether pain, if present, is being adequately controlled.

The amount of observation possible will depend upon the type of dressing that is used, since some dressings are meant to remain in place for several days, according to manufacturers' guidelines.

With each dressing change or at least weekly (and more often when indicated by wound complications or changes in wound characteristics), an evaluation of the PU/PI should be documented. At a minimum, documentation should include the date observed and:

- Location and staging;
- Size (perpendicular measurements of the greatest extent of length and width of the PU/PI), depth; and the presence, location and extent of any undermining or tunneling/sinus tract;
- Exudate, if present: type (such as purulent/serous), color, odor and approximate amount;
- Pain, if present: nature and frequency (e.g., whether episodic or continuous);
- Wound bed: Color and type of tissue/character including evidence of healing (e.g., granulation tissue), or necrosis (slough or eschar); and
- Description of wound edges and surrounding tissue (e.g., rolled edges, redness, hardness/induration, maceration) as appropriate.

Photographs may be used to support this documentation, if the facility has developed a protocol consistent with professional standards and issues related to resident privacy and dignity are considered and maintained.

Healing Pressure Ulcers/Injuries

Ongoing evaluation and research have indicated that PU/PIs do not heal in a reverse sequence, that is, the body does not replace the types and layers of tissue (muscle, fat and dermis) that were lost during development. The healing process varies depending on the stage of the pressure injury.

There are different types of clinical documentation to describe the progression of the healing PU/PI. Facilities are required to use the RAI. Directions on describing PU/PIs can be found in the RAI manual – these are intended for coding purposes of the MDS. (**NOTE**: Information on coding for the MDS is located on the CMS MDS website (http://www.cms.gov/NursingHomeQualityInits/45_NHQIMDS30TrainingMaterials.asp#TopOfPage)

It is important to evaluate and modify interventions for a resident with an existing PU/PI such as the following:

- Residents with PU/PIs on the sacrum/coccyx or ischia should limit sitting to three times a day in periods of 60 minutes or less. Consult a seating specialist to prescribe an appropriate seating surface and/or positioning techniques to avoid or minimize pressure on the PU/PI. While sitting is important for overall health, every effort should be made to avoid or minimize pressure on the PU/PI.

- Residents with an ischial injury should not be seated in a fully erect posture in chair or in bed. Modify sitting time schedules and re-evaluate the seating surface and the individual's posture if the PU/PI worsens or fails to improve.

If a PU/PI fails to show some evidence of progress toward healing within 2-4 weeks, the area and the resident's overall clinical condition should be reassessed. Re-evaluation of the treatment plan includes determining whether to continue or modify the current interventions. Results may vary depending on the resident's overall condition and interventions/treatments used. The complexity of the resident's condition may limit responsiveness to treatment or tolerance for certain treatment modalities. The clinicians, if deciding to retain the current regimen, should document the rationale for continuing the present treatment to explain why some, or all, of the plan's interventions remain relevant despite little or no apparent healing.

Pressure ulcers/injuries may progress or may be associated with complications, such as infection of the soft tissues around the wound (cellulitis), infection of the bone (osteomyelitis), infection of a joint (septic arthritis), abscess, spread of bacteria into the bloodstream (bacteremia/septicemia), chronic infection, or development of a sinus tract. Sometimes these complications may occur despite apparent improvement in the PU/PI itself. The physician's involvement is integral whenever significant changes in the nature of the wound or overall resident condition are identified.

Infections

A PU/PI infection may be acute or chronic. In acute wounds, the classic signs of inflammation (redness, edema, pain, increased exudate, and periwound surface warmth) persist beyond the normal time frame of three to four days. In residents who are immunosuppressed, the signs of inflammation often are diminished or masked because of an ineffective immune response. Often the only observable symptom of infection is a complaint of pain.

All chronic wounds, including PU/PIs, have bacteria. Since bacteria reside in non-viable tissue, debridement of this tissue and wound cleansing are important to reduce bacteria and avoid adverse outcomes such as sepsis.

The first sign of infection may be a delay in healing and an increase in exudates. In a chronic wound, the signs of infection may be more subtle. Signs may include the following:

- Increase in amount or change in characteristics of exudate,

- Decolorization and friability of granulation tissue,
- Undermining,
- Abnormal odor,
- Epithelial bridging (a bridge of epithelial tissue across a wound bed) at the base of the wound, or
- Sudden pain.

The physician diagnosis of infections present in a PU/PI are based on resident history and clinical findings, such as a wound culture. Pus, slough or necrotic tissue should not be cultured. Findings such as an elevated white blood cell count, bacteremia, sepsis, or fever may signal an infection related to a PU/PI area or a co-existing infection from a different source. The treatment of an infection will depend on the type of infection present.

Pain

The assessment and treatment of a resident's pain are integral components of PU/PI prevention and management. Pain that interferes with movement and/or affects mood may contribute to immobility and contribute to the potential for developing or for delayed healing or non-healing of an already existing PU/PI. Refer to §483.25(k), F697, for additional guidance related to Pain Management.

Dressings and Treatments

Determination of the need for treatment for a PU/PI is based upon the individual practitioner's clinical judgment, facility protocols, and current professional standards of practice.

Product selection should be based upon the relevance of the specific product to the identified PU/PI(s) characteristics, the treatment goals, and the manufacturer's recommendations for use. Current literature does not indicate significant advantages of any single specific product over another, but does confirm that not all products are appropriate for all PU/PIs. Wound characteristics should be assessed throughout the healing process to assure that the treatments and dressings being used are appropriate to the nature of the wound.

Evidenced-based practice suggests that PU/PI dressing protocols may use clean technique rather than sterile, but that appropriate sterile technique may be needed for those wounds that recently have been surgically debrided or repaired. Clean technique (also known as non-sterile) involves approved hand hygiene and glove use, maintaining a clean environment by preparing a clean field, using clean instruments, and preventing direct

contamination of materials and supplies. Clean technique is considered most appropriate for long-term care; for residents who are not at high risk for infection; and for residents receiving routine dressings for chronic wounds such as venous ulcers, or wounds healing by secondary intention with granulation tissue.

A facility should be able to show that its treatment protocols are based upon current professional standards of practice and are in accord with the facility's policies and procedures as developed with the medical director's review and approval.

INVESTIGATIVE PROTOCOL

Use

Use the Pressure Ulcer Critical Element (CE) Pathway, along with the above interpretive guidelines when determining if the facility meets requirements to ensure a resident receives care consistent with professional standards of practice, to prevent pressure ulcers/injuries development, prevent the development of additional pressure ulcers/injuries, and to promote the healing of existing pressure ulcers/injuries.

Summary of Skin Integrity Investigative Procedure

Briefly review the comprehensive assessments, care plans, and physician orders to identify whether the facility has practices in place to identify if a resident is at risk for a pressure ulcer/injury, evaluate a resident for pressure ulcers/injuries, and intervene to prevent and/or heal pressure ulcers. During this review, identify the extent to which the facility has developed and implemented interventions in accordance with ensuring a resident receives care consistent with professional standards of practice. If the resident has been in the facility for less than 14 days (before completion of all the Resident Assessment Instrument (RAI) is required), review the baseline care plan which must be completed within 48 hours to determine if the facility is providing appropriate care and services based on information available at the time of admission.
This information will guide observations and interviews to be made to corroborate concerns identified.

NOTE: In addition to actual or potential physical harm, always *observe for visual cues of psychosocial distress and* consider whether psychosocial harm has occurred when determining severity level (See *guidance on Severity and Scope Levels and* Psychosocial Outcome Severity Guide *located in the Survey Resources zip file located at https://www.cms.gov/medicare/provider-enrollment-and-certification/guidanceforlawsandregulations/nursing-homes*).

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F686, the surveyor's investigation will generally show that the facility failed to do one or more of the following:

- Provide preventive care, consistent with professional standards of practice, to residents who may be at risk for development of pressure injuries; or

- Provide treatment, consistent with professional standards of practice, to an existing pressure injury; or

- Ensure that a resident did not develop an avoidable PU/PI.

NOTE: To cite F686, it is not necessary to prove that a PU/PI developed. F686 can be cited when it has been determined that the provider failed to implement interventions to prevent the development of a PU/PI for a resident identified at risk.

DEFICIENCY CATEGORIZATION

Examples of Severity Level 4 Noncompliance: Immediate Jeopardy to Resident Health or Safety include, but are not limited to:

- The facility failed to implement interventions to prevent PU/PI development for a resident who was admitted without PU/PIs, but who had multiple co-morbidities and was totally dependent on staff, placing her at increased risk for PU/PI development; and failed to provide ongoing skin assessments for the same resident. The resident developed a stage IV pressure ulcer on her heel within three weeks of her admission.

- Development of avoidable Stage IV pressure ulcer(s): As a result of the facility's non-compliance, permanent tissue damage (whether or not healing occurs) has compromised the resident, increasing the potential for serious complications including osteomyelitits and sepsis.

- Admitted with a Stage IV pressure ulcer(s) that has shown no signs of healing or shows signs of deterioration: As a result of the facility's non-compliance, a Stage IV pressure ulcer has shown signs of deterioration or a failure to progress towards healing with an increased potential for serious complications including osteomyelitis and sepsis.

- Stage III or IV pressure ulcers with associated soft tissue or systemic infection: As a result of the facility's failure to assess or treat a resident with an infectious complication of a pressure ulcer, the resident developed Stage III or IV pressure ulcers with associated soft tissue or systemic infection. (See discussion in guidelines and definitions that distinguishes colonization from infection.)

- Extensive failure in multiple areas of pressure ulcer care: As a result of the facility's extensive noncompliance in multiple areas of pressure ulcer care, the resident developed recurrent and/or multiple, avoidable Stage III or Stage IV pressure ulcer(s).

Examples of Severity Level 3 Noncompliance Actual Harm that is not Immediate Jeopardy include, but are not limited to:

- The facility failed to provide necessary equipment, interventions, monitoring, and care, for a resident who was identified to be at risk for developing PU/PIs due to the presence of contractures and had no PU/PIs upon admission. The facility's occupational therapist (OT) assessed the resident and provided a pressure relieving device for use on the resident's left hand, which was to be in place at all times except when daily hygiene was being provided. The interventions were not recorded on the resident's care plan. During observation and interviews with staff, the assistive device was unable to be located and was not in use. This resulted in the resident developing a Stage III pressure injury.

- The development of recurrent or multiple avoidable Stage II pressure ulcer(s): As a result of the facility's non-compliance, the resident developed multiple and/or recurrent avoidable Stage II ulcers.

- Failure to implement the comprehensive care plan for a resident who has a pressure ulcer: As a result of a facility's failure to implement a portion of an existing plan related to pressure ulcer care, such as failure to provide for pressure redistribution, or inappropriate treatment/dressing changes, a wound increased in size or failed to progress towards healing as anticipated, or the resident experienced untreated pain.

Examples of Severity Level 2 Noncompliance No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy include, but are not limited to:

- The facility failed to assure that a resident with a healed Stage I PI in the coccyx area received care to prevent the development of another PU/PI. The resident's care plan identified the use of a pressure-relieving device while up in the chair and repositioning every 30 minutes. During observations, the pressure relieving device was not present on the seat of the wheelchair but staff did reposition resident every 30 minutes. The device was available, but the staff person interviewed stated that although it was usually on his wheelchair, it had not been placed that day. The resident's skin was intact and did not indicate the presence of a stage I PI based on observation, but the likelihood existed of a PU/PI developing as a result of not implementing care as identified in the plan of care.

- The facility failed to assess the skin condition of a resident who used continual oxygen for management of a chronic respiratory disease. The resident's oxygen was provided via nasal cannula and the resident voiced discomfort and irritation with the tubing on his nares. There was a small reddened area where the tubing contacted the nares. The resident had mentioned this to the staff, but was not addressed, and the resident continued to experience discomfort and irritation.