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Provider Certification

Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal 4

Date: NOVEMBER 12, 2004

SUBJECT: Guidance to Surveyors for Long Term Care Facilities

I. SUMMARY OF CHANGES: Appendix PP, Tag F314, current Guidance to Surveyors, is entirely replaced by this revision which is to be inserted in the Appendix immediately after the regulatory text for F314. To complement the revision of F314, new language is being added to Tag F309 to include certain definitions of non-pressure related ulcers. Hypertext links are added for all Web sites listed in the Overview, (www.ahrq.gov, www.npuap.org, www.amda.org, www.medqic.org, www.wocn.org, and www.healthinaging.org). Hypertext link is added in the Endnotes section to link to a CMS site (www.cms.hhs.gov/medicaid/survey-cert/siqhome.asp) for further information.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: November 12, 2004

IMPLEMENTATION DATE: November 12, 2004

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)
(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix PP/483.25/Quality of Care/Tag F309
R	Appendix PP/483.25(c)/Pressure Sores/Tag F314

III. FUNDING: Medicare contractors shall implement these instructions within their current operating budgets.

IV. ATTACHMENTS:

	Business Requirements
x	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

*Unless otherwise specified, the effective date is the date of service.

F309

(Rev.4, Issued 11-12-04, Effective: 11-12-04, Implementation: 11-12-04)

§483.25 Quality of Care

Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.

Use F309 for quality of care deficiencies not covered by §483.25(a)-(m).

Intent: §483.25

The facility must ensure that the resident obtains optimal improvement or does not deteriorate within the limits of a resident's right to refuse treatment, and within the limits of recognized pathology and the normal aging process.

Definitions: §483.25

- “Highest practicable” is defined as the highest level of functioning and well-being possible, limited only by the individual’s presenting functional status and potential for improvement or reduced rate of functional decline. Highest practicable is determined through the comprehensive resident assessment by competently and thoroughly addressing the physical, mental or psychosocial needs of the individual.
- “*Skin Ulcer/Wound*”

NOTE: Skin ulcer definitions are included to clarify clinical terms related to skin ulcers. At the time of the assessment and diagnosis, the clinician is expected to document the clinical basis (e.g., underlying condition contributing to the ulceration, ulcer edges and wound bed, location, shape, condition of surrounding tissues) which permit differentiating the ulcer type, especially if the ulcer has characteristics consistent with a pressure ulcer, but is determined not to be one.

- “*Arterial Ulcer*” is ulceration that occurs as the result of arterial occlusive disease when non-pressure related disruption or blockage of the arterial blood flow to an area causes tissue necrosis.

Inadequate blood supply to the extremity may initially present as intermittent claudication. Arterial/Ischemic ulcers may be present in

individuals with moderate to severe peripheral vascular disease, generalized arteriosclerosis, inflammatory or autoimmune disorders (such as arteritis), or significant vascular disease elsewhere (e.g., stroke or heart attack). The arterial ulcer is characteristically painful, usually occurs in the distal portion of the lower extremity and may be over the ankle or bony areas of the foot (e.g., top of the foot or toe, outside edge of the foot). The wound bed is frequently dry and pale with minimal or no exudate. The affected foot may exhibit: diminished or absent pedal pulse, coolness to touch, decreased pain when hanging down (dependent) or increased pain when elevated, blanching upon elevation, delayed capillary fill time, hair loss on top of the foot and toes, toenail thickening.

- *“Diabetic neuropathic ulcer” requires that the resident be diagnosed with diabetes mellitus and have peripheral neuropathy. The diabetic ulcer characteristically occurs on the foot, e.g., at mid-foot, at the ball of the foot over the metatarsal heads, or on the top of toes with Charcot deformity.*
- *“Pressure ulcer”. See Guidance at 42 CFR 483.25(c)-F314.*
- *“Venous insufficiency ulcer” (previously known as “stasis ulcer”) is an open lesion of the skin and subcutaneous tissue of the lower leg, usually occurring in the pretibial area of the lower leg or above the medial ankle. Venous ulcers are reported to be the most common vascular ulceration and may be difficult to heal, may occur off and on for several years, and may occur after relatively minor trauma. The ulcer may have a moist, granulating wound bed, may be superficial, and may have minimal to copious serous drainage unless the wound is infected. The resident may experience pain which may be increased when the foot is in a dependent position, such as when a resident is seated with her or his feet on the floor. Recent literature implicates venous hypertension as a causative factor. Earlier, the ulceration was believed to be due to the pooling of blood in the veins.*

Venous hypertension may be caused by one (or a combination of) factor(s) including: loss of (or compromised) valve function in the vein, partial or complete obstruction of the vein (e.g., deep vein thrombosis, obesity, malignancy), and/or failure of the calf muscle to pump the blood (e.g., paralysis, decreased activity). Venous insufficiency may result in edema and induration, dilated superficial veins, cellulitis in the lower third of the leg or dermatitis (typically characterized by change in skin pigmentation). The pigmentation may appear as darkening skin, tan or purple areas in light skinned residents and dark purple, black or dark brown in dark skinned residents.

F314

(Rev.4, Issued 11-12-04, Effective: 11-12-04, Implementation: 11-12-04)

§483.25(c) Pressure Sores

Based on the Comprehensive Assessment of a resident, the facility must ensure that-
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(1) A 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

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: *Although 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*
 - *“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.

- *“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”*
 - *“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”*
 - *“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.*
 - *“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.*
 - *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 in undermining and the absence of a channel or tract extending from the pressure ulcer under the adjacent intact skin.*

OVERVIEW

A pressure ulcer can occur wherever pressure has impaired circulation to the tissue. Critical steps in pressure ulcer prevention and healing include: identifying the individual resident at risk for developing pressure ulcers, identifying and evaluating the risk factors and changes in the resident’s condition, identifying and evaluating factors that can be removed or modified, implementing individualized interventions to attempt to stabilize, reduce or remove underlying risk factors, monitoring the impact of the interventions, and modifying the interventions as appropriate. It is important to recognize and evaluate each resident’s risk factors and to identify and evaluate all areas at risk of constant pressure.

A complete assessment is essential to an effective pressure ulcer prevention and treatment program. A comprehensive individual evaluation helps the facility to:

- *Identify the resident at risk of developing pressure ulcers, the level and nature of risk(s); and*
- *Identify the presence of pressure ulcers.*

This information allows the facility to develop and implement a comprehensive care plan that reflects each resident’s identified needs.

The care process should include efforts to stabilize, reduce or remove underlying risk factors; to monitor the impact of the interventions; and to modify the interventions as appropriate.

The facility should have a system/procedure to assure: assessments are timely and appropriate; interventions are implemented, monitored, and revised as appropriate; and changes in condition are recognized, evaluated, reported to the practitioner, and

addressed. The quality assessment and assurance committee may help the facility evaluate existing strategies to reduce the development and progression of pressure ulcers, monitor the incidence and prevalence of pressure ulcers within the facility, and ensure that facility policies and procedures are consistent with current standards of practice.

Research into appropriate practices for the prevention, management and treatment of pressure ulcers, continues to evolve. As such, there are many recognized clinical resources regarding the prevention and management of pressure ulcers (including wound care, and complications such as infections and pain). Some of these resources include:

- The Clinical Practice Guidelines from the Agency for Healthcare Research and Quality (AHRQ) www.ahrq.gov (Guideline No. 15: Treatment of Pressure Ulcers and Guideline No.3: Pressure Ulcers in Adults: Prediction and Prevention)(AHRQ was previously known as the Agency for Health Care Policy and Research [AHCPR]);*
- The National Pressure Ulcer Advisory Panel (NPUAP) www.npuap.org;*
- The American Medical Directors Association (AMDA) www.amda.com (Clinical Practice Guidelines: Pressure Ulcers, 1996 and Pressure Ulcer Therapy Companion, 1999);*
- The Quality Improvement Organizations, Medicare Quality Improvement Community Initiatives site at www.medqic.org;*
- The Wound, Ostomy, and Continence Nurses Society (WOCN) www.wocn.org;*
and
- The American Geriatrics Society guideline “The Management of Persistent Pain in Older Persons”, www.healthinaging.org.*

NOTE: *References to non-CMS sources or sites on the Internet 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 as of the date of this publication.*

PREVENTION OF PRESSURE ULCERS

42 CFR 483.25 (c) requires that a resident who is admitted without a pressure ulcer doesn't develop a pressure ulcer unless clinically unavoidable, and that a resident who has an ulcer receives care and services to promote healing and to prevent additional ulcers.

The first step in prevention is the identification of the resident at risk of developing

pressure ulcers. This is followed by implementation of appropriate individualized interventions and monitoring for the effectiveness of the interventions.

ASSESSMENT

An admission evaluation helps identify the resident at risk of developing a pressure ulcer, and the resident with existing pressure ulcer(s) or areas of skin that are at risk for breakdown. Because a resident at risk can develop a pressure ulcer within 2 to 6 hours of the onset of pressure,¹¹ the at-risk resident needs to be identified and have interventions implemented promptly to attempt to prevent pressure ulcers. The admission evaluation helps define those initial care approaches.

In addition, the admission evaluation may identify pre-existing signs (such as a purple or very dark area that is surrounded by profound redness, edema, or induration)¹² suggesting that deep tissue damage has already occurred and additional deep tissue loss may occur. This deep tissue damage could lead to the appearance of an unavoidable Stage III or IV pressure ulcer or progression of a Stage I pressure ulcer to an ulcer with eschar or exudate within days after admission. Some situations, which may have contributed to this tissue damage, include pressure resulting from immobility during hospitalization or surgical procedures, during prolonged ambulance transport, or while waiting to be discovered or assisted after a debilitating event, such as a fall or a cerebral vascular accident.

Some evidence suggests that because it may be harder to identify erythema in an older adult with darkly pigmented skin, older individuals with darkly pigmented skin may be more at risk for developing pressure ulcers.^{13, 14, 15, 16} It may be necessary, therefore, in a darker skinned individual to focus more on other evidence of pressure ulcer development, such as boggy, induration, coolness, or increased warmth as well as signs of skin discoloration.

Multiple factors, including pressure intensity, pressure duration, and tissue tolerance, significantly affect the potential for the development and healing of pressure ulcers. An individual may also have various intrinsic risks due to aging, for example: decreased subcutaneous tissue and lean muscle mass, decreased skin elasticity, and impaired circulation or innervation.

The comprehensive assessment, which includes the Resident Assessment Instrument (RAI), evaluates the resident's intrinsic risks, the resident's skin condition, other factors (including causal factors) which place the resident at risk for developing pressure ulcers and/or experiencing delayed healing, and the nature of the pressure to which the resident may be subjected. The assessment should identify which risk factors can be removed or modified.

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.

This comprehensive assessment should address those factors that have been identified as having an impact on the development, treatment and/or healing of pressure ulcers, including, at a minimum: risk factors, pressure points, under-nutrition and hydration deficits, and moisture and the impact of moisture on skin. Each of these factors is discussed in additional detail in the following sections.

Risk Factors

Many studies and professional documents identify risk factors that increase a resident's susceptibility to develop or to not heal pressure ulcers.^{17, 18, 19} 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 wound 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*
- A healed ulcer. The history of a healed pressure ulcer and its stage [if known] is important, since areas of healed Stage III or IV pressure ulcers are more likely to have recurrent breakdown.*

Some residents have many risk factors for developing pressure ulcers, such as diabetic neuropathy, frailty, cognitive impairment, and under nutrition. Not all factors are fully modifiable and some potentially modifiable factors (e.g., under-nutrition) may not be corrected immediately, despite prompt intervention, while other factors such as pressure may be modified promptly. It may be necessary to stabilize, when possible, the underlying causes (e.g., control blood sugars or ensure adequate food and fluid intake).

Although the requirements do not mandate any specific assessment tool, other than the RAI, validated instruments are available to assess risk for developing pressure ulcers. Research has shown that a significant number of pressure ulcers develop within the first

four weeks after admission to a long term care facility.²⁰ Therefore, many clinicians recommend using a standardized pressure ulcer risk assessment tool to assess a resident's pressure ulcer risks upon admission, weekly for the first four weeks after admission for each resident at risk, then quarterly, or whenever there is a change in cognition or functional ability.^{21, 22} 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.

Regardless of any resident's total risk score, the clinicians responsible for the resident's care should review each risk factor and potential cause(s) individually²³ to: a) Identify those that increase the potential for the resident to develop pressure ulcers; b) Decide whether and to what extent the factor(s) can be modified, stabilized, removed, etc., and c) Determine whether targeted management protocols need to be implemented. In other words, an overall risk score indicating the resident is not at high risk of developing pressure ulcers does not mean that existing risk factors or causes should be considered less important or addressed less vigorously than those factors or causes in the resident whose overall score indicates he or she is at a higher risk of developing a pressure ulcer.

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 and tissue tolerance (ability of the skin and its supporting structures to endure the effects of pressure without adverse effects) after pressure to that area has been reduced or redistributed.

Tissue closest to the bone may be the first tissue to undergo necrosis. Pressure ulcers 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 on a static surface may be more prone to get ischial ulceration. Slouching in a chair may predispose an at-risk resident to pressure ulcers of the spine, scapula, or elbow (elbow ulceration is often related to arm rests or lap boards). Friction and shearing are also important factors in tissue ischemia, necrosis and pressure ulcer formation.

Pressure ulcers may develop at other sites where pressure has impaired the circulation to the tissue, such as pressure from positioning or use of medical devices. For example, pressure ulcers may develop from pressure on an ear lobe related to positioning of the head; pressure or friction on areas (e.g., nares, urinary meatus, extremities) caused by tubes, casts, orthoses, braces, cervical collars, or other medical devices; pressure on the labia or scrotum related to positioning (e.g., against a pommel type cushion); pressure on the foot related to ill-fitting shoes causing blistering; or pressure on legs, arms and fingers due to contractures or deformity resulting from rheumatoid arthritis, etc.

While pressure ulcers on the sacrum remain the most common location, pressure ulcers on the heel are occurring more frequently,²⁴ are difficult to assess and heal, and require early identification of skin compromise over the heel.

It is, therefore, important for clinical staff to regularly conduct thorough skin assessments on each resident who is at risk for developing pressure ulcers.

Under-Nutrition and Hydration Deficits

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; skin breakdown may be the most visible evidence of a general catabolic state.

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 pressure ulcer 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 pressure ulcer 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. Unless contraindicated, nutritional goals for a resident with nutritional compromise who has a pressure ulcer or is at risk of developing pressure ulcers should include protein intake of approximately 1.2-1.5 gm/kg body weight daily (higher end of the range for those with larger, more extensive, or multiple wounds). A simple multivitamin is appropriate, but unless the resident has a specific vitamin or mineral deficiency, supplementation with additional vitamins or minerals may not be indicated.

NOTE: *Although some laboratory tests may help clinicians evaluate nutritional issues in a resident with pressure ulcers, no laboratory test is specific or sensitive enough to warrant serial/repeated testing. Serum albumin, pre-albumin and cholesterol may be useful to help establish overall prognosis; however, they may not correlate well with clinical observation of nutritional status.^{25, 26} At his or her discretion, a practitioner may order test(s) that provide useful additional information or help with management of treatable conditions.*

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 with a pressure ulcer or at risk of developing an ulcer, be identified and that hydration needs be addressed.

(The surveyor should refer to the Guidance at 42 CFR 483.25 (i), F325, Nutrition, and 483.25(j), F327 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 sufficient to cite a pressure ulcer deficiency.)

Moisture and Its Impact

Both urine and feces contain substances that may irritate the epidermis and may make the skin more susceptible to breakdown. Some studies have found that fecal incontinence may pose a greater threat to skin integrity,²⁷ most likely 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 skin loss (pressure ulcer). This differentiation should be based on the clinical evidence and review of presenting risk factors. A Stage I pressure ulcer usually presents as a localized area of erythema or skin discoloration, while perineal dermatitis may appear as a more diffuse area of erythema or discoloration where the urine or stool has come into contact with the skin. The dermatitis may occur in the area where the incontinence brief or underpad has been used. Also, the dermatitis/rash more typically presents as intense erythema, scaling, itching, papules, weeping and eruptions.²⁸

INTERVENTIONS

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

In the context of the resident's choices, clinical condition, and physician input, the resident's plan of care 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 pressure ulcers. Alternatively, facility staff and practitioners should document clinically valid reasons why such interventions were not appropriate or feasible. Repeated hospitalizations or emergency room visits within a 6-month period may indicate overall decline or instability.

Resident Choice

In order for a resident to exercise his or her right appropriately to make informed choices about care and treatment or to refuse treatment, the facility and the resident (or the resident's legal 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 refused specific treatments. (See Resident Rights at 42 CFR 483.10(b)(3) and (4), F154 and F155.)

Advance Directive

A resident 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 surrogate or representative, in accordance with state law).

If a resident has a valid Advance Directive, the facility's care must reflect a resident's wishes as expressed in the Directive, 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 Advance Directive. If the facility has implemented individualized approaches for end-of-life care in accordance with the resident's wishes, and has implemented appropriate efforts to try to stabilize the resident's condition (or indicated why the condition cannot or should not be stabilized) and to provide care to prevent or treat the pressure ulcer (including pertinent, routine, lesser aggressive approaches, such as, cleaning, turning, repositioning), then the development, continuation, or progression of a pressure ulcer may be consistent with regulatory requirements.

NOTE: *The presence of a "Do Not Resuscitate" (DNR) order is not sufficient to indicate the resident is declining other appropriate treatment and services. It only indicates that the resident should not be resuscitated if respirations and/or cardiac function cease.*

Based upon the assessment and the resident's clinical condition, choices and identified needs, basic or routine care should include interventions to: a) Redistribute pressure (such as repositioning, protecting heels, etc); b) Minimize exposure to moisture and keep skin clean, especially of fecal contamination; c) Provide appropriate, pressure-redistributing, support surfaces; d) Provide non-irritating surfaces; and e) 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 pressure ulcers or for non-healing pressure ulcers (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.

Repositioning

Repositioning is a common, effective intervention for an individual with a pressure ulcer or who is at risk of developing one.^{29, 30} 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 plan of care consistent with the resident's need and goals. Repositioning is critical for a resident who is immobile or dependent upon staff for repositioning. 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 pressure ulcer should be avoided since it puts additional pressure on tissue that is already compromised and may impede healing.

Surveyors should consider the following repositioning issues:

- 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.*
- 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 tolerance of the tissue load (pressure). Depending on the individualized assessment, more frequent repositioning may be warranted for individuals who are at higher risk for pressure ulcer development or who show evidence (e.g., Stage I pressure ulcers) that repositioning at 2-hour intervals is inadequate. With rare exception (e.g., both sacral and ischial pressure ulcers 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.*
- 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.³¹ Based upon an assessment including evidence of tissue tolerance while sitting (checking for Stage I ulcers as noted above), the resident may not tolerate sitting in a chair in the same position for 1 hour at a time and may require a more frequent position change.*
- Postural alignment, weight distribution, sitting balance and stability, and pressure redistribution should all be considered when positioning a resident in a chair.³² A teachable resident should be taught to shift his/her weight*

approximately every 15 minutes while sitting in a chair.

- *Wheelchairs are often used for transporting residents, but they may severely limit repositioning options and increase the risk of pressure ulcer 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.*
- *There isn't evidence that momentary pressure relief followed by return to the same position (that is a "microshift" of five or 10 degrees or a 10-15 second lift from a seated position) is beneficial. This approach does not allow sufficient capillary refill and tissue perfusion for a resident at risk of developing pressure ulcers. Ongoing monitoring of the resident's skin integrity and tissue tolerance is critical to prevent development or deterioration of pressure ulcers.*

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 (reduction of interface pressure, not necessarily below capillary closure pressure) and pressure relief (reduction of interface pressure below capillary closure pressure).

Appropriate support surfaces or devices should be chosen by matching a device's potential therapeutic benefit with the resident's specific situation; for example, multiple ulcers, limited turning surfaces, ability to maintain position. The effectiveness of pressure redistribution devices (e.g., 4-inch convoluted foam pads, gels, 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" (completely compressing the overlay, when, for example, the caregiver can feel 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 (e.g., solid foam, convoluted foam, gel mattress) may be indicated when a resident is at risk for pressure ulcer 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.*
- *Dynamic pressure reduction surfaces may be helpful when: 1) The resident*

cannot assume a variety of positions without bearing weight on a pressure ulcer, 2) The resident completely compresses a static device that has retained its original integrity, or 3) The pressure ulcer 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.

MONITORING

At least daily, staff should remain alert to potential changes in the skin condition and should evaluate and document identified changes. For example, a resident's complaint about pain or burning at a site where there has been pressure or a nursing assistant's 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 to including prevention and management interventions with measurable goals. Many clinicians recommend evaluating skin condition (e.g., 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.

The resident should be monitored for condition changes that might increase the risk for breakdown and the defined interventions should be implemented and monitored for effectiveness.

ASSESSMENT AND TREATMENT OF PRESSURE ULCER(S)

It is important that each existing pressure ulcer be identified, whether present on admission or developed after admission, and that factors that influenced its development, the potential for development of additional ulcers or for the deterioration of the pressure ulcer(s) be recognized, assessed and addressed (see discussion under Prevention

regarding overall assessment and interventions). Any new pressure ulcer suggests a need to reevaluate the adequacy of the plan for preventing pressure ulcers.

When assessing the ulcer itself, it is important to:

- Differentiate the type of ulcer (pressure-related versus non-pressure-related) because interventions may vary depending on the specific type of ulcer;
- Determine the ulcer's stage;
- Describe and monitor the ulcer's characteristics;
- Monitor the progress toward healing and for potential complications;
- Determine if infection is present;
- Assess, treat and monitor pain, if present; and
- Monitor dressings and treatments.

TYPES OF ULCERS

Three of the more common types of ulcers are pressure, vascular insufficiency/ischemia (venous stasis and arterial ischemic ulcers) and neuropathic. See Guidance to Surveyors at 42 CFR 483.25 (F309) for definition and description of ulcer types other than pressure ulcers.

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/ulcer, location, shape, ulcer edges and wound bed, condition of surrounding tissues) for any determination that an ulcer is not pressure-related, especially if the injury/ulcer has characteristics consistent with a pressure ulcer, but is determined not to be one.

ULCER 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 pressure ulcer is present, daily monitoring, (with accompanying documentation, when a complication or change is identified), should include:

- An evaluation of the ulcer, 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 ulcer (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 pressure ulcer wound 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 ulceration), 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 accepted standards³³ (e.g., frequency, consistent distance from the wound, type of equipment used, means to assure digital images are accurate and not modified, inclusion of the resident identification/ulcer location/dates/etc. within the photographic image, and parameters for comparison).

STAGES OF PRESSURE ULCERS

The staging system is one method of summarizing certain characteristics of pressure ulcers, including the extent of tissue damage. This is the system used within the RAI.

Stage I pressure ulcers may be difficult to identify because they are not readily visible and they present with greater variability. Advanced technology (not commonly available in nursing homes) has shown that a Stage I pressure ulcer may have minimal to substantial tissue damage in layers beneath the skin's surface, even when there is no visible surface penetration. The Stage I indicators identified below will generally persist or be evident after the pressure on the area has been removed for 30-45 minutes.

The definitions for the stages of pressure ulcers identified below, are from the NPUAP and used with permission.^{3,4}

- **“Stage I”** - *An observable, pressure-related alteration of intact skin, whose indicators as compared to an adjacent or opposite area on the body may include changes in one or more of the following parameters:*
 - *Skin temperature (warmth or coolness);*
 - *Tissue consistency (firm or boggy);*
 - *Sensation (pain, itching); and/or*
 - *A defined area of persistent redness in lightly pigmented skin, whereas in darker skin tones, the ulcer may appear with persistent red, blue, or purple hues.*
- **“Stage II”** - *Partial thickness skin loss involving epidermis, dermis, or both. The ulcer is superficial and presents clinically as an abrasion, blister, or shallow crater.*
- **“Stage III”** - *Full thickness skin loss involving damage to, or necrosis of, subcutaneous tissue that may extend down to, but not through, underlying fascia. The ulcer presents clinically as a deep crater with or without undermining of adjacent tissue.*
- **“Stage IV”** - *Full thickness skin loss with extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures (e.g., tendon, joint capsule). Undermining and sinus tracts also may be associated with Stage IV pressure ulcers.*

NOTE: *If eschar and necrotic tissue are covering and preventing adequate staging of a pressure ulcer, the RAI User’s Manual Version 2 instructs the assessor to code the pressure ulcer as a Stage IV. These instructions must be followed for MDS coding purposes until they are revised. Although the AHCP and NPUAP system for*

staging pressure ulcers indicates that the presence of eschar precludes accurate staging of the ulcer, the facility must use the RAI directions in order to code the MDS, but not necessarily to render treatment.

THE HEALING PRESSURE ULCER

Ongoing evaluation and research have indicated that pressure ulcers do not heal in a reverse sequence, that is, the body does not replace the types and layers of tissue (e.g., muscle, fat and dermis) that were lost during the pressure ulcer development.

There are different types of clinical documentation to describe the progression of the healing pressure ulcer(s). The regulation at 42 CFR 483.20(b)(1), F272, requires that facilities use the Resident Assessment Instrument (RAI), which includes direction to describe the healing of the pressure ulcer(s) for coding purposes for the MDS: The RAI User's Manual Version 2.0, instructs staff to identify the stages of pressure ulcer(s) by describing depth in reverse order from deepest to lesser stages to describe the healing or improvement of a pressure ulcer (e.g., a Stage IV becomes a Stage III and so forth. This has been referred to as "reverse staging" or "back staging").

Some clinicians utilize validated instruments to describe the healing of a pressure ulcer. Although such instruments are appropriate for making treatment decisions, they may not be utilized for coding the MDS. Until the MDS is revised, the present coding system (reverse staging) must be used for completion of the RAI.

Clinicians may use the National Pressure Ulcer Advisory Panel - Pressure Ulcer Scale for Healing (NPUAP-PUSH) tool. The NPUAP always refers to a healed pressure ulcer as a healed ulcer at the deepest stage of its development (e.g., a healed Stage IV or a healing Stage IV). The NPUAP cautions that the tool does not represent a comprehensive pressure ulcer assessment, and other factors may need to be considered when selecting pressure ulcer treatment options.

Since surveyors may encounter clinician's notes in which the NPUAP-PUSH tool is used as part of the facility's documentation protocol, the following description of the tool is provided. The NPUAP-PUSH tool documents pressure ulcer healing consistent with the healing process, describes a healing pressure ulcer in terms of three ulcer characteristics, and assigns a numeric value to the characteristics: length (cm) x width (cm), exudate amount, and type of tissue (closed with epithelium; new pink, shiny epithelial tissue; clean, pink or beefy red, shiny, moist granulation tissue; slough tissue; or necrotic, eschar tissue).

The 1994 AHCPH Guidelines and current literature³⁵ indicate that a clean pressure ulcer with adequate blood supply and innervation should show evidence of stabilization or some healing within 2-4 weeks. Evidence accumulating since 1962 indicates that management of wound exudate coupled with a clean, moist wound environment allows a chronic wound (e.g., pressure ulcer) to lay down healthy granulating tissue more

efficiently.^{36, 37}

If a pressure ulcer fails to show some evidence of progress toward healing within 2-4 weeks, the pressure ulcer (including potential complications) and the resident's overall clinical condition should be reassessed. Re-evaluation of the treatment plan including determining whether to continue or modify the current interventions is also indicated. Results may vary depending on the resident's 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 (for example, why some, or all, of the plan's interventions remain relevant despite little or no apparent healing).

Pressure ulcers 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 pressure ulcer itself. The physician's involvement is integral whenever significant changes in the nature of the wound or overall resident condition are identified.

INFECTIONS RELATED TO PRESSURE ULCERS

Current literature reports that all Stage II, III, and IV pressure ulcers are colonized with bacteria but may not be infected. Identification, diagnosis and treatment of infection, when present, are critical to healing a pressure ulcer.³⁸ The infection occurs when the bacteria have invaded the tissue surrounding or within the pressure ulcer.

As with any infection, classic signs and symptoms of infection may include purulent exudate, peri-wound warmth, swelling, induration or erythema (erythema may not be readily determined in individuals with dark skin pigmentation), increasing pain or tenderness around the site or delayed wound healing. These classic signs may not be as evident in someone with a granulating, chronic wound or an immuno-compromised or aged resident. Some infections may present primarily with pain or delayed healing without other typical clinical signs of infection.³⁹ Clinicians have developed some tools, which may facilitate identifying and assessing an infection^{40, 41} and documenting progress toward healing.

Wounds may be classified as infected if the signs and symptoms of infection are present and/or a wound culture (obtained in accord with accepted standards, such as sterile tissue aspirate, a "quantitative surface swab" using the Levine technique or semi-quantitative swab) contains 100,000 (10^5) or greater micro-organisms per gram of tissue. A superficial swab may show the presence of bacteria, but is not a reliable method to identify infection.

Findings such as an elevated white blood cell count, bacteremia, sepsis, or fever may

signal an infection related to a pressure ulcer area or a co-existing infection from a different source.

PAIN

The assessment and treatment of a resident's pain are integral components of pressure ulcer prevention and management. "The goal of pain management in the pressure ulcer patient is to eliminate the cause of pain, to provide analgesia, or both."⁴² Pain that interferes with movement and/or affects mood may contribute to immobility and contribute to the potential for developing a pressure ulcer or for delayed healing or non-healing of an already existing ulcer.

It may be difficult to assess the degree of pain in a resident who is cognitively impaired. Some strategies and tools exist to help determine the presence and characteristics of pain (e.g., nature, intensity and frequency).^{43, 44} Recent research suggests that a resident with a Stage IV pressure ulcer can feel as much pain as those with a Stage I or II ulcer.⁴⁵ The relationship of pain to the pressure ulcer healing process is not yet clear. Pain is an individual perception and response and an individual's report of pain is a generally valid indicator of pain. One resident may experience pain of varying intensity and frequency (e.g., continually or periodically) or episodically in association with treatments (e.g., debridement, dressing changes) or movement or infection, while another resident may not have or report pain.

DRESSINGS AND TREATMENTS

Research has found that chronic wounds such as pressure ulcers heal differently from acute wounds, primarily because of differing biochemical and cellular characteristics. Current clinical practice indicates that Stage III and Stage IV ulcers should be covered. Determination of the need for a dressing for a Stage I or Stage II ulcer is based upon the individual practitioner's clinical judgment and facility protocols based upon current clinical standards of practice. No particular dressing promotes healing of all pressure ulcers within an ulcer classification.⁴⁶

For those pressure ulcers with significant exudate, management of the exudate is critical for healing. A balance is needed to assure that the wound is moist enough to support healing but not too moist to interfere with healing.⁴⁷ Since excess wound exudate generally impairs wound healing, selecting an appropriate absorptive dressing is an important part of managing chronic wound exudate.

Product selection should be based upon the relevance of the specific product to the identified pressure ulcer(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 pressure ulcers. 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.

Present literature suggests that pressure ulcer 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.⁴⁸

Debridement of non-viable tissue is frequently performed to reduce the amount of wound debris or non-viable tissue and to reduce the risk of sepsis. A variety of debridement methods (e.g., mechanical, sharp or surgical, enzymatic, autolytic, MDT) are available. Removal of necrotic tissue should enhance wound healing. Ongoing monitoring (and timely intervention in case of change in the character of the wound) is critical for areas with eschar and those areas that have been debrided.⁴⁹ Many clinicians believe that stable, dry, adherent and intact eschar on the foot/heel should not be debrided, unless signs and symptoms of local infection or instability are detected.⁵⁰

Some facilities may use “wet to dry gauze dressings” or irrigation with chemical solutions to remove slough. The use of wet-to-dry dressings or irrigations may be appropriate in limited circumstances, but repeated use may damage healthy granulation tissue in healing ulcers and may lead to excessive bleeding and increased resident pain.

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

ENDNOTES

(For more information on the references below, visit the CMS Sharing Innovations in Quality website: www.cms.hhs.gov/medicaid/survey-cert/siqhome.asp.)

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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:*
 - *If erythema or color change are noted, return approximately ½ - ¾ hours later to determine if the changes or other Stage I characteristics persist;*
 - *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 non-compliance in either or both aspects of this requirement.

Criteria for Compliance

- *Compliance with 42 CFR 483.25(c)(1), F314, Pressure Sore*
 - *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*
 - *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 osteomyelitis 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.

