SELF SURVEY MODULE
483.25 (c) PRESSURE SORES

TAG F314

REGULATION: F314 §483.25(c) Pressure Sores

Based on the comprehensive Assessment of a resident, the facility must ensure that--

(1) resident who enters the facility without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrates that they were unavoidable; and

(2) resident having pressure sores receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing.

Intent: (F314) 42 CFR 483.25(c)

The intent of this requirement is that the resident does not develop pressure ulcers unless clinically unavoidable and that the facility provides care and services to:

• Promote the prevention of pressure ulcer development;

• Promote the healing of pressure ulcers that are present (including prevention of infection to the extent possible); and

• Prevent development of additional pressure ulcers.

NOTE: **A**though the regulatory language refers to pressure sores, the nomenclature widely accepted presently refers to pressure ulcers, and the guidance provided in this document will refer to pressure ulcers.

DEFINITIONS

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

• "Pressure Ulcer"- A pressure ulcer is any lesion caused by unrelieved pressure that results in damage to the underlying tissue(s).[1] Although friction and shear are not primary causes of pressure ulcers, friction and shear are important contributing factors to the development of pressure ulcers.

• "Avoidable/Unavoidable" Pressure Ulcers

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

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

• "Cleansing/Irrigation"

o "Cleansing" refers to the use of an appropriate device and solution to clean the surface of the wound bed and to remove the looser foreign debris or contaminants in order to decrease microbial growth.[2]

- “Irrigation” refers to a type of mechanical debridement, which uses an appropriate solution delivered under pressure to the wound bed to vigorously attempt to remove debris from the wound bed.[3]

• “Colonized/Infected” Wound [4, 5]

- “Colonized” refers to the presence of bacteria 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. [6, 7, 8]

Various debridement methods include:

- “Autolytic debridement” refers to the use of moisture retentive dressings to cover a wound and allow devitalized tissue to self-digest by the action of enzymes present in the wound fluids.
- “Enzymatic (chemical) debridement” refers to the topical application of substances e.g., enzymes to break down devitalized tissue.
- “Mechanical debridement” refers to the removal of foreign material and devitalized or contaminated tissue from a wound by physical rather than by chemical or autolytic means.
- “Sharp or surgical debridement” refers to removal of foreign material or devitalized tissue by a surgical instrument.
- “Maggot debridement therapy (MDT)” or medicinal maggots refers to a type of sterile intentional biological larval or biosurgical debridement that uses disinfected (sterile) maggots to clean wounds by dissolving the dead and infected tissue and by killing bacteria.[9]

• “Eschar/Slough”

- “Eschar” is described as thick, leathery, frequently black or brown in color, necrotic (dead) or devitalized tissue that has lost its usual physical properties and biological activity. Eschar may be loose or firmly adhered to the wound.
- “Slough” is necrotic/avascular tissue in the process of separating from the viable portions of the body and is usually light colored, soft, moist, and stringy (at times).

• “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” is the interaction of both gravity and friction against the surface of the skin. Friction is always present when shear force is present.[10] Shear 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”

- o "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"-Tunnel and sinus tract are often used interchangeably.
- o "Tunneling" is a passageway of tissue destruction under the skin surface that has an opening at the skin level from the edge of the wound.
- o A "sinus tract" is a cavity or channel underlying a wound that involves an area larger than the visible surface of the wound.
- o "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 in undermining and the absence of a channel or tract extending from the pressure ulcer under the adjacent intact skin.

INVESTIGATIVE PROTOCOL

PRESSURE ULCER

Objectives

- To determine if the identified pressure ulcer(s) is avoidable or unavoidable; and
- To determine the adequacy of the facility's interventions and efforts to prevent and treat pressure ulcers.

Use

Use this protocol for a sampled resident having--or at risk of developing-- a pressure ulcer.

If the resident has an ulcer, determine if it was identified as non-pressure related, e.g., vascular insufficiency or a neuropathic ulcer. If record review, staff and/or physician interview, and observation (unless the dressing protocol precludes observing the wound) support the conclusion that the ulcer is not pressure related, do not proceed with this protocol unless the resident is at risk for developing, or also has, pressure ulcers. Evaluate care and services regarding non-pressure related ulcers at F309, Quality of Care.

Procedures

Briefly review the assessment, care plan and orders to identify facility interventions and to guide observations to be made. For a newly admitted resident either at risk or with a pressure ulcer, the staff is expected to assess and provide appropriate care from the day of admission. Corroborate observations by interview and record review.

1. Observation

Observe whether staff consistently implements the care plan over time and across various shifts. During observations of the interventions, note and/or follow up on deviations from the care plan as well as potential negative outcomes, including but not limited to the following:

- Erythema or color changes on areas such as the sacrum, buttocks, trochanters, posterior thigh, popliteal area, or heels when moved off an area:
- o If erythema or color change are noted, return approximately ½ - ¾ hours later to determine if the changes or other Stage I characteristics persist;
- o If the changes persist and exhibit tenderness, hardness, or alteration in temperature from surrounding skin, ask staff how they determine repositioning schedules and how they evaluate and address a potential Stage I pressure ulcer;

• Previously unidentified open areas;
• Whether the positioning avoids pressure on an existing pressure ulcer(s);
• Measures taken to prevent or reduce the potential for shearing or friction during transfers, elevation, and repositioning; and
• Whether pressure-redistributing devices for the bed and/or chair, such as gel-type surfaces or overlays are in place, working, and used according to the manufacturer's recommendations.

Observation of Existing Ulcer/Wound Care
If a dressing change is scheduled during the survey, observe the wound care to determine if the record reflects the current status of the ulcer(s) and note:
• Characteristics of the wound and surrounding tissues such as presence of granulation tissue, the Stage, presence of exudates, necrotic tissue such as eschar or slough, or evidence of erythema or swelling around the wound;
• The form or type of debridement, if used;
• Whether treatment and infection control practices reflect current standards of practice; and
• Based on location, steps taken to cleanse and protect the wound from likely contamination by urine or fecal incontinence.

If unable to observe the dressing change due to the dressing protocol, observe the area surrounding the ulcer(s). For ulcers with dressings that are not scheduled to be changed, the surveyor may request that the dressing be removed to observe the wound and surrounding area if other information suggests a possible treatment or assessment problem.

If the resident expresses (or appears to be in) pain related to the ulcer or treatment, determine if the facility:
• Assessed for pain related to the ulcer, addressed and monitored interventions for effectiveness; and/or
• Assessed and took preemptive measures for pain related to dressing changes or other treatments, such as debridement/irrigations, and monitored for effectiveness.

2. Resident/Staff Interviews
Interview the resident, family or responsible party to the degree possible to identify:
• Involvement in care plan, choices, goals, and if interventions reflect preferences;
• Awareness of approaches, such as pressure redistribution devices or equipment, turning/repositioning, weight shifting to prevent or address pressure ulcer(s);
• Presence of pain, if any, and how it is managed;
• If treatment(s) was refused, whether counseling on alternatives, consequences, and/or other interventions was offered; and
• Awareness of current or history of an ulcer(s). For the resident who has or has had a pressure ulcer, identify, as possible, whether acute illness, weight loss or other condition changes occurred prior to developing the ulcer.
Interview staff on various shifts to determine:
• Knowledge of prevention and treatment, including facility-specific guidelines/protocols and specific interventions for the resident;
• If nursing assistants know what, when, and to whom to report changes in skin condition; and

• Who monitors for the implementation of the care plan, changes in the skin, the development of pressure ulcers, and the frequency of review and evaluation of an ulcer.

3. Record Review

Assessment

Review the RAI and other documents such as physician orders, progress notes, nurses' notes, pharmacy or dietary notes regarding the assessment of the resident's overall condition, risk factors and presence of a pressure ulcer(s) to determine if the facility identified the resident at risk and evaluated the factors placing the resident at risk:

• For a resident who was admitted with an ulcer or who developed one within 1 to 2 days, review the admission documentation regarding the wound site and characteristics at the time of admission, the possibility of underlying tissue damage because of immobility or illness prior to admission, skin condition on or within a day of admission, history of impaired nutrition; and history of previous pressure ulcers; and

• For a resident who subsequently developed or has an existing pressure ulcer, review documentation regarding the wound site, characteristics, progress and complications including reassessment if there were no signs of progression towards healing within 2 to 4 weeks.

In considering the appropriateness of a facility's response to the presence, progression, or deterioration of a pressure ulcer, take into account the resident's condition, complications, time needed to determine the effectiveness of a treatment, and the facility's efforts, where possible, to remove, modify, or stabilize the risk factors and underlying causal factors.

Care Plan

For the resident at risk for developing or who has a pressure ulcer, determine if the facility developed an individualized care plan that addresses prevention, care and treatment of any existing pressure ulcers, including specific interventions, measurable objectives and approximate time frames.

If the facility's care of a specific resident refers to a treatment protocol that contains details of the treatment regimen, the care plan should refer to that protocol. The care plan should clarify any major deviations from, or revisions to, that protocol in a specific resident.

A specific care plan intervention for risk of pressure ulcers is not needed if other components of the care plan address related risks adequately. For example, the risk of skin breakdown posed by fecal/urinary incontinence might be addressed in that part of the care plan that deals with incontinence management.

If the resident refuses or resists staff interventions to reduce risk or treat existing pressure ulcers, determine if the care plan reflects efforts to seek alternatives to address the needs identified in the assessment.

Revision of the Care Plan

Determine if the staff have been monitoring the resident's response to interventions for prevention and/or treatment and have evaluated and revised the care plan based on the resident's

response, outcomes, and needs. Review the record and interview staff for information and/or evidence that:

• Continuing the current approaches meets the resident's needs, if the resident has experienced recurring pressure ulcers or lack of progression toward healing and staff did not revise the care plan; and
• The care plan was revised to modify the prevention strategies and to address the presence and treatment of a newly developed pressure ulcer, for the resident who acquired a new ulcer.

4. Interviews with Health Care Practitioners and Professionals

If the interventions defined or care provided appear not to be consistent with recognized standards of practice, interview one or more health care practitioners and professionals as necessary (e.g., physician, charge nurse, director of nursing) who, by virtue of training and knowledge of the resident, should be able to provide information about the causes, treatment and evaluation of the resident's condition or problem. Depending on the issue, ask about:

• How it was determined that chosen interventions were appropriate;
• Risks identified for which there were no interventions;
• Changes in condition that may justify additional or different interventions; or
• How they validated the effectiveness of current interventions.

If the attending physician is unavailable, interview the medical director, as appropriate.

DETERMINATION OF COMPLIANCE (Task 6, Appendix P)

Synopsis of Regulation (F314)

The pressure ulcer requirement has two aspects. The first aspect requires the facility to prevent the development of pressure ulcer(s) in a resident who is admitted without pressure ulcer(s), unless the development is clinically unavoidable. The second aspect requires the facility to provide necessary treatment and services to promote healing, prevent infection and prevent new ulcers from developing. A facility may have noncompliance in either or both aspects of this requirement.

Criteria for Compliance

• Compliance with 42 CFR 483.25(c)(1), F314, Pressure Sore

o For a resident who developed a pressure ulcer after admission, the facility is in compliance with this requirement, if staff have:

• Recognized and assessed factors placing the resident at risk for developing a pressure ulcer, including specific conditions, causes and/or problems, needs and behaviors;
• Defined and implemented interventions for pressure ulcer prevention in accordance with resident needs, goals and recognized standards of practice;
• Monitored and evaluated the resident's response to preventive efforts; and
• Revised the approaches as appropriate. If not, the development of the pressure ulcer is avoidable, cite at F314.

• Compliance with 42 CFR 483.25(c)(2), F314, Pressure Sore

o For a resident who was admitted with a pressure ulcer, who has a pressure ulcer that is not healing, or who is at risk of developing subsequent pressure ulcers, the facility is in compliance with this requirement if they:

• Recognized and assessed factors placing the resident at risk of developing a new pressure ulcer or experiencing non-healing or delayed healing of a current pressure ulcer, including specific conditions, causes and/or problems, needs and behaviors;
• Defined and implemented interventions for pressure ulcer prevention and treatment in accordance with resident needs, goals and recognized standards of practice;
• Addressed the potential for infection;
• Monitored and evaluated the resident's response to preventive efforts and treatment interventions; and
• Revised the approaches as appropriate. If not, cite at F314.

Non-compliance for F314

After completing the Investigative Protocol, analyze the data in order to determine whether or not noncompliance with the regulation exists. Non-compliance for F314 may include (but is not limited to) one or more of the following, including failure to:
• Accurately or consistently assess a resident's skin integrity on admission and as indicated thereafter;
• Identify a resident at risk of developing a pressure ulcer(s);
• Identify and address risk factors for developing a pressure ulcer, or explain adequately why they could not or should not do so;
• Implement preventive interventions in accord with the resident's need and current standards of practice;
• Provide clinical justification for the unavoidable development or non-healing/delayed healing or deterioration of a pressure ulcer;
• Provide appropriate interventions, care and treatment to an existing pressure ulcer to minimize infections and to promote healing;
• Implement interventions for existing wounds;
• Notify the physician of the resident's condition or changes in the resident's wound(s);
• Adequately implement pertinent infection management practices in relation to wound care; and
• Identify or know how to apply relevant policies and procedures for pressure ulcer prevention and treatment.

Potential Tags for Additional Investigation

During the investigation of F314, 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:
• 42 CFR 483.10(b)(11)(i)(B)&(C), F157, Notification of Changes
  - Determine if staff notified the physician of significant changes in the resident's condition or failure of the treatment plan to prevent or heal pressure ulcers; or the resident's representative (if known) of significant changes in the resident's condition in relation to the development of a pressure ulcer or a change in the progression of healing of an existing pressure ulcer.
• 42 CFR 483.20(b)(1), F272, Comprehensive Assessments

- Determine if the facility comprehensively assessed the resident's skin condition, including existing pressure ulcers, and resident-specific risk factors (including potential causative factors) for the development of a pressure ulcer or non-healing of the ulcer.

• 42 CFR 483.20(k)(1), F279, Comprehensive Care Plans
- Determine if the facility developed a care plan that was consistent with the resident's specific conditions, risks, needs, behaviors, and preferences and current standards of practice and included measurable objectives and timetables, specific interventions/services to prevent the development of pressure ulcers and/or to treat existing pressures ulcers.

• 42 CFR 483.20(k)(2)(iii), F280, Comprehensive Care Plan Revision
- Determine if the care plan was periodically reviewed and revised as necessary to prevent the development of pressure ulcers and to promote the healing of existing pressure ulcers.

• 42 CFR 483.20(k)(3)(i), F281, Services Provided Meet Professional Standards
- Determine if pressure ulcer care was provided in accordance with accepted professional standards.

• 42 CFR 483.25, F309, Quality of Care
- Determine if staff identified and implemented appropriate measures for the management of pain as indicated as related to pressure ulcers and pressure ulcer treatment.

• 42 CFR 482.30(a), F353, Sufficient Staff
- Determine if the facility had qualified staff in sufficient numbers to assure the resident was provided necessary care and services, based upon the comprehensive assessment and care plan, to prevent or treat pressure ulcers.

• 42 CFR 483.40(a)(1), F385, Physician Supervision
- Determine if the physician has assessed and developed a treatment regimen relevant to preventing or healing a pressure ulcer and responded appropriately to the notice of changes in condition.

• 42 CFR 483.75(i)(2), F501, Medical Director
- Determine whether the medical director assisted the facility in the development and implementation of policies and procedures for pressure ulcer prevention and treatment, and that these are based on current standards of practice; and whether the medical director interacts with the physician supervising the care of the resident if requested by the facility to intervene on behalf of the resident with a pressure ulcer(s).

V. DEFICIENCY CATEGORIZATION (Part V, Appendix P)

Once the team has completed its investigation, analyzed the data, reviewed the regulatory requirement, and identified the deficient practices that demonstrate that the facility failed to provide care and treatment to prevent or treat pressure ulcers and that non-compliance exists, the team must determine the severity of the deficient practice(s) and the resultant harm or potential for harm to the resident. The key elements for severity determination for F314 are as follows:

1. **Presence of harm/negative outcome(s) or potential for negative outcomes because of lack of appropriate treatment and care.** Actual or potential harm/negative outcome for F314 may include but is not limited to:
   • Potential for development of, occurrence or recurrence of (an) avoidable pressure ulcer(s);
   • Complications such as sepsis or pain related to the presence of avoidable pressure ulcer(s); and/or

• Pressure ulcers that fail to improve as anticipated or develop complications such as sepsis or pain because of the lack of appropriate treatment and care.

2. **Degree of harm (actual or potential) related to the non-compliance**
   Identify how the facility practices caused, resulted in, allowed or contributed to the actual or potential for harm:
   • If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise or discomfort; and
   • If harm has not yet occurred, determine how likely is the potential for serious injury, impairment, death, compromise or discomfort to occur to the resident.
3. **The immediacy of correction required**
   Determine whether the non-compliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.

The survey team must evaluate the harm or potential for harm based upon the following levels of severity for tag F314. First, the team must rule out whether Severity Level 4, Immediate Jeopardy to a resident's health or safety exists by evaluating the deficient practice in relation to immediacy, culpability and severity. (Follow the guidance in Appendix Q.)

Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety
Immediate Jeopardy is a situation in which the facility's non-compliance:

• With one or more requirements of participation has caused/resulted in, or is likely to cause, serious injury, harm, impairment or death to a resident; and
• Requires immediate correction as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.

Examples of possible avoidable negative outcomes may include:

• 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. (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).

NOTE: If immediate jeopardy has been ruled out based upon the evidence, then evaluate whether actual harm that is not immediate jeopardy exists at Severity Level 3.

Severity Level 3 Considerations: Actual Harm that is not Immediate Jeopardy

Level 3 indicates noncompliance that results in actual harm, and can include but may not be limited to clinical compromise, decline, or the resident's ability to maintain and/or reach his/her highest practicable well-being.

Examples of avoidable negative outcomes may include but are not limited to:

- **The development of avoidable Stage III pressure ulcer(s):** As a result of the facility's non-compliance, Stage III pressure ulcers occurred, which are open wounds in which damage has occurred into the subcutaneous level and may be painful.
- **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.

NOTE: If Severity Level 3 (actual harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate as to whether Level 2 (no actual harm with the potential for more than minimal harm) exists.

Severity Level 2 Considerations: No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy

Level 2 indicates noncompliance that results in a resident outcome of no more than minimal discomfort and/or has the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well being. The potential exists for greater harm to occur if interventions are not provided.

Examples of avoidable negative outcomes may include but are not limited to:

- **The development of a single avoidable Stage II pressure ulcer that is receiving appropriate treatment:** As a result of the facility's non-compliance, a resident developed an avoidable Stage II pressure ulcer.
- **The development of an avoidable Stage I pressure ulcer**: As a result of the facility's non-compliance, a resident developed an avoidable Stage I pressure ulcer.
- **Failure to implement an element of the care plan for a resident who has a pressure ulcer however, there has been no evidence of decline or failure to heal.**
- **Failure to recognize or address the potential for developing a pressure ulcer:** As a result of the facility's non-compliance, staff failed to identify the risks, develop a plan of care and/or consistently implement a plan that has been developed to prevent pressure ulcers.

Severity Level 1: No Actual Harm with Potential for Minimal Harm

The failure of the facility to provide appropriate care and services to prevent pressure ulcers or heal existing pressure ulcers is more than minimal harm. Therefore, Severity Level 1 doesn't apply for this regulatory requirement.