The NPUAP selected “Quality of Care Regulations” made easy:
F-tag 314 – Pressure Ulcers
F-tag 315 – Urinary Incontinence
F-tag 322 – Naso-Gastric Tubes
F-tag 325 – Nutrition
F-tag 327 – Hydration
INTRODUCTION

Federal regulations for nursing homes are commonly referred to as F-tags. There are approximately 171 F-tags. The F-tags are broken down into 15 categories.

One of these categories is “Quality of Care” category which containing 21 F-tags. Five of which address pressure ulcers and nutrition:

1. 314-Pressure Ulcers
2. 315-Incontinence
3. 322-Naso Gastric tubes
4. 325-Nutrition
5. 327-Hydration

Each of the five F-tags is divided into nine sections:

1. Definition
2. Overview
3. Assessment
4. Interventions
5. Investigative Protocols
6. Determination of Compliance
7. Deficiency Citations
8. MDS Section
9. CMS References.

This publication has been developed as an attempt to simplify what can seem like a very over burdensome issue.

The information in this publication is current at the time of publication (1-••-2014). Updates are continual. The State Operations Manual Guidance to Surveyors for Long Term Care Facilities has had seventy revisions since January 7, 2011. Further updates and revisions can be found at www.guideline.gov.

We hope this publication will enable you to find the answers you are looking for in the above five “Quality of Care” F-tags for pressure ulcers and nutrition.

We hope this publication will simplify and make it much easier for you to find the answer you are looking for in the Quality of Care tags for Pressure ulcers and nutrition.

NPUAP F-tag committee:
Karen Lou Kennedy-Evans       Karen Zulkowski
Mary Litchford                 Nancy Munoz
Michelle Deppisch
Thank you.

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1. F 314 Pressure ulcers

TAG F 314 (§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.

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

(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

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

INTENT (F 314) 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:

**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.

**Pressure Ulcer** A pressure ulcer is any lesion caused by unrelieved pressure that results in damage to the underlying tissue(s). 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.

**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.

**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.

**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.
- **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.

**Colonized/Infected Wound**

- **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** the removal of devitalized/necrotic tissue and foreign matter from a wound to improve or facilitate the healing process. 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.

**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** 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** 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.

**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.

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**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);
- 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 following websites:

- The Clinical Practice Guidelines from the Agency for Healthcare Research and Quality (AHRQ) [www.ahrq.gov](http://www.ahrq.gov) (Guideline No. 15: Treatment of Pressure Ulcers and Guideline No.3: Pressure Ulcers in Adults: Prediction and Prevention)(Note: AHRQ was previously known as the Agency for Health Care Policy and Research [AHCPR]);
- The National Pressure Ulcer Advisory Panel (NPUAP) [www.npuap.org](http://www.npuap.org)
- The American Medical Directors Association (AMDA) [www.amda.com](http://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](http://www.medqic.org)
- The Wound, Ostomy, and Continence Nurses Society (WOCN) [www.wocn.org](http://www.wocn.org)

**NOTE:** References to non-CMS sources or websites 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 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, 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) 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. It may be necessary, therefore, in a darker skinned individual to focus more on other evidence of pressure ulcer development, such as bogginess, 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
determination 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.
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.
Therefore, many clinicians recommend using a standardized pressure ulcer risk
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. 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) individually
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

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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, 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 issue in a resident with pressure ulcers, no laboratory test is specific or sensitive enough to warrant serial/repeated testing. Serum albumin, prealbumin and cholesterol may be useful to help establish overall prognosis; however, they may not correlate well with clinical observation of nutritional status. 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, 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.

**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);
  - 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 standards (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.

**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 AHCPR 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.

**Healing of pressure ulcers** 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 AHCPR Guidelines and current literature 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.

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. 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. Clinicians have developed some tools, which may facilitate identifying and assessing an infection 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 microorganisms per gram of tissue. A superficial swab may show the presence of bacteria, but is not a reliable method to identify infection.

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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.” 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). 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. 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.

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. 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.

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. 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.

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.

**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.

Additional interventions. 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. 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 1 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. 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. 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

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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. NOTE: Static and dynamic are terms that were changed under the NPUAP S3I. (See NPUAP website for details)

- 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.

**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** 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;
- 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;
- 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;
• 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:

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• 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
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
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;
  ▪ Revised the approaches as appropriate.
If not, the development of the pressure ulcer is avoidable, cite at F314.
Compliance with F314 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:

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• 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 with 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;
• 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:

1) 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.

2) **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.

3) **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 pressure ulcers.

4) **FR 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.

5) **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.

6) **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.

7) **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.

8) **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.

9) **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).

**DEFICIENCY CATEGORIZATION**

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 noncompliance 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:

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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);
- 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.

1. **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;
   - 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.

2. **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.

**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.

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**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.

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**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.
### Section M  Skin Conditions

**Report based on highest stage of existing ulcer(s) at its worst; do not "reverse" stage**

#### M0100. Determination of Pressure Ulcer Risk

- Check all that apply
- A. Resident has a stage 1 or greater, a scar over bony prominence, or a non-removable dressing/device
- B. Formal assessment instrument/tool (e.g., Braden, Norton, or other)
- C. Clinical assessment
- D. None of the above

#### M0150. Risk of Pressure Ulcers

- Enter Code
- a. Is this resident at risk of developing pressure ulcers?
  - 0. No
  - 1. Yes

#### M0210. Unhealed Pressure Ulcer(s)

- Enter Code
- Does this resident have one or more unhealed pressure ulcer(s) at Stage 1 or higher?
  - 0. No — Skip to M0000, Healed Pressure Ulcers
  - 1. Yes — Continue to M0300, Current Number of Unhealed (non-epithelialized) Pressure Ulcers at Each Stage

#### M0300. Current Number of Unhealed (non-epithelialized) Pressure Ulcers at Each Stage

- Enter Code
- A. Number of Stage 1 pressure ulcers
  - Stage 1: Intact skin with non-blanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have a visible blanching. In dark skin tones only it may appear with persistent blue or purple hues

- Enter Code
- B. Stage 2: Partial thickness loss of dermis presenting as a shallow open ulcer with a red or pink wound bed, without slough. May also present as an intact or open/ruptured blister

- Enter Code
- 1. Number of Stage 2 pressure ulcers - If 0 — Skip to M0300C, Stage 3

- Enter Code
- 2. Number of these Stage 2 pressure ulcers that were present upon admission/reentry - enter how many were noted at the time of admission

- Enter Code
- 3. Date of oldest Stage 2 pressure ulcer - Enter dashes if date is unknown:
  
  Month — Day — Year

- Enter Code
- C. Stage 3: Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscle is not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunneling

- Enter Code
- 1. Number of Stage 3 pressure ulcers - If 0 — Skip to M0300D, Stage 4

- Enter Code
- 2. Number of these Stage 3 pressure ulcers that were present upon admission/reentry - enter how many were noted at the time of admission

- Enter Code
- D. Stage 4: Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present on some parts of the wound bed. Often includes undermining and tunneling

- Enter Code
- 1. Number of Stage 4 pressure ulcers - If 0 — Skip to M0300E, Unstageable: Non-removable dressing

- Enter Code
- 2. Number of these Stage 4 pressure ulcers that were present upon admission/reentry - enter how many were noted at the time of admission

**M0300 continued on next page**

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## Section M
### Skin Conditions

**M0300. Current Number of Unhealed (non-epithelialized) Pressure Ulcers at Each Stage - Continued**

<table>
<thead>
<tr>
<th>E. Unstageable - Non-removable dressing: Known but not stageable due to non-removable dressing/device</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Number of unstageable pressure ulcers due to non-removable dressing/device - If 0 → Skip to M0300F, Unstageable: Slough and/or eschar</td>
</tr>
<tr>
<td>2. Number of these unstageable pressure ulcers that were present upon admission/admittance - enter how many were noted at the time of admission</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>F. Unstageable - Slough and/or eschar: Known but not stageable due to coverage of wound bed by slough and/or eschar</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Number of unstageable pressure ulcers due to coverage of wound bed by slough and/or eschar - If 0 → Skip to M0300G, Unstageable: Deep tissue</td>
</tr>
<tr>
<td>2. Number of these unstageable pressure ulcers that were present upon admission/admittance - enter how many were noted at the time of admission</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>G. Unstageable - Deep tissue: Suspected deep tissue injury in evolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Number of unstageable pressure ulcers with suspected deep tissue injury in evolution - If 0 → Skip to M0610, Dimension of Unhealed Stage 3 or 4 Pressure Ulcers or Eschar</td>
</tr>
<tr>
<td>2. Number of these unstageable pressure ulcers that were present upon admission/admittance - enter how many were noted at the time of admission</td>
</tr>
</tbody>
</table>

**M0610. Dimensions of Unhealed Stage 3 or 4 Pressure Ulcers or Eschar**

Complete only if M0300C1, M0300D1 or M0300F1 is greater than 0

If the resident has one or more unhealed (non-epithelialized) Stage 3 or 4 pressure ulcers or an unstageable pressure ulcer due to slough or eschar, identify the pressure ulcer with the largest surface area (length x width) and record in centimeters:

<table>
<thead>
<tr>
<th>A. Pressure ulcer length: Longest length from head to toe</th>
</tr>
</thead>
<tbody>
<tr>
<td>B. Pressure ulcer width: Widest width of the same pressure ulcer, side-to-side perpendicular (90-degree angle) to length</td>
</tr>
<tr>
<td>C. Pressure ulcer depth: Depth of the same pressure ulcer from the visible surface to the deepest area (if depth is unknown, enter a dash in each box)</td>
</tr>
</tbody>
</table>

**M0700. Most Severe Tissue Type for Any Pressure Ulcer**

Select the best description of the most severe type of tissue present in any pressure ulcer bed

1. **Epithelial tissue** - new skin growing in superficial ulcer. It can be light pink and shiny, even in persons with darkly pigmented skin
2. **Granulation tissue** - pink or red tissue with shiny, moist, granular appearance
3. Slough - yellow or white tissue that adheres to the ulcer bed in strings or thick clumps, or is mucus
4. Necrotic tissue (Eschar) - black, brown, or tan tissue that adheres firmly to the wound bed or ulcer edges, may be softer or harder than surrounding skin

**M0800. Worsening in Pressure Ulcer Status Since Prior Assessment (OBRA, PPS, or Discharge)**

Complete only if A0310E = 0

Indicate the number of current pressure ulcers that were not present or were at a lesser stage on prior assessment (OBRA, PPS, or Discharge), if no current pressure ulcer at a given stage, enter 0

<table>
<thead>
<tr>
<th>A. Stage 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>B. Stage 3</td>
</tr>
<tr>
<td>C. Stage 4</td>
</tr>
</tbody>
</table>
### Section M  
#### Skin Conditions

**M0900. Healed Pressure Ulcers**  
Complete only if A0310E = 0

- **A. Were pressure ulcers present on the prior assessment (OBRA, PPS, or Discharge)?**
  - No: Skip to M1030, Number of Venous and Arterial Ulcers
  - Yes: Continue to M0900, Stage

  Indicate the number of pressure ulcers that were noted on the prior assessment (OBRA, PPS, or Discharge) that have completely closed (resurfacied with epithelium). If no healed pressure ulcer at a given stage since the prior assessment (OBRA, PPS, or Discharge), enter 0

- **B. Stage 2**

- **C. Stage 3**

- **D. Stage 4**

**M1030. Number of Venous and Arterial Ulcers**

Enter the total number of venous and arterial ulcers present.

**M1040. Other Ulcers, Wounds and Skin Problems**

Check all that apply

- **Foot Problems**
  - A. Infection of the foot (e.g., cellulitis, purulent drainage)
  - B. Diabetic foot ulcer(s)
  - C. Other open lesion(s) on the foot

- **Other Problems**
  - D. Open lesion(s) other than ulcers, rashes, cuts (e.g., cancer lesion)
  - E. Surgical wound(s)
  - F. Burn(s) (second or third degree)
  - None of the Above
  - Z. None of the above were present

**M1200. Skin and Ulcer Treatments**

Check all that apply

- A. Pressure reducing device for chair
- B. Pressure reducing device for bed
- C. Turning/repositioning program
- D. Nutrition or hydration intervention to manage skin problems
- E. Ulcer care
- F. Surgical wound care
- G. Application of nonsurgical dressings (with or without topical medications) other than to feet
- H. Applications of ointments/medications other than to feet
- I. Application of dressings to feet (with or without topical medications)
- Z. None of the above were provided
REFERENCES


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2. F315 Urinary Incontinence

1) A resident who enters the facility without an indwelling catheter is not catheterized unless the resident’s clinical condition demonstrates that catheterization was necessary 483.25(d) and

2) A resident who is incontinent of bladder receives appropriate treatment and services to prevent urinary tract infections and to restore as much normal bladder function as possible. §483.25(d)

**INTENT**: CFR 483.25 (d) (1) and (2) Urinary Incontinence and Catheters

The intent of this requirement is to ensure that:

- Each resident who is incontinent of urine is identified, assessed and provided appropriate treatment and services to achieve or maintain as much normal urinary function as possible;
- An indwelling catheter is not used unless there is valid medical justification;
- An indwelling catheter for which continuing use is not medically justified is discontinued as soon as clinically warranted;
- Services are provided to restore or improve normal bladder function to the extent possible, after the removal of the catheter;
- A resident, with or without a catheter, receives the appropriate care and services to prevent infections to the extent possible.

Urinary Incontinence requires that a resident who is incontinent of bladder receives appropriate treatment and services to prevent urinary tract infections and to restore as much normal bladder function as possible.

Urinary incontinence generally involves a number of transitory or chronic progressive factors that affect the bladder and/or the urethral sphincter. Any condition, medication, or factor that affects lower urinary tract function, bladder capacity, urination, or the ability to toilet can predispose residents to urinary incontinence and may contribute to incomplete bladder emptying.

The first steps toward assuring that a resident receives appropriate treatment and services to restore as much bladder function as possible or to treat and manage the incontinence are to identify the resident already experiencing some level of incontinence or at risk of developing urinary incontinence and to complete an accurate, thorough assessment of factors that may predispose the resident to having urinary incontinence. This is followed by implementing appropriate, individualized interventions that address the incontinence, including the resident’s capabilities and underlying factors that can be removed, modified, or stabilized, and by monitoring the effectiveness of the interventions and modifying them, as appropriate. The practitioner, may at his or her option, refer residents to various practitioners who specialize in diagnosing and treating conditions that affect urinary function.

**DEFINITIONS**

- **Bacteremia** is defined as the presence of bacteria in the bloodstream.
- **Urinary Incontinence** the involuntary loss or leakage of urine. There are several types of urinary incontinence, and the individual resident may experience more than
Identifying the nature of the incontinence is a key aspect of the assessment and helps identify the appropriate program/interventions to address incontinence. Types include:

**Functional Incontinence** refers to loss of urine that occurs in residents whose urinary tract function is sufficiently intact that they should be able to maintain continence, but who cannot remain continent because of external factors (e.g., inability to utilize the toilet facilities in time); Functional Incontinence refers to incontinence that is secondary to factors other than inherently abnormal urinary tract function. It may be related to physical weakness or poor mobility/dexterity (e.g., due to poor eyesight, arthritis, deconditioning, stroke, contracture), cognitive problems (e.g., confusion, dementia, unwillingness to toilet), various medications (e.g., anti-cholinergics, diuretics) or environmental impediments (e.g., excessive distance of the resident from the toilet facilities, poor lighting, low chairs that are difficult to get out of, physical restraints and toilets that are difficult to access). Refer to 42 CFR 483.15(e) (1) for issues regarding unmet environmental needs (e.g., handicap toilet, lighting, assistive devices).

**NOTE:** Treating the physiological causes of incontinence, without attending to functional components that may have an impact on the resident’s continence, may fail to solve the incontinence problem.

**Mixed Incontinence** is the combination of stress incontinence and urge incontinence; Many elderly persons (especially women) will experience symptoms of both urge and stress called mixed incontinence.

**Overflow Incontinence** is associated with leakage of small amounts of urine when the bladder has reached its maximum capacity and has become distended; Overflow Incontinence occurs when the bladder is distended from urine retention. Symptoms of overflow incontinence may include: weak stream, hesitancy, or intermittency; dysuria; nocturia; frequency; incomplete voiding; frequent or constant dribbling. Urine retention may result from outlet obstruction (e.g., benign prostatic hypertrophy (BPH), prostate cancer, and urethral stricture), hypotonic bladder (detrusor under activity) or both. Hypotonic bladder may be caused by outlet obstruction, impaired or absent contractility of the bladder (neurogenic bladder) or other causes. Neurogenic bladder may also result from neurological conditions such as diabetes mellitus, spinal cord injury, or pelvic nerve damage from surgery or radiation therapy. In overflow incontinence, post void residual (PVR) volume (the amount of urine remaining in the bladder within 5 to 10 minutes following urination) exceeds 200 milliliters (ml). Normal PVR is usually 50 ml. or less. A PVR of 150 to 200 may suggest a need for retesting to determine if this finding is clinically significant. Overflow incontinence may mimic urge or stress incontinence but is less common than either of those.

**Stress Incontinence** (outlet incompetence) is associated with impaired urethral closure (malfuction of the urethral sphincter) which allows small amounts of urine leakage when intra-abdominal pressure on the bladder is increased by sneezing, coughing, laughing, lifting, standing from a sitting position, climbing stairs, etc.; Stress Incontinence is the loss of a small amount of urine with physical activity such as coughing, sneezing, laughing, walking stairs or lifting. Urine leakage results from an increase in intra-
abdominal pressure on a bladder that is not over distended and is not the result of detrusor contractions. It is the second most common type of urinary incontinence in older women.

**Transient Incontinence** refers to temporary episodes of urinary incontinence that are reversible once the cause(s) of the episode(s) is (are) identified and treated. Transient Incontinence refers to temporary or occasional incontinence that may be related to a variety of causes, for example: delirium, infection, atrophic urethritis or vaginitis, some pharmaceuticals (such as sedatives/hypnotics, diuretics, anticholinergic agents), increased urine production, restricted mobility or fecal impaction. The incontinence is transient because it is related to a potentially improvable or reversible cause.

**Urge Incontinence** (overactive bladder) is associated with detrusor muscle overactivity (excessive contraction of the smooth muscle in the wall of the urinary bladder resulting in a sudden, strong urge (also known as urgency) to expel moderate to large amounts of urine before the bladder is full). Urge Incontinence is characterized by abrupt urgency, frequency, and nocturia (part of the overactive bladder diagnosis). It may be age-related or have neurological causes (e.g., stroke, diabetes mellitus, Parkinson’s Disease, multiple sclerosis) or other causes such as bladder infection, urethral irritation, etc. The resident can feel the need to void, but is unable to inhibit voiding long enough to reach and sit on the commode. It is the most common cause of urinary incontinence in elderly persons.

**Urinary Retention** is the inability to completely empty the urinary bladder by micturition.

**Urinary Tract Infection** (UTI) is a clinically detectable condition associated with invasion by disease causing microorganisms of some part of the urinary tract, including the urethra (urethritis), bladder (cystitis), ureters (ureteritis), and/or kidney (pyelonephritis). An infection of the urethra or bladder is classified as a lower tract UTI and infection involving the ureter or kidney is classified as an upper tract UTI.

**Urosepsis** refers to the systemic inflammatory response to infection (sepsis) that appears to originate from a urinary tract source. It may present with symptoms such as fever, hypotension, reduced urine output, or acute change in mental status.

**OVERVIEW**

Urinary incontinence is not normal. Although aging affects the urinary tract and increases the potential for urinary incontinence, urinary incontinence is not a normal part of aging. In the younger person, urinary incontinence may result from a single cause. In the older individual, urinary incontinence generally involves psychological, physiological, pharmacological and/or pathological factors or co-morbid conditions (e.g., later stages of dementia, diabetes, prostatectomy, medical conditions involving dysfunction of the central nervous system, urinary tract infections, etc.). Because urinary incontinence is a symptom of a condition and may be reversible, it is important to understand the causes and to address incontinence to the extent possible. If the underlying condition is not reversible, it is important to treat or manage the incontinence to try to reduce complications.
Many older adults are incontinent of urine prior to admission to a nursing home. Urinary incontinence and related loss of independence are prominent reasons for a nursing home admission. Articles and data currently available, including CMS data (e.g., MDS Active Resident Information Report (Item H1b) at www.cms.hhs.gov/states/mdsreports, indicate that more than 50% of the nursing home population experience some degree of urinary incontinence. Whether the resident is incontinent of urine on admission or develops incontinence after admission, the steps of assessment, monitoring, reviewing, and revising approaches to care (as needed) are essential to managing urinary incontinence and to restoring as much normal bladder function as possible.

Various conditions or situations may aggravate the severity of urinary incontinence in nursing home residents. In addition, urinary incontinence may be associated with changes in skin integrity, skin irritation or breakdown, urinary tract infections, falls and fractures, sleep disturbances, and psychosocial complications including social withdrawal, embarrassment, loss of dignity, feelings of isolation, and interference with participation in activities.

Various factors common to elderly individuals may increase the risk of infection including: underlying diseases (e.g., diabetes mellitus), medications that affect immune responses to infection (e.g., steroids and chemotherapy, history of multiple antibiotic usage), conditions that cause incontinence, and indwelling urinary catheters.

The urinary tract is a common source of bacteremia in nursing home residents. Urinary tract infection (UTI) is one of the most common infections occurring in nursing homes and is often related to an indwelling urinary catheter. Without a valid clinical rationale for an indwelling catheter, its use is not an acceptable approach to manage urinary incontinence. Although UTIs can result from the resident’s own flora, they may also be the result of microorganisms transmitted by staff when handling the urinary catheter drainage system and/or providing incontinence care. Hand washing remains one of the most effective infection control tools available.

**ASSESSMENT**

Factors contributing to urinary incontinence sometimes may be resolved after a careful examination and review of history. In addition, for a resident who is incontinent of urine, determining the type of urinary incontinence can allow staff to provide more individualized programming or interventions to enhance the resident’s quality of life and functional status. A resident should be evaluated at admission and whenever there is a change in cognition, physical ability, or urinary tract function. This evaluation is to include identification of individuals with reversible and irreversible (e.g., bladder tumors and spinal cord disease) causes of incontinence. If the resident has urinary incontinence that has already been investigated, documented, and determined to be irreversible or not significantly improvable, additional studies may be of limited value, unless there has been advancement in available treatments.

Documentation of assessment information may be found throughout the medical record, such as in an admission assessment, hospital records, history and physical, and the Resident Assessment Instrument (RAI). The location of RAI assessment information is identified on the Resident Assessment Protocol (RAP)
summary form. It is important that staff, when completing the comprehensive assessment, consider the following:

- Prior history of urinary incontinence, including onset, duration and characteristics, precipitants of urinary incontinence, associated symptoms (e.g., dysuria, polyuria, hesitancy) and previous treatment and/or management, including the response to the interventions and the occurrence of persistent or recurrent UTI;
- Voiding patterns (such as frequency, volume, nighttime or daytime, quality of stream) and, for those already experiencing urinary incontinence, voiding patterns over several days;
- Medication review, particularly those that might affect continence, such as medications with anticholinergic properties (may cause urinary retention and possible overflow incontinence), sedative/hypnotics (may cause sedation leading to functional incontinence), diuretics (may cause urgency, frequency, overflow incontinence), narcotics, alpha-adrenergic agonists (may cause urinary retention in men) or antagonists (may cause stress incontinence in women) calcium channel blockers (may cause urinary retention);
- Patterns of fluid intake, such as amounts, time of day, alterations and potential complications, such as decreased or increased urine output;
- Use of urinary tract stimulants or irritants (e.g., frequent caffeine intake);
- Pelvic and rectal examination to identify physical features that may directly affect urinary incontinence, such as prolapsed uterus or bladder, prostate enlargement, significant constipation or fecal impaction, use of a urinary catheter, atrophic vaginitis, distended bladder, or bladder spasms;
- Functional and cognitive capabilities that could enhance urinary continence and limitations that could adversely affect continence, such as impaired cognitive function or dementia, impaired immobility, decreased manual dexterity, the need for task segmentation, decreased upper and lower extremity muscle strength, decreased vision, pain with movement;
- Type and frequency of physical assistance necessary to assist the resident to access the toilet, commode, urinal, etc. and the types of prompting needed to encourage urination;
- Pertinent diagnoses such as congestive heart failure, stroke, diabetes mellitus, obesity, and neurological disorders (e.g., Multiple Sclerosis, Parkinson’s Disease or tumors that could affect the urinary tract or its function);
- Identification of and/or potential of developing complications such as skin irritation or breakdown;
- Tests or studies indicated to identify the type(s) of urinary incontinence (e.g., post-void residual(s) for residents who have, or are at risk of, urinary retention, results of any urine culture if the resident has clinically significant systemic or urinary symptoms), or evaluations assessing the resident’s readiness for bladder rehabilitation programs;
- Environmental factors and assistive devices that may restrict or facilitate a resident's ability to access the toilet (e.g., grab bars, raised or low toilet seats, inadequate lighting, distance to toilet or bedside commodes, availability of urinals, use of bed rails or restraints, or fear of falling).
INTERVENTIONS

It is important that the facility follow the care process (accurate assessment, care planning, consistent implementation and monitoring of the care plan with evaluation of the effectiveness of the interventions, and revision, as appropriate). Recording and evaluating specific information (such as frequency and times of incontinence and toileting and response to specific interventions) is important for determining progress, changes, or decline.

A number of factors may contribute to the decline or lack of improvement in urinary continence, for example: underlying medical conditions, an inaccurate assessment of the resident’s type of incontinence (or lack of knowledge about the resident’s voiding patterns) may contribute to inappropriate interventions or unnecessary use of an indwelling catheter. Facility practices that may promote achieving the highest practicable level of functioning, may prevent or minimize a decline or lack of improvement in degree of continence include providing treatment and services to address factors that are potentially modifiable, such as:

- Managing pain and/or providing adaptive equipment to improve function for residents suffering from arthritis, contractures, neurological impairments, etc;
- Removing or improving environmental impediments that affect the resident’s level of continence (e.g., improved lighting, use of a bedside commode or reducing the distance to the toilet);
- Treating underlying conditions that have a potentially negative impact on the degree of continence (e.g., delirium causing urinary incontinence related to acute confusion);
- Possibly adjusting medications affecting continence (e.g., medication cessation, dose reduction, selection of an alternate medication, change in time of administration);
- Implementing a fluid and/or bowel management program to meet the assessed needs.

Options for managing urinary incontinence in nursing home residents include primarily behavioral programs and medication therapy. Other measures and supportive devices used in the management of urinary incontinence and/or urinary retention may include intermittent catheterization; pelvic organ support devices (pessaries); the use of incontinence products, garments and an external collection system for men and women; and environmental accommodation and/or modification.

Behavioral programs - Interventions involving the use of behavioral programs are among the least invasive approaches to address urinary incontinence and have no known adverse complications. Behavior programs involve efforts to modify the resident’s behavior and/or environment. Critical aspects of a successful behavioral program include education of the caregiver and the resident, availability of the staff and the consistent implementation of the interventions.

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NOTE: It is important for the comprehensive assessment to identify the essential skills the resident must possess to be successful with specific interventions being attempted. These skills include the resident’s ability to: comprehend and follow through on education and instructions; identify urinary urge sensation; learn to inhibit or control the urge to void until reaching a toilet; contract the pelvic floor muscle (Kegel exercises) to lessen urgency and/or urinary leakage; and/or respond to prompts to void. Voiding records help detect urinary patterns or intervals between incontinence episodes and facilitate planning care to avoid or reduce the frequency of episodes.

Programs that require the resident’s cooperation and motivation in order for learning and practice to occur include the following:  
Bladder Rehabilitation/Bladder Retraining is a behavioral technique that requires the resident to resist or inhibit the sensation of urgency (the strong desire to urinate), to postpone or delay voiding, and to urinate according to a timetable rather than to the urge to void. Depending upon the resident’s successful ability to control the urge to void, the intervals between voiding may be increased progressively. Bladder training generally consists of education, scheduled voiding with systematic delay of voiding, and positive reinforcement.

This program is difficult to implement in cognitively impaired residents and may not be successful in frail, elderly, or dependent residents. The resident who may be appropriate for a bladder rehabilitation (retraining) program is usually fairly independent in activities of daily living, has occasional incontinence, is aware of the need to urinate (void), may wear incontinence products for episodic urine leakage, and has a goal to maintain his/her highest level of continence and decrease urine leakage. Successful bladder retraining usually takes at least several weeks.

Residents who are assessed with urge or mixed incontinence and are cognitively intact may be candidates for bladder retraining;  
Pelvic Floor Muscle Rehabilitation, also called Kegel and pelvic floor muscle exercise, is performed to strengthen the voluntary periurethral and perivaginal muscles that contribute to the closing force of the urethra and the support of the pelvic organs. These exercises are helpful in dealing with urge and stress incontinence. Pelvic floor muscle exercises (PFME) strengthen the muscular components of urethral supports and are the cornerstone of noninvasive treatment of stress urinary incontinence. PFME requires residents who are able and willing to participate and the implementation of careful instructions and monitoring provided by the facility. Poor resident adherence to the exercises may occur even with close monitoring.

• Programs that are dependent on staff involvement and assistance, as opposed to resident function, include the following:  
Prompted Voiding is a behavioral technique appropriate for use with dependent or more cognitively impaired residents. Prompted voiding techniques have been shown to reduce urinary incontinence episodes up to 40% for elderly incontinent nursing home residents, regardless of their type of urinary incontinence or cognitive deficit—provided that they at least are able to say their name or reliably point to one of two objects. Prompted voiding has three components: regular monitoring with encouragement to report continence status; prompting to toilet on a scheduled basis; and praise and positive feedback when the resident is continent and attempts
to toilet. These methods require training, motivation and continued effort by the resident and caregivers to ensure continued success. Prompted voiding focuses on teaching the resident, who is incontinent, to recognize bladder fullness or the need to void, to ask for help, or to respond when prompted to toilet.

- Residents who are assessed with urge or mixed incontinence and are cognitively impaired may be candidates for prompted voiding. As the resident's cognition changes, the facility should consider other factors, such as mobility, when deciding to conduct a voiding trial to determine feasibility of an ongoing toileting program;

**Habit Training/Scheduled Voiding** is a behavioral technique that calls for scheduled toileting at regular intervals on a planned basis to match the resident's voiding habits. Unlike bladder retraining, there is no systematic effort to encourage the resident to delay voiding and resist urges. Habit training includes timed voiding with the interval based on the resident's usual voiding schedule or pattern. Scheduled voiding is timed voiding, usually every three to four hours while awake. Residents who cannot self-toilet may be candidates for habit training or scheduled voiding programs.

**Intermittent Catheterization** - Sterile insertion and removal of a catheter through the urethra every 3-6 hours for bladder drainage may be appropriate for the management of acute or chronic urinary retention. See additional discussion below in “Catheterization”.

**Medication Therapy** - Medications are often used to treat specific types of incontinence, including stress incontinence and those categories associated with an overactive bladder, which may involve symptoms including urge incontinence, urinary urgency, frequency and nocturia. The current literature identifies classifications and names of medications used for various types of incontinence. When using medications, potentially problematic anticholinergic and other side effects must be recognized. The use of medication therapy to treat urinary incontinence may not be appropriate for some residents because of potential adverse interactions with their other medications or other co-morbid conditions. Therefore, it is important to weigh the risks and benefits before prescribing medications for continence management and to monitor for both effectiveness and side effects. As with all approaches attempting to improve control or management of incontinence, the education and discussion with the resident (or the resident’s surrogate) regarding the benefits and risks of pharmacologic therapies is important.

**Pessary** - A pessary is an intra-vaginal device used to treat pelvic muscle relaxation or prolapse of pelvic organs. Women whose urine retention or urinary incontinence is exacerbated by bladder or uterine prolapse may benefit from placement of a pessary. Female residents may be admitted to the nursing home with a pessary device. The assessment should note whether the resident has a pessary in place or has had a history of successful pessary use. If a pessary is to be used, it is important to develop a plan of care for ongoing management and for the prevention of and monitoring for complications.

**Absorbent Products, Toileting Devices, and External Collection Devices** - Absorbent incontinence products include perineal pads or panty liners for slight leakage, undergarments and protective underwear for moderate to heavy leakage, guards and drip collection pouches for men, and products (called adult briefs) for
Absorbent products can be a useful, rational way to manage incontinence; however, every absorbent product has a saturation point. Factors contributing to the selection of the type of product to be used should include the severity of incontinence, gender, fit, and ease of use.

**Advantages** of using absorbent products to manage urinary incontinence include the ability to contain urine (some may wick the urine away from the skin), provide protection for clothing, and preserve the resident’s dignity and comfort.

**NOTE:** Although many residents have used absorbent products prior to admission to the nursing home and the use of absorbent products may be appropriate, absorbent products should not be used as the primary long term approach to continence management until the resident has been appropriately evaluated and other alternative approaches have been considered.

The potential **disadvantages** of absorbent products are the impact on the resident’s dignity, cost, the association with skin breakdown and irritation, and the amount of time needed to check and change them.

It is important that residents using various toileting devices, absorbent products, external collection devices, etc., be checked (and changed as needed) on a schedule based upon the resident’s voiding pattern, accepted standards of practice, and the manufacturer’s recommendations.

**Skin-related complications** Skin problems associated with incontinence and moisture can range from irritation to increased risk of skin breakdown. Moisture may make the skin more susceptible to damage from friction and shear during repositioning. One form of early skin breakdown is maceration or the softening of tissue by soaking. Macerated skin has a white appearance and a very soft, sometimes "soggy" texture.

The persistent exposure of perineal skin to urine and/or feces can irritate the epidermis and can cause severe dermatitis or skin erosion. Skin erosion is the loss of some or all of the epidermis (comparable to a deep chemical peel) leaving a slightly depressed area of skin. One key to preventing skin breakdown is to keep the perineal skin clean and dry. Research has shown that a soap and water regimen alone may be less effective in preventing skin breakdown compared with moisture barriers and no-rinse incontinence cleansers. Because frequent washing with soap and water can dry the skin, the use of a perineal rinse may be indicated. Moisturizers help preserve the moisture in the skin by either sealing in existing moisture or adding moisture to the skin. Moisturizers include creams, lotions or pastes. However, moisturizers should be used sparingly—if at all—on already macerated or excessively moist skin.

**Catheterization** Urinary Incontinence requires that a resident who enters the facility without an indwelling catheter is not catheterized unless the resident’s clinical condition demonstrates that catheterization was necessary. Some residents are admitted to the facility with indwelling catheters that were placed elsewhere (e.g., during a recent acute hospitalization). The facility is responsible for the assessment of the resident at risk for urinary catheterization and/or the ongoing assessment for the resident who currently has a catheter. This is followed by implementation of appropriate individualized interventions and monitoring for the effectiveness of the interventions.
**Assessment** A resident may be admitted to the facility with or without an indwelling urinary catheter (urethral or suprapubic) and may be continent or incontinent of urine. Regardless of the admission status, a comprehensive assessment should address those factors that predispose the resident to the development of urinary incontinence and the use of an indwelling urinary catheter.

An admission evaluation of the resident’s medical history and a physical examination helps identify the resident at risk for requiring the use of an indwelling urinary catheter. This evaluation is to include detection of reversible causes of incontinence and identification of individuals with incontinence caused by conditions that may not be reversible, such as bladder tumors and spinal cord diseases. (See the assessment factors discussed under incontinence.) The assessment of continence/incontinence is based upon an interdisciplinary review. The comprehensive assessment should include underlying factors supporting the medical justification for the initiation and continuing need for catheter use, determination of which factors can be modified or reversed (or rationale for why those factors should not be modified), and the development of a plan for removal. The clinician’s decision to use an indwelling catheter in the elderly should be based on valid clinical indicators.

For the resident with an indwelling catheter, the facility’s documented assessment and staff knowledge of the resident should include information to support the use of an indwelling catheter. Because of the risk of substantial complications with the use of indwelling urinary catheters, they should be reserved primarily for short-term decompression of acute urinary retention. The assessment should include consideration of the risks and benefits of an indwelling (suprapubic or urethral) catheter; the potential for removal of the catheter; and consideration of complications resulting from the use of an indwelling catheter, such as symptoms of blockage of the catheter with associated bypassing of urine, expulsion of the catheter, pain, discomfort and bleeding.

**Intermittent catheterization** Intermittent catheterization can often manage overflow incontinence effectively. Residents who have new onset incontinence from a transient, hypotonic/atonic bladder (usually seen following indwelling catheterization in the hospital) may benefit from intermittent bladder catheterization until the bladder tone returns (e.g., up to approximately 7 days). A voiding trial and post void residual can help identify when bladder tone has returned.

**Indwelling catheter use** The facility’s documented assessment and staff approach to the resident should be based on evidence to support the use of an indwelling catheter. Appropriate indications for continuing use of an indwelling catheter beyond 14 days may include:

- Urinary retention that cannot be treated or corrected medically or surgically, for which alternative therapy is not feasible, and which is characterized by:
  - Documented post void residual (PVR) volumes in a range over 200 milliliters (ml);
  - Inability to manage the retention/incontinence with intermittent catheterization; and
  - Persistent overflow incontinence, symptomatic infections, and/or renal dysfunction.
• Contamination of Stage III or IV pressure ulcers with urine which has impeded healing, despite appropriate personal care for the incontinence; and
• Terminal illness or severe impairment, which makes positioning or clothing changes uncomfortable, or which is associated with intractable pain.

**Catheter-related complications** An indwelling catheter may be associated with significant complications, including bacteremia, febrile episodes, bladder stones, fistula formation, erosion of the urethra, epididymitis, chronic renal inflammation and pyelonephritis. In addition, indwelling catheters are prone to blockage. Risk factors for catheter blockage include alkaline urine, poor urine flow, proteinuria, and preexisting bladder stones. In the absence of evidence indicating blockage, catheters need not be changed routinely as long as monitoring is adequate. Based on the resident’s individualized assessment, the catheter may need to be changed more or less often than every 30 days.

Some residents with indwelling catheters experience persistent leakage around the catheter. Examples of factors that may contribute to leakage include irritation by a large balloon or by catheter materials, excessive catheter diameter, fecal impaction, and improper catheter positioning. Because leakage around the catheter is frequently caused by bladder spasm, leakage should generally not be treated by using increasingly larger catheter sizes, unless medically justified. Current standards indicate that catheterization should be accomplished with the narrowest, softest tube that will serve the purpose of draining the bladder.

Additional care practices related to catheterization include:
• Educating the resident or responsible party on the risks and benefits of catheter use;
• Recognizing and assessing for complications and their causes, and maintaining a record of any catheter-related problems;
• Attempts to remove the catheter as soon as possible when no indications exist for its continuing use;
• Monitoring for excessive post void residual, after removing a catheter that was inserted for obstruction or overflow incontinence;
• Keeping the catheter anchored to prevent excessive tension on the catheter, which can lead to urethral tears or dislodging the catheter;
• Securing the catheter to facilitate flow of urine.

Research has shown that catheterization is an important, potentially modifiable, risk factor for UTI. By the 30th day of catheterization, bacteriuria is nearly universal. The potential for complications can be reduced by:
• Identifying specific clinical indications for the use of an indwelling catheter;
• Assessing whether other treatments and services would appropriately address those conditions;
• Assessing whether residents are at risk for other possible complications resulting from the continuing use of the catheter, such as obstruction resulting from catheter encrustation, urethral erosion, bladder spasms, hematuria, and leakage around the catheter.

**Urinary Tract Infections**
Catheter-related bacteriuria and UTIs/urosepsis Most individuals with indwelling catheters for more than 7 days have bacteriuria. Bacteriuria alone in a catheterized individual should not be treated with antibiotics.

A long term indwelling catheter (>2 to 4 weeks) increases the chances of having a symptomatic UTI and urosepsis. The incidence of bacteremia is 40 times greater in individuals with a long term indwelling catheter than in those without one. For suspected UTIs in a catheterized individual, the literature recommends removing the current catheter and inserting a new one and obtaining a urine sample via the newly inserted catheter.

Clinical evidence that may suggest UTI Clinically, an acute deterioration in stable chronic symptoms may indicate an acute infection. Multiple co-existing findings such as fever with hematuria are more likely to be from a urinary source.

No one lab test alone proves that a UTI is present. For example, a positive urine culture will show bacteriuria but that alone is not enough to diagnose a symptomatic UTI. However, several test results in combination with clinical findings can help to identify UTIs such as the presence of pyuria (more than minimal white cells in the urine) on microscopic urinalysis, or a positive urine dipstick test for leukocyte esterase (indicating significant pyuria) or for nitrites (indicating the presence of Enterobacteriaceae). A negative leukocyte esterase or the absence of pyuria strongly suggests that a UTI is not present. A positive leukocyte esterase test alone does not prove that the individual has a UTI.

In someone with nonspecific symptoms such as a change in function or mental status, bacteriuria alone does not necessarily warrant antibiotic treatment. Additional evidence that could confirm a UTI may include hematuria, fever (which could include a variation from the individual’s normal or usual temperature range), or evidence of pyuria (either by microscopic examination or by dipstick test). In the absence of fever, hematuria, pyuria, or local urinary tract symptoms, other potential causes of nonspecific general symptoms, such as fluid and electrolyte imbalance or adverse drug reactions, should be considered instead of, or in addition to, a UTI. Although sepsis, including urosepsis, can cause dizziness or falling, there is not clear evidence linking bacteriuria or a localized UTI to an increased fall risk.

Indications to treat a UTI Because many residents have chronic bacteriuria, the research-based literature suggests treating only symptomatic UTIs. Symptomatic UTIs are based on the following criteria:

Residents without a catheter should have at least three of the following signs and symptoms:

- Fever (increase in temperature of >2 degrees F (1.1 degrees C) or rectal temperature >99.5 degrees F (37.5 degrees C) or single measurement of temperature >100 degrees F (37.8 degrees C));
- New or increased burning pain on urination, frequency or urgency; New flank or suprapubic pain or tenderness;
- Change in character of urine (e.g., new bloody urine, foul smell, or amount of sediment) or as reported by the laboratory (new pyuria or microscopic hematuria);
• Worsening of mental or functional status (e.g., confusion, decreased appetite, unexplained falls, incontinence of recent onset, lethargy, decreased activity).¹⁵

Residents with a catheter should have at least two of the following signs and symptoms:

• Fever or chills;
• New flank pain, or suprapubic pain or tenderness;
• Change in character of urine (e.g., new bloody urine, foul smell, or amount of sediment) or as reported by the laboratory (new pyuria or microscopic hematuria);
• Worsening of mental or functional status. Local findings such as obstruction, leakage, or mucosal trauma (hematuria) may also be present.

Follow-up of UTIs: The goal of treating a UTI is to alleviate systemic or local symptoms, not to eradicate all bacteria. Therefore, a post-treatment urine culture is not routinely necessary but may be useful in select situations. Continued bacteriuria without residual symptoms does not warrant repeat or continued antibiotic therapy. Recurrent UTIs (2 or more in 6 months) in a noncatheterized individual may warrant additional evaluation (such as a determination of an abnormal post void residual (PVR) urine volume or a referral to a urologist) to rule out structural abnormalities such as enlarged prostate, prolapsed bladder, periurethral abscess, strictures, bladder calculi, polyps and tumors.

Recurrent symptomatic UTIs in a catheterized or noncatheterized individual should lead the facility to check whether perineal hygiene is performed consistently to remove fecal soiling in accordance with accepted practices. Recurrent UTIs in a catheterized individual should lead the facility to look for possible impairment of free urine flow through the catheter, to re-evaluate the techniques being used for perineal hygiene and catheter care, and to reconsider the relative risks and benefits of continuing the use of an indwelling catheter.

Because the major factors (other than an indwelling catheter) that predispose individuals to bacteriuria, including physiological aging changes and chronic comorbid illnesses, cannot be modified readily, the facility should demonstrate that they:

• Employ standard infection control practices in managing catheters and associated drainage system;
• Strive to keep the resident and catheter clean of feces to minimize bacterial migration into the urethra and bladder (e.g., cleaning fecal material away from, rather than towards, the urinary meatus);
• Take measures to maintain free urine flow through any indwelling catheter;
• Assess for fluid needs and implement a fluid management program (using alternative approaches as needed) based on those assessed needs.

INVESTIGATIVE PROTOCOLS URINARY CONTINENCE AND CATHETERS

Objectives

• To determine whether the initial insertion or continued use of an indwelling catheter is based upon clinical indication for use of a urinary catheter;
To determine the adequacy of interventions to prevent, improve and/or manage urinary incontinence; and
To determine whether appropriate treatment and services have been provided to prevent and/or treat UTIs.

Use this protocol for a sampled resident with an indwelling urinary catheter or for a resident with urinary incontinence.

Procedures Briefly review the assessment, care plan and orders to identify facility interventions and to guide observations to be made. Staff are expected to assess and provide appropriate care from the day of admission, for residents with urinary incontinence or a condition that may contribute to incontinence or the presence of an indwelling urinary catheter (including newly admitted residents). Corroborate observations by interview and record review. NOTE: Criteria established in this protocol provide general guidelines and best practices which should be considered when making a determination of compliance, and is not an exhaustive list of mandatory elements.

1. Observation Observe whether staff consistently implemented care plan interventions across various shifts. During observations of the interventions, note and/or follow up on deviations from the care plan or from current standards of practice, as well as potential negative outcomes.

Observe whether staff make appropriate resident accommodations consistent with the assessment, such as placing the call bell within reach and responding to the call bell, in relation to meeting toileting needs; maintaining a clear pathway and ready access to toilet facilities; providing (where indicated) elevated toilet seats, grab bars, adequate lighting, and assistance needed to use devices such as urinals, bedpans and commodes.

Observe whether assistance has been provided to try to prevent incontinence episodes, such as whether prompting, transfer, and/or stand-by assist to ambulate were provided as required for toileting.

For a resident who is on a program to restore continence or is on a prompted void or scheduled toileting program, note:
- The frequency of breakthrough or transient incontinence;
- How staff respond to the incontinence episodes; and
- Whether care is provided in accord with standards of practice (including infection control practices) and with respect for the resident’s dignity.

For a resident who has been determined by clinical assessment to be unable to participate in a program to restore continence or in a scheduled toileting program and who requires care due to incontinence of urine, observe:
- Whether the resident is on a scheduled check and change program; and
- Whether staff check and change in a timely fashion.

For a resident who has experienced an incontinent episode, observe:
• The condition of the pads/sheets/clothing (a delay in providing continence care may be indicated by brown rings/circles, saturated linens/clothing, odors, etc.);
• The resident’s physical condition (such as skin integrity, maceration, erythema, erosion);
• The resident’s psychosocial outcomes (such as embarrassment or expressions of humiliation, resignation, about being incontinent);
• Whether staff implemented appropriate hygiene measures (e.g., cleansing, rinsing, drying and applying protective moisture barriers or barrier films as indicated) to try to prevent skin breakdown from prolonged exposure of the skin to urine;
• Whether the staff response to incontinence episodes and the provision of care are consistent with standards of practice (including infection control practices) and with respect for the resident’s dignity.

For a resident with an indwelling catheter, observe the delivery of care to evaluate:
• Whether staff use appropriate infection control practices regarding hand washing, catheter care, tubing, and the collection bag;
• Whether staff recognize and assess potential evidence of symptomatic UTI or other related changes in urine condition (such as onset of bloody urine, cloudiness, or oliguria, if present);
• How staff manage and assess urinary leakage from the point of catheter insertion to the bag, if present;
• If the resident has catheter-related pain, how staff assess and manage the pain;
• What interventions (such as anchoring the catheter, avoiding excessive tugging on the catheter during transfer and care delivery) are being used to prevent inadvertent catheter removal or tissue injury from dislodging the catheter.

For a resident experiencing incontinence and who has an indwelling or intermittent catheter, observe whether the resident is provided and encouraged to take enough fluids to meet the resident’s hydration needs, as reflected in various measures of hydration status (approximately 30ml/kg/day or as indicated based on the resident’s clinical condition). For issues regarding hydration, see Guidance at 42 CFR 483.25(j), F327.

2. Interviews
Interview the resident, family or responsible party to the degree possible to identify:
• Their involvement in care plan development including defining the approaches and goals, and whether interventions reflect preferences and choices;
• Their awareness of the existing continence program and how to use devices or equipment;
• If timely assistance is provided as needed for toileting needs, hydration and personal hygiene and if continence care and/or catheter care is provided according to the care plan;
• If the resident comprehends and applies information and instructions to help
improve or maintain continence (where cognition permits);
- Presence of urinary tract-related pain, including causes and management;
- If interventions were refused, whether consequences and/or other alternative approaches were presented and discussed;
- Awareness of any current UTI, history of UTIs, or perineal skin problems.

If the resident has a skin problem that may be related to incontinence, or staff are not following the resident's care plan and continence/catheter care program, interview the nursing assistants to determine if they:
- Are aware of, and understand, the interventions specific to this resident (such as the bladder or bowel restorative/management programs);
- Have been trained and know how to handle catheters, tubing and drainage bags and other devices used during the provision of care; and
- Know what, when, and to whom to report changes in status regarding bowel and bladder function, hydration status, urine characteristics, and complaints of urinary-related symptoms.

3. Record Review
   
   **Assessment and Evaluation.** Review the RAI, the history and physical, and other information such as physician orders, progress notes, nurses' notes, pharmacist reports, lab reports and any flow sheets or forms the facility uses to document the resident's voiding history, including the assessment of the resident's overall condition, risk factors and information about the resident's continence status, rationale for using a catheter, environmental factors related to continence programs, and the resident's responses to catheter/continence services. Request staff assistance, if the information is not readily available.

   Determine if the facility assessment is consistent with or corroborated by documentation within the record and comprehensively reflects the status of the resident for:
   - Patterns of incontinent episodes, daily voiding patterns or prior routines;
   - Fluid intake and hydration status;
   - Risks or conditions that may affect urinary continence;
   - Use of medications that may affect continence and impaired continence that could reflect adverse drug reactions;
   - Type of incontinence (stress, urge, overflow, mixed, functional, or transient incontinence) and contributing factors;
   - Environmental factors that might facilitate or impede the ability to maintain bladder continence, such as access to the toilet, call bell, type of clothing and/or continence products, ambulation devices (walkers, canes), use of restraints, side rails;
   - Type and frequency of physical assistance necessary to facilitate toileting;
   - Clinical rationale for use of an indwelling catheter;
   - Alternatives to extended use of an indwelling catheter (if possible);
   - Evaluation of factors possibly contributing to chronically recurring or persistent UTIs.

**Care Plan.** If the care plan refers to a specific facility treatment protocol that
contains details of the treatment regimen, the protocol must be available to the direct care staff, so that they may be familiar with it and use it. The care plan should clarify any significant deviations from such a protocol for a specific resident. If care plan interventions that address aspects of continence and skin care related to incontinence are integrated within the overall care plan, the interventions do not need to be repeated in a separate continence care plan.

Review the care plan to determine if the plan is based upon the goals, needs and strengths specific to the resident and reflects the comprehensive assessment. Determine if the plan:

- Identifies quantifiable, measurable objectives with time frames to be able to assess whether the objectives have been met;
- Identifies interventions specific enough to guide the provision of services and treatment (e.g., toilet within an hour prior to each meal and within 30 minutes after meals, or check for episodes of incontinence within 30 minutes after each meal or specific times based upon the assessment of voiding patterns);
- Is based upon resident choices and preferences;
- Promotes maintenance of resident dignity;
- Addresses potential psychosocial complications of incontinence or catheterization such as social withdrawal, embarrassment, humiliation, isolation, resignation;
- Includes a component to inform the resident and representative about the risks and benefits of catheter use, on continence management approaches, medications selected, etc.;
- Addresses measures to promote sufficient fluid intake, including alternatives such as food substitutes that have a high liquid content, if there is reduced fluid intake;
- Defines interventions to prevent skin breakdown from prolonged exposure to urine and stool;
- Identifies and addresses the potential impact on continence of medication and urinary tract stimulants or irritants (e.g., caffeine) in foods and beverages;
- Identifies approaches to minimize risk of infection (personal hygiene measures and catheter/tubing/bag care);
- Defines environmental approaches and devices needed to promote independence in toileting, to maintain continence, and to maximize independent functioning.

For the resident who is not on a scheduled toileting program or a program to restore normal bladder function to the extent possible, determine if the care plan provides specific approaches for a check and change program.

For the resident who is on a scheduled toileting or restorative program (e.g., retraining, habit training, scheduled voiding, prompted voiding, toileting devices), determine whether the care plan:

- Identifies the type of urinary incontinence and bases the program on the resident’s voiding/elimination patterns; and
- Has been developed by considering the resident’s medical/health condition, cognitive and functional ability to participate in a relevant continence
program, and needed assistance. For the resident with a catheter, determine whether the care plan:

- Defines the catheter, tubing and bag care, including indications, according to facility protocol, for changing the catheter, tubing or bag;
- Provides for assessment and removal of the indwelling catheter when no longer needed; and
- Establishes interventions to minimize catheter-related injury, pain, encrustation, excessive urethral tension, accidental removal, or obstruction of urine outflow.

Care Plan Revision. Determine if the resident’s condition and effectiveness of the care plan interventions have been monitored and care plan revisions were made (or justifications for continuing the existing plan) based upon the following:

- The outcome and/or effects of goals and interventions;
- A decline or lack of improvement in continence status;
- Complications associated with catheter usage;
- Resident failure to comply with a continence program and alternative approaches that were offered to try to maintain or improve continence, including counseling regarding the potential consequences of not following the program;
- Change in condition, ability to make decisions, cognition, medications, behavioral symptoms or visual problems;
- Input by the resident and/or the responsible person;
- An evaluation of the resident’s level of participation in, and response to, the continence program.

Interviews with Health Care Practitioners and Professionals. If inconsistencies in care or potential negative outcomes have been identified, or care is not in accord with standards of practice, interview the nurse responsible for coordinating or overseeing the resident’s care. Determine:

- How the staff monitor implementation of the care plan, changes in continence, skin condition, and the status of UTIs;
- If the resident resists toileting, how staff have been taught to respond;
- Types of interventions that have been attempted to promote continence (i.e., special clothing, devices, types and frequency of assistance, change in toileting schedule, environmental modifications);
- If the resident is not on a restorative program, how it was determined that the resident could not benefit from interventions such as a scheduled toileting program;
- For the resident on a program of toileting, whether the nursing staff can identify the programming applicable to the resident, and:
  - The type of incontinence;
  - The interventions to address that specific type;
  - How it is determined that the schedule and program is effective (i.e., how continence is maintained or if there has been a decline or improvement in continence, how the program is revised to address the changes);
  - Whether the resident has any physical or cognitive limitations that
influence potential improvement of his/her continence;

- For residents with urinary catheters, whether the nursing staff:
  - Can provide appropriate justification for the use of the catheter;
  - Can identify previous attempts made (and the results of the attempts) to remove a catheter;
  - Can identify a history of UTIs (if present), and interventions to try to prevent recurrence.

If the interventions defined or care provided do not appear 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 the 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; and
- How they monitor the approaches to continence programs (e.g., policies/procedures, staffing requirements, how staff identify problems, assess the toileting pattern of the resident, develop and implement continence-related action plans, how staff monitor and evaluate resident’s responses, etc.).

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

**COMPLIANCE DETERMINATION**

**Synopsis of regulation (F315)** The urinary incontinence requirement has three aspects. The first aspect requires that a resident who does not have an indwelling urinary catheter does not have one inserted unless the resident’s clinical condition demonstrates that it was necessary. The second aspect requires the facility to provide appropriate treatment and services to prevent urinary tract infections; and the third is that the facility attempt to assist the resident to restore as much normal bladder function as possible.

**Criteria for Compliance**

Compliance with F315, Urinary Incontinence

- For a resident who was admitted with an indwelling urinary catheter or who had one placed after admission, the facility is in compliance with this requirement, if staff have:
  - Recognized and assessed factors affecting the resident’s urinary function and identified the medical justification for the use of an indwelling urinary catheter;
  - Defined and implemented pertinent interventions to try to minimize complications from an indwelling urinary catheter, and to remove it if clinically indicated, consistent with resident
conditions, goals, and recognized standards of practice;
• Monitored and evaluated the resident’s response to interventions;
• Revised the approaches as appropriate.

If not, the use of an indwelling urinary catheter is not medically justified, and/or the ongoing treatment and services for catheter care were not provided consistent with the resident’s needs. Cite F315.

• For a resident who is incontinent of urine, the facility is in compliance with this requirement if they:
  • Recognized and assessed factors affecting the risk of symptomatic urinary tract infections and impaired urinary function;
  • Defined and implemented interventions to address correctable underlying causes of urinary incontinence and to try to minimize the occurrence of symptomatic urinary tract infections in accordance with resident needs, goals, and recognized standards of practice;
  • Monitored and evaluated the resident’s response to preventive efforts and treatment interventions;
  • Revised the approaches as appropriate.

If not, the facility is not in compliance with the requirement to assist the resident to maintain or improve the continence status, and/or prevent the decline of the condition of urinary incontinence for the resident. Cite F315.

• For a resident who has or has had a symptomatic urinary tract infection, the facility is in compliance with this requirement if they have:
  • Recognized and assessed factors affecting the risk of symptomatic urinary tract infections and impaired urinary function;
  • Defined and implemented interventions to try to minimize the occurrence of symptomatic urinary tract infections and to address correctable underlying causes, in accordance with resident needs, goals, and recognized standards of practice;
  • Monitored and evaluated the resident’s responses to preventive efforts and treatment interventions;
  • Revised the approaches as appropriate.

If not, the development of a symptomatic urinary tract infection, and/or decline of the resident with one, was not consistent with the identified needs of the resident. Cite F315.

**Noncompliance for F315** After completing the Investigative Protocol, analyze the data in order to determine whether or not noncompliance with the regulation exists. Noncompliance for F315 may include (but is not limited to) one or more of the following, including failure to:

• Provide care and treatment to prevent incontinence and/or improve urinary continence and restore as much normal bladder function as possible;
• Provide medical justification for the use of a catheter or provide services for a resident with a urinary catheter;
• Assess, prevent (to the extent possible) and treat a symptomatic urinary tract
infection (as indicated by the resident’s choices, clinical condition and physician treatment plan);  
- Accurately or consistently assess a resident's continence status on admission and as indicated thereafter;  
- Identify and address risk factors for developing urinary incontinence;  
- Implement interventions (such as bladder rehabilitative programs) to try to improve bladder function or prevent urinary incontinence, consistent with the resident's assessed need and current standards of practice;  
- Provide clinical justification for developing urinary incontinence or for the failure of existing urinary incontinence to improve;  
- Identify and manage symptomatic urinary tract infections, or explain adequately why they could or should not do so;  
- Implement approaches to manage an indwelling urinary catheter based upon standards of practice, including infection control procedures;  
- Identify and apply relevant policies and procedures to manage urinary incontinence, urinary catheters and/or urinary tract infections;  
- Notify the physician of the resident’s condition or changes in the resident’s continence status or development of symptoms that may represent a symptomatic UTI (in contrast to asymptomatic bacteriuria).  

**Potential Tags for Additional Investigation** During the investigation for 42 CFR 483.25(d)(1) and (2), the surveyor may have identified concerns related to outcome, process and/or structure requirements. The surveyor should investigate these requirements before determining whether noncompliance may be present. The following are examples of related outcome, process and/or structure requirements that should be considered:  

1) **42 CFR 483.10(b)(11), F157, Notification of Changes** Determine if staff notified the physician of significant changes in the resident’s continence, catheter usage, or the development, treatment and/or change in symptomatic UTIs; or notified the resident or resident’s representative (where one exists) of significant changes as noted above.  

2) **42 CFR 483.15(a), F241, Dignity** Determine if staff provide continence care and/or catheter care to the resident in a manner that respects his/her dignity, strives to meet needs in a timely manner, monitors and helps the resident who cannot request assistance, and strives to minimize feelings of embarrassment, humiliation and/or isolation related to impaired continence.  

3) **42 CFR 483.20(b)(1), F272, Comprehensive Assessments** Determine if the facility comprehensively assessed the resident’s continence status and resident-specific risk factors (including potential causes), and assessed for the use of continence-related devices, including an indwelling catheter.  

4) **42 CFR 483.20(k), F279, Comprehensive Care Plans** Determine if the facility developed a care plan (1) that was consistent with the resident’s specific conditions, risks, needs, behaviors, and preferences and with current standards of practice and (2) that includes measurable objectives, approximate timetables, specific interventions and/or services needed to prevent or address incontinence, provide catheter care; and to prevent UTIs.
to the extent possible.

5) **42 CFR 483.20(k)(2)(iii), F280, Comprehensive Care Plan Revision**
   Determine if the care plan was reviewed and revised periodically, as necessary, related to preventing, managing, or improving incontinence, managing an indwelling urinary catheter, possible discontinuation of an indwelling catheter, and attempted prevention and management of UTIs.

6) **42 CFR 483.20(k)(3)(i), F281, Services Provided Meet Professional Standards**
   Determine if services and care were provided for urinary incontinence, catheter care and/or symptomatic UTIs in accordance with accepted professional standards.

7) **42 CFR 483.25, F309, Quality of Care**
   Determine if staff identified and implemented appropriate measures to address any pain related to the use of an indwelling urinary catheter or skin complications such as maceration, and to provide the necessary care and services in accordance with the comprehensive assessment plan of care.

8) **42 CFR 483.25 (a)(3) F312, Quality of Care**
   Determine if staff identified and implemented appropriate measures to provide good personal hygiene for the resident who cannot perform relevant activities of daily living, and who has been assessed as unable to achieve and/or restore normal bladder function.

9) **42 CFR 483.40(a), F385, Physician Supervision**
   Determine if the physician has evaluated and addressed, as indicated, medical issues related to preventing or managing urinary incontinence, catheter usage, and symptomatic UTIs.

10) **42 CFR 483.65(b)(3), F444, Infection Control: Hand Washing**
    Determine if staff wash their hands after providing incontinence care, and before and after providing catheter care.

11) **42 CFR 483.75(f), F498, Proficiency of Nurse Aides**
    Determine if nurse aides correctly deliver continence and catheter care, including practices to try to minimize skin breakdown, UTIs, catheter-related injuries, and dislodgement.

12) **42 CFR 483.30(a), F353, Sufficient Staff**
    Determine if the facility had qualified staff in sufficient numbers to provide necessary care and services on a 24-hour basis, based upon the comprehensive assessment and care plan, to prevent, manage and/or improve urinary incontinence where possible.

13) **42 CFR 483.75(i)(2), F501, Medical Director**
    Determine whether the medical director, in collaboration with the facility and based on current standards of practice, has developed policies and procedures for the prevention and management of urinary incontinence, for catheter care, and for the identification and management of symptomatic urinary tract infections; and whether the medical director interacts, if requested by the facility, with the physician supervising the care of the resident related to the management of urinary incontinence, catheter or infection issues.

**DEFICIENCY CATEGORIES**

Once the team has completed its investigation, analyzed the data, reviewed the regulatory requirements, and determined that non-compliance exists, the team must...
determine the severity of each deficiency, based on the resultant effect or potential for harm to the resident.

The key elements for severity determination for F315 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 F315 may include, but is not limited to:
   - Development, recurrence, persistence, or increasing frequency of urinary incontinence, which is not the result of underlying clinical conditions;
   - Complications such as urosepsis or urethral injury related to the presence of an indwelling urinary catheter that is not clinically justified;
   - Significant changes in psychosocial functioning, such as isolation, withdrawal, or embarrassment, related to the presence of un-assessed or unmanaged urinary incontinence and/or a decline in continence, and/or the use of a urinary catheter without a clinically valid medical justification;
   - Complications such as skin breakdown that are related to the failure to manage urinary incontinence;

2. Degree of harm (actual or potential) related to the noncompliance. 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;
   - If harm has not yet occurred, determine the potential for serious injury, impairment, death, or compromise or discomfort to occur to the resident; and

3. The immediacy of correction required. Determine whether the noncompliance 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 F315. 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.

**Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety** Immediate Jeopardy is a situation in which the facility's noncompliance with one or more requirements of participation:

- Has allowed/caused/resulted in, or is likely to allow/cause/result in 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 negative outcomes as a result of the facility's deficient practices may include:
• **Complications resulting from utilization of urinary appliance(s) without medical justification:** As a result of incorrect or unwarranted (i.e., not medically indicated) utilization of a urinary catheter, pessary, etc., the resident experiences injury or trauma (e.g., urethral tear) that requires surgical intervention or repair.

• **Extensive failure in multiple areas of incontinence care and/or catheter management:** As a result of the facility’s noncompliance in multiple areas of continence care or catheter management, the resident developed urosepsis with complications leading to prolonged decline or death.

**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 a symptomatic UTI:** As a result of the facility’s noncompliance, the resident developed a symptomatic UTI, without long term complications, associated with the use of an indwelling catheter for which there was no medical justification.

- **The failure to identify, assess and manage urinary retention:** As a result of the facility’s noncompliance, the resident had persistent overflow incontinence and/or developed recurrent symptomatic UTIs.

- **The failure to provide appropriate catheter care:** As a result of the facility’s noncompliance, the catheter was improperly managed, resulting in catheter-related pain, bleeding, urethral tears or urethral erosion.

- **Medically unjustified use of an indwelling catheter with complications:** As a result of the facility’s noncompliance, a resident who was admitted with a urinary catheter had the catheter remain for an extended period of time without a valid medical justification for its continued use, or a urinary catheter was inserted after the resident was in the facility and used for an extended time without medical justification, during which the resident experienced significant complications such as recurrent symptomatic UTIs.

- **Decline or failure to improve continence status:** As a result of the facility’s failure to assess and/or re-assess the resident’s continence status, utilize sufficient staffing to implement continence programs and provide other related services based on the resident’s assessed needs, and/or to evaluate the possible adverse effects of medications on continence status, the resident failed to maintain or improve continence status.

- **Complications due to urinary incontinence:** As a result of the facility’s failure to provide care and services to a resident who is incontinent of urine, in accordance with resident need and accepted standards of practice, the resident developed skin maceration and/or erosion or declined to attend or participate in social situations (withdrawal) due to
embarrassment or humiliation related to unmanaged urinary incontinence.

**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 potentially avoidable negative outcomes may include, but are not limited to:

- **Medically unjustified use of an indwelling catheter:** As a result of the facility's noncompliance, the resident has the potential for experiencing complications, such as symptomatic UTIs, bladder stones, pain, etc.

- **Complications associated with inadequate care and services for an indwelling catheter:** As a result of the facility’s noncompliance, the resident has developed potentially preventable non-life-threatening problems related to the catheter, such as leaking of urine due to blockage of urine outflow, with or without skin maceration and/or dermatitis.

- **Potential for decline or complications:** As a result of the facility’s failure to consistently implement a scheduled voiding program defined in accordance with the assessed needs, the resident experiences repeated episodes of incontinence but has not demonstrated a decline or developed complications.

**Severity Level 1: No actual harm with potential for minimal harm** The failures of the facility to provide appropriate care and services to improve continence, manage indwelling catheters, and minimize negative outcome places residents at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.
# MDS Section H Bowel and Bladder

<table>
<thead>
<tr>
<th>Section H: Bladder and Bowel</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hb100. Appliances</strong></td>
</tr>
<tr>
<td>A. Indwelling catheter (including suprapubic catheter and nephrostomy tube)</td>
</tr>
<tr>
<td>B. External catheter</td>
</tr>
<tr>
<td>C. Ostomy (including urostomy, ileostomy, and colostomy)</td>
</tr>
<tr>
<td>D. Intermittent catheterization</td>
</tr>
<tr>
<td>Z. None of the above</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Hb200. Urinary Tolloiting Program</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Has a trial of a tolloting program (e.g., scheduled toileting, prompted voiding, or bladder training) been attempted on admission/transfer or since urinary incontinence was noted in this facility?</td>
</tr>
<tr>
<td>0. No</td>
</tr>
<tr>
<td>1. Yes</td>
</tr>
<tr>
<td>9. Unable to determine</td>
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<tr>
<th><strong>Hb200B. Response</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>What was the resident's response to the trial program?</td>
</tr>
<tr>
<td>0. No improvement</td>
</tr>
<tr>
<td>1. Decreased wetness</td>
</tr>
<tr>
<td>2. Completely dry (constant)</td>
</tr>
<tr>
<td>9. Unable to determine or trial in progress</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Hb200C. Current toolloting program or trial</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Is a toolloting program e.g., scheduled toileting, prompted voiding, or bladder training, currently being used to manage the resident's urinary incontinence?</td>
</tr>
<tr>
<td>0. No</td>
</tr>
<tr>
<td>1. Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Hb300. Urinary Continence</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Urinary Continence - Select the one category that best describes the resident</td>
</tr>
<tr>
<td>0. Always continent</td>
</tr>
<tr>
<td>1. Occasionally Incontinent (less than 7 episodes of incontinence)</td>
</tr>
<tr>
<td>2. Frequently Incontinent (7 or more episodes of urinary incontinence, but at least one episode of continent voiding)</td>
</tr>
<tr>
<td>3. Always Incontinent (no episodes of continent voiding)</td>
</tr>
<tr>
<td>9. Not rated, resident had a catheter (indwelling, condom), urinary ostomy, or no urine output for the entire 7 days</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th><strong>Hb400. Bowel Continence</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Bowel Continence - Select the one category that best describes the resident</td>
</tr>
<tr>
<td>0. Always continent</td>
</tr>
<tr>
<td>1. Occasionally Incontinent (one episode of bowel incontinence)</td>
</tr>
<tr>
<td>2. Frequently Incontinent (2 or more episodes of bowel incontinence, but at least one continent bowel movement)</td>
</tr>
<tr>
<td>3. Always Incontinent (no episodes of continent bowel movements)</td>
</tr>
<tr>
<td>9. Not rated, resident had an ostomy or did not have a bowel movement for the entire 7 days</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Hb500. Bowel Toolloting Program</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Is a toolloting program currently being used to manage the resident's bowel continence?</td>
</tr>
<tr>
<td>0. No</td>
</tr>
<tr>
<td>1. Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Hb600. Bowel Patterns</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Constipation present?</td>
</tr>
<tr>
<td>0. No</td>
</tr>
<tr>
<td>1. Yes</td>
</tr>
</tbody>
</table>
REFERENCES Incontinence

3. There are 3 F tags that fall under MDS Section K Swallowing/ Nutritional Status

F322 Naso Gastric tubes
  483.25(g) Naso-Gastric Tubes*

F325 Nutrition
  §483.25(i) Nutrition

F327 Hydration
  §483.25(j) Hydration

Tag F322 Naso Gastric Tubes
Based on the comprehensive assessment of a resident, the facility must ensure that
(1) A resident who has been able to eat enough alone or with assistance is not fed
by naso-gastric tube unless the resident’s clinical condition demonstrates that use
of a naso-gastric tube was unavoidable;

(2) A resident who is fed by a naso-gastric or gastrostomy tube receives the
appropriate treatment and services to prevent aspiration pneumonia, diarrhea,
vomiting, dehydration, metabolic abnormalities, and nasal-pharyngeal ulcers and to
restore, if possible, normal eating skills.

INTENT: The intent of this regulation is that:
- The feeding tube is utilized only after adequate assessment determines that
  the resident's clinical condition makes this intervention medically necessary;
- A feeding tube is utilized in accordance with current clinical standards of
  practice and services are provided to prevent complications to the extent
  possible;
- Services are provided to restore normal eating skills to the extent possible.

NOTE: For the purpose of the interpretative guidelines at F tag 322 the
regulatory title “§483.25(g) ”Naso-gastric tubes” is considered to include any
feeding tube used to provide enteral nutrition to a resident by bypassing oral
intake. Since the regulation was promulgated, use of naso-gastric tubes has
become extremely rare, and use of other types of enteral feeding tubes (such as
those listed in the definitions section) has become prominent.

DEFINITIONS
Use of a Feeding Tube
  Avoidable use of a feeding tube Avoidable” means there is not a clear
  indication for using a feeding tube or there is insufficient evidence that it
  provides a benefit that outweighs associated risks.
  Unavoidable use of a feeding tube Unavoidable” means there is a clear
indication for using a feeding tube or there is sufficient evidence that it provides a benefit that outweighs associated risks.

**Bolus feeding** is the administration of a limited volume of enteral formula over brief periods of time.

**Continuous feeding** is the uninterrupted administration of enteral formula over extended periods of time.

**Enteral nutrition** (a.k.a. “tube feeding”) is the delivery of nutrients through a feeding tube directly into the stomach, duodenum, or jejunum.

**Feeding tube** refers to a medical device used to provide enteral nutrition to a resident by bypassing oral intake.

**Gastrostomy tube** (“G-tube”) is a tube that is placed directly into the stomach through an abdominal wall incision for administration of food, fluids, and medications. The most common type is a percutaneous endoscopic gastrostomy (PEG) tube.

**Jejunostomy tube** (a.k.a. “percutaneous endoscopic jejunostomy” (PEJ) or “J-tube”) is a feeding tube placed directly into the small intestine.

**Nasogastric feeding tube** (“NG tube”) is a tube that is passed through the nose and down through the nasopharynx and esophagus into the stomach.

**Transgastric jejunal feeding tube** (“G-J tube”) is a feeding tube that is placed through the stomach into the jejunum and that has dual ports to access both the stomach and the small intestine.

**Tube feeding** (a.k.a. “enteral feeding”) is at §483.25(g the delivery of nutrients through a feeding tube directly into the stomach, duodenum, or jejunum.

### OVERVIEW

A decision to use a feeding tube has a major impact on a resident and his or her quality of life. It is important that any decision regarding the use of a feeding tube be based on the resident’s clinical condition and wishes as well as applicable federal and state laws and regulations for decision making about life-sustaining treatments. The use of feeding tubes varies widely within and among states. Reasons for this variability are unclear, but they may include diverse opinions about the benefits and risks of non-oral nutrition, and variable facility policies and usual practices.

**NOTE:** Refer to §483.10(b)(4) and (b)(8), Notice of Rights and Services, Right to Refuse Treatment and Experimental Research and to Formulate Advance Directives; and §483.15(b), Self-Determination and Participation, in order to determine if the use of a feeding tube is consistent with the wishes and instructions of the resident, if known (e.g., verbal or handwritten instructions, advance directive or living will) or the instructions of the resident’s legal representative, if the resident is unable to make his or her wishes known.

**Considerations regarding the use of feeding tubes** The regulations at §483.25(g require that the resident’s clinical condition demonstrates the use of a feeding tube to be unavoidable. A feeding tube may be considered unavoidable only if no other viable alternative to maintain adequate nutrition and/or hydration is possible and the use of the feeding tube is consistent with the clinical objective of trying to maintain or improve nutritional and hydration parameters.

Several factors may be involved in the decision to use a feeding tube including medical conditions that impair the resident’s ability to maintain appropriate nutritional and hydration parameters.
nutritional parameters (e.g., cerebrovascular accident, esophageal cancer, delirium, reconstructive facial or oral surgery), the need to improve the resident’s nutritional status or level of comfort, or the desire to prolong the resident’s life. The duration of use of a feeding tube may vary, depending on the clinical situation.

The interdisciplinary team, with support and guidance from the physician, is responsible for assuring the ongoing review, evaluation and decision-making regarding the continuation or discontinuation of all treatments, devices or approaches implemented to care for the resident. Involving the resident, family, and/or the resident’s legal representative in discussions about the indications, use, potential benefits and risks of tube feeding, types of approaches, and alternatives helps support the resident’s right to make an informed decision to use or not use artificial nutrition and hydration.

A clinically pertinent rationale for using a feeding tube includes, but is not limited to:

- An assessment of the resident’s nutritional status, which may include usual food and fluid intake, pertinent laboratory values, appetite, and usual weight and weight changes;
- An assessment of the resident’s clinical status, which may include the ability to chew, swallow, and digest food and fluid; underlying conditions affecting those abilities (e.g., coma, stroke, esophageal stricture, potentially correctable malnutrition that cannot be improved sufficiently by oral intake alone); factors affecting appetite and intake (e.g., medications known to affect appetite, taste, or nutrition utilization); and prognosis;
- Relevant functional and psychosocial factors (e.g., inability to sufficiently feed self, stroke or neurological injury that results in loss of appetite, psychosis that prevents eating); and
- Interventions prior to the decision to use a feeding tube and the resident’s response to them. (Refer to F325 for discussion and examples of interventions to improve and restore normal nutritional parameters.)

NOTE: Refer to §483.20 Resident Assessment and the Assessment Section of the General Investigative Protocol at Quality of Care (F309) for discussion of the comprehensive evaluation that comprises an assessment.

The use of a feeding tube may potentially benefit or may adversely affect a resident’s clinical condition and/or psychosocial well-being. Examples of some possible benefits of using a feeding tube may include:

- Addressing malnutrition and dehydration;
- Promoting wound healing;
- Allowing the resident to gain strength, receive appropriate interventions that may help restore the resident’s ability to eat and, perhaps, return to oral feeding.

Examples of some possible adverse effects of using a feeding tube may include:

- Diminishing socialization, including, but not limited to, the close human contact associated with being assisted to eat or being with others at mealtimes;
- Not having the opportunity to experience the taste, texture, and chewing of foods;
- Causing tube-associated complications;
- Reducing the freedom of movement related to efforts to prevent the
resident from pulling on the tube or other requirements related to the tube or the tube feeding.

In order to assure that the resident being fed by a feeding tube maintains the highest degree of quality of life possible, it is important to minimize possible social isolation or negative psychosocial impact to the degree possible (e.g., continuing to engage in appropriate activities, socializing in the dining room). Because of the possible side-effects and discomfort associated with the use of nasogastric tubes, there should be clinically pertinent documentation for extended use of nasogastric tubes (e.g., greater than 30 days).

Nutrition and feeding issues and their underlying causes in the resident with advanced dementia or other chronic neurological disorders such as Parkinson’s disease present a particular set of issues and considerations that are discussed in F325. The extended use of enteral feeding tubes in individuals with advanced dementia remains controversial. The literature regarding enteral feeding of these individuals suggests that there is little evidence that enteral feeding improves clinical outcomes (e.g., prevents aspiration or reduces mortality).

**Resident Rights** The regulations at 483.10(d)(2) state that the resident has the right to be fully informed in advance about care and treatment and of any changes in the care or treatment that may affect the resident’s well-being. In addition, the regulations at 483.10(b)(4) state that the resident has the right to refuse treatment and to formulate an advance directive.

If a resident has had a feeding tube placed prior to admission or in another setting while residing in the facility, the physician and interdisciplinary care team review the basis (e.g., precipitating illness or condition change) for the initial placement of the feeding tube and the resident's current condition to determine if there is a continued rationale for its use and to ensure that its continued use is consistent with the resident's treatment goals and wishes. Decisions to continue or discontinue the use of a feeding tube are made through collaboration between the resident (or a legal representative for a resident who lacks capacity to make and communicate such decisions), the physician, and the interdisciplinary care team. This includes a discussion of the relevance of a feeding tube to attaining a resident’s goals (e.g., whether the nutritional intervention is likely to have a significant impact on the individual's underlying condition or overall status).

**Technical and nutritional aspects of feeding tubes** It is important that staff providing care and services to the resident who has a feeding tube are aware of, competent in, and utilize facility protocols regarding feeding tube nutrition and care. These protocols are required to be developed with the medical director in order to assure staff implement and provide care and services according to resident needs and clinical standards of practice.

**Technical Aspects of Feeding Tubes** Facility procedures regarding the technical aspects of feeding tubes include, but are not limited to, the following:

**Location of the feeding tube.** Direction to staff regarding how to monitor and check that the feeding tube is in the right location (e.g., stomach or small intestine, depending on the tube) or verify that placement was checked, such as:

- Techniques to verify that tube placement is appropriate before beginning a feeding and before administering medications; and
• The frequency with which staff should monitor for proper location of the feeding tube to assure that the enteral retention device is properly approximated to the abdominal wall and the surrounding skin is intact.

Care of the feeding tube. Direction to staff on how to provide care such as:
• Securing a feeding tube externally;
• Providing needed personal, skin, oral, and nasal care to the resident;
• Examining and cleaning the insertion site in order to identify, lessen or resolve possible skin irritation and local infection;
• Using infection control precautions and related techniques to minimize the risk of contamination; for example, in connecting the tube and the tube feeding;
• Defining the frequency of and volume used for flushing, including flushing for medication administration, and when a prescriber’s order does not specify.

Feeding tube replacement. Direction for staff regarding the conditions and circumstances under which a tube is to be changed, such as:
• When to replace and/or change a feeding tube (generally replaced either as planned/scheduled or as needed such as when a long-term feeding tube comes out unexpectedly or a tube is worn or clogged);
• How and when to examine a feeding tube and the infusion plug to identify splits or cracks that could produce leakage;
• Instances when a tube can be replaced within the facility and by whom;
• Instances when a tube must be replaced in another setting (e.g., hospital, ambulatory surgery center);
• Notification of the practitioner when the need for a tube change arises unexpectedly.

Nutritional aspects of feeding tubes When a resident is receiving nutrition via a feeding tube, the practitioner and the interdisciplinary team identify the resident’s nutritional needs and facility procedures that direct staff in providing care and services to the resident. The practitioner’s orders related to tube feeding typically include the following components: kind of feeding and its caloric value; volume, duration, and mechanism of administration (e.g., gravity or pump); and frequency of flush.
Facility procedures regarding the nutritional aspects of feeding tubes include, but are not limited to:

Enteral nutrition. Direction to staff regarding the nutritional product and meeting the resident’s nutritional needs such as:
• Types of enteral nutrition formulas available for use;
• How to determine whether the tube feedings meet the resident’s nutritional needs and when to adjust them accordingly;
• How to balance essential nutritional support with efforts to minimize complications related to the feeding tube;
• Ensuring that the selection and use of enteral nutrition is consistent with manufacturer’s recommendations;
• Ensuring that the administration of enteral nutrition is consistent with and follows the practitioner’s orders; Ensuring that the product has not
exceeded the expiration date.

**Flow of feeding.** Direction for staff regarding how to manage and monitor the rate of flow, such as:

- Use of gravity flow;
- Use of a pump;
- Periodic evaluation of the amount of feeding being administered for consistency with practitioner’s orders;
- Calibration of enteral feeding pumps to ensure that pump settings accurately provide the rate and volume consistent with the resident’s care plan;
- Periodic maintenance of feeding pumps consistent with manufacturer’s instructions to ensure proper mechanical functioning.

**Complications related to the feeding tube** An enteral feeding tube may be associated with significant complications, including aspiration, leaking around the insertion site, abdominal wall abscess, or erosion at the insertion site including the nasal areas. Feeding tubes can perforate the stomach or small intestine, with resultant peritonitis. Esophageal complications of feeding tubes may also occur including esophagitis, ulcerations, strictures, and tracheoesophageal fistulas. The use of tubes not designed or intended for enteral feeding may increase the risk of complications.

Tubes may clog for various reasons, including plugging by formula, pill fragments, or the precipitation of medications incompatible with the formula. Flushing feeding tubes regularly and in association with medication administration, as indicated by current clinical standards of practice and provided in the resident care policies, can help reduce the risk of clogging.

**Complications related to the administration of the enteral nutrition product**

The administration of an enteral nutrition product may be associated with other complications including, but not limited to, nausea, vomiting, diarrhea, abdominal cramping, inadequate nutrition and aspiration. Additionally, interactions between the formula and various medications can affect the absorption and/or effectiveness of the medication. For example, the effectiveness of phenytoin sodium may be reduced by the drug binding with the enteral feeding’s protein component, leading to less free drug availability and possibly inadequate therapeutic levels.

Metabolic complications related to tube feeding may include inadequate calorie or protein intake, altered hydration, hypo- or hyperglycemia, and altered electrolyte and nutrient levels. These risks may be reduced by calculating the nutritional needs of the resident, taking into account comorbid conditions and medications that affect these balances, monitoring for adequate nutritional status and complications, and adjusting the tube feeding accordingly.

While a feeding tube may be initiated with the intent to address certain medical conditions, the use of a feeding tube does not necessarily decrease the risk of aspiration for individuals with other risk factors, such as moderate or less severe swallowing abnormalities. Aspiration risk may potentially be affected by factors such as diminished level of consciousness, improper positioning of the resident during administration of the feeding, and failure to assure the feeding tube is correctly
positioned within the stomach or intestine. The evidence is inconsistent and conflicting regarding any connection between gastric residual volume and the risk or occurrence of aspiration.

Risk of aspiration should be assessed individually and appropriate interventions (e.g., proper positioning, rate of flow) implemented accordingly. There may be situations where other coexisting factors influence decisions about elevating the head of the bed; for example, a resident being fed by a tube who may be at risk for shearing by sliding down the sheets when the head of the bed is elevated to a recommended angle.

Complications Management
The facility is expected to identify and address actual or potential complications related to the feeding tube or tube feeding and to notify and involve the practitioner in evaluating and managing care to address these complications and risk factors.

INVESTIGATIVE PROTOCOL FOR FEEDING TUBES

Objectives
- To determine if a feeding tube is utilized only after adequate assessment determines that the resident's clinical condition makes this intervention medically necessary;
- To determine if a feeding tube is utilized in accordance with current clinical standards of practice and if services are provided to prevent complications to the extent possible; and
- To determine if services are provided to restore normal eating skills to the extent possible.

Use
Use this protocol for a resident who has a feeding tube.

Procedures
The surveyor(s) should conduct the following observations, interviews and record reviews. If there are concerns regarding the facility’s use and care of feeding tubes, review facility policies and practices with regard to the use and care of feeding tubes.

Observations
During various shifts, observe staff interactions with the resident and provision of care including: initiation, continuation, and termination of feedings; care of the tube site and equipment; and medication administration via the feeding tube, if possible. Use the observations to determine whether staff follow clinical standards of practice, facility policy, the resident care plan, and prescriber’s orders and if they try to minimize the risk for complications including but not limited to:
- Implementing interventions to minimize the negative psychosocial impact that may occur as a result of tube feeding;
- Providing mouth care, including teeth, gums, and tongue;
- Checking that the tubing remains in the correct location;
- Properly positioning the resident consistent with the resident’s individual needs;
- Using universal precautions and clean technique and following the manufacturer’s recommendations when stopping, starting, flushing, and giving medications through the feeding tube;
- Ensuring the cleanliness of the feeding tube, insertion site, dressing (if
• Providing the type, rate, volume and duration of the feeding as ordered by the practitioner and consistent with the manufacturer’s recommendations.

Note staff response if there is evidence of possible complications, such as diarrhea, nausea, vomiting, abdominal discomfort, nasal discomfort (if a nasogastric tube is being used); evidence of leakage and/or skin irritation at the tube insertion site; or risk of inadvertent removal of the tube.

**Interviews**  
**Resident/Representative**  
Interview the resident and/or resident’s legal representative (as appropriate) regarding involvement in development of the care plan including goals and preferences; whether the interventions reflect the resident’s choices and preferences; and the resident’s response to the tube feeding, including the following:

- Whether staff provided assistance to the resident to increase the food intake, prior to inserting a feeding tube (e.g., identifying underlying causes of anorexia; hand feeding; changing food consistency, texture, form; offering alternate food choices; and/or providing assistive devices);
- Whether the resident and/or the resident’s legal representative (as appropriate) was informed about the relevant benefits and risks of tube feeding, and involved in discussing alternatives and making the decision about using a feeding tube;
- Whether the resident has had any significant new or worsening physical, functional or psychosocial changes; whether the resident informed the staff; and how the problems were addressed;
- Whether there has been a reassessment and discussion with the resident or the resident’s legal representative regarding the continued appropriateness/necessity of the feeding tube.

**NOTE:** Prior to inserting a feeding tube, the prescriber reviews the resident’s choices/instructions and goals, including all relevant information that may be identified in advance directives (See F155, F156 and F242).

**Facility staff**  
Interview staff that provide direct care on various shifts to determine:

- How staff and practitioner determined the cause(s) of decreased oral intake/weight loss or impaired nutrition and attempted to maintain oral intake prior to the insertion of a feeding tube, such as did staff collaborate with the physician to identify medical causes of decreased appetite or try to help the resident eat enough food (e.g., cueing or hand feeding; changing food consistency, texture, form; seeking and addressing causes of anorexia; providing assistive devices);
- What the specific care needs for the resident are (e.g., special positioning, personal care, insertion site care, amount of feeding taken in);
- How the staff determined the resident’s nutritional status was being met such as periodically weighing the resident and how they decide whether the tube feeding is adequate to maintain acceptable nutrition parameters;
- Whether the resident has voiced any complaints or exhibited any physical or psychosocial complications that may be associated with the tube feeding.
(e.g., nausea or vomiting, diarrhea, pain associated with the tube, abdominal discomfort, depression, withdrawal); and how these problems have been addressed;
• To whom a staff member has reported the resident’s signs or symptoms; and
• Whether there has been a periodic reassessment and discussion with the resident or his/her legal representative regarding the continued appropriateness/necessity of the feeding tube; and whether the care plan has been revised and implemented as necessary.

Health care practitioners and professionals
The assigned surveyor should review, as indicated, the facility’s policies, procedures, records of incidents and corrective actions related to feeding tubes; documentation of staff knowledge and skills related to the aspects of administering tube feeding; and should, as necessary, interview facility staff with responsibility for overseeing or training in this aspect of care to determine:
• How the facility identified the resident at risk for impaired nutrition, identified and addressed causes of impaired nutrition, and determined that use of a feeding tube was unavoidable;
• How staff calculated nutritional needs for the resident and how they ensure that the resident receives close to the calculated amount of nutrition daily;
• How staff monitor the resident for the benefits and risks related to a feeding tube, and address adverse consequences of the feeding tube use (e.g., altered mood, nausea and vomiting, pain, or restraint use to try to prevent the resident from removing the feeding tube);
• How staff are trained and directed regarding management of feeding tubes and tube feedings in general, and in addressing any specific issues related to this individual resident;
• Whether the physician and staff attempted to identify the circumstances that led to the placement of the feeding tube (e.g., when the tube was placed in another facility);
• Whether the resident was periodically reassessed for the continued appropriateness/necessity of the feeding tube; and whether the care plan was revised and implemented, as necessary, with input from the resident or his/her legal representative, to the extent possible.

NOTE: During the course of the review, if the surveyor needs to contact the attending physician regarding questions related to the treatment regimen, it is recommended that the facility’s staff have the opportunity to provide the necessary information about the resident and the concerns to the physician for his/her review prior to responding to the surveyor’s inquiries. If the attending physician is unavailable, interview the medical director, as appropriate.

Record Review
Review information such as physician orders, tube feeding records, multidisciplinary progress notes, RAI/MDS and any available assessment regarding the rationale for feeding tube insertion and the potential to restore normal eating skills, including the interventions tried (to avoid using the feeding tube before its insertion, restore oral intake after tube insertion, and prevent potential complications). In order to identify concerns or to further investigate identified concerns about tube feedings, review to determine:
• How the staff verify that the feeding tube is properly placed;
• That staff are assigned responsibilities for various aspects of enteral feedings consistent with their position and training (e.g., administering the feeding, determining and verifying correct formula; calculating the amount of formula, feeding intervals, flow rate);
• How staff have monitored a resident for possible complications (e.g., diarrhea, nutritional deficits, aspiration, depression, withdrawal, etc.) related to a feeding tube and the tube feeding, and have identified and addressed such complications;
• That the resident was periodically reassessed and the care plan was revised and implemented, as necessary with input from the resident or his/her legal representative, to the extent possible.

**Review of Facility Practices** Related concerns may have been identified that would suggest the need for a review of facility practices. Examples of such activities may include a review of policies, staffing, and staff training, functional responsibilities, and interviews with staff (including facility management). If there is a pattern of residents who have issues related to the indications, utilization, complications, process or performance issues with feeding tubes, determine whether the facility has incorporated into its quality assurance activities a review of appropriateness and management of tube feedings.

**DETERMINATION OF COMPLIANCE**

**Synopsis of Regulation (F322)** The feeding tube requirement has two aspects. The first aspect requires that the facility utilizes a feeding tube only after it determines that a resident's clinical condition demonstrates this intervention was unavoidable. The second aspect requires that the facility provides to the resident who is fed by a tube, services to prevent complications, to the extent possible, and services to restore normal eating skills, if possible.

**Criteria for Compliance**

- **Compliance for F322** The facility is in compliance with 42 CFR §483.25(g), if staff:

  - Use a feeding tube to provide nutrition and hydration only when the resident's clinical condition makes this intervention necessary based on adequate assessment and after other efforts to maintain or improve the resident's nutritional status have failed;
  - Manage all aspects of a feeding tube and enteral feeding consistent with current clinical standards of practice in order to meet the resident's nutritional and hydration needs and to prevent complications;
  - Identify and address the potential risks and/or complications associated with feeding tubes, and provide treatment and services to restore, if possible, adequate oral intake.

If not, cite at F322.

- **Noncompliance for F322** After completing the Investigative Protocol, analyze the data in order to determine whether noncompliance with the regulation...
exists. Noncompliance for F322 may include, but is not limited to, failure to do one or more of the following:

- Appropriately assess a resident's nutritional status and needs, and identify a clinically pertinent rationale for the use of a feeding tube;
- Identify nutritional requirements for a resident fed by a feeding tube and ensure that a tube feeding meets those needs;
- Adequately address the nutritional aspects of enteral feeding and the management of the feeding tube, including prevention of related complications;
- Use and monitor a feeding tube per facility protocol and pertinent clinical standards of practice, provide services to attempt to restore, if possible, normal eating skills, or identify and manage tube-related or enteral feeding-related complications.

**Potential Tags for Additional Investigations.** If an additional concern has been identified, the surveyor must investigate the identified concern. Do not cite any related or associated requirements before first conducting an investigation to determine compliance or non-compliance with the related or associated requirements. Some examples include, but are not limited to, the following:

1) **42 CFR §483.10(b)(3);(d)(2), F154, Right to Be Fully Informed.** Determine if the facility has fully informed the resident of his or her total health status and has provided the resident with information about the use of a feeding tube (including risks, benefits and alternatives) so that an informed decision can be made.

2) **42 CFR §483.10(b)(4)(8), F155, Notice of Rights and Services, Right to Refuse Treatment and Experimental Research and to Formulate Advance Directives, Maintenance and Provision of Written Policies of These Rights**
   a. Determine if the facility has given the resident or legal representative the opportunity to participate in the decision about tube feeding and informed the resident of the right to make advance directives and to decline life-sustaining treatments including artificial nutrition and hydration;
   b. Determine if the facility maintains written policies and procedures regarding advance directives;
   c. Determine if the facility informs and provides written information to all adult residents concerning the right to accept or refuse medical treatment and formulate advance directives.

3) **42 CFR §483.10(b)(11), F157, Notification of Changes.** Determine if staff notified:
   The physician when they suspected or identified inability to maintain adequate oral intake or complications related to use of the feeding tube; and
   The resident and the resident’s legal representative (if known) of significant changes in the resident’s condition in relation to the feeding tube or inability to take nutrition orally;

4) **42 CFR §483.15(a), F241, Dignity.** Determine whether the staff provided respectful care for the resident being tube fed to maintain and enhance the
5) **42 CFR §483.15(b), F242, Self-determination and Participation.** Determine whether staff provided the resident with relevant information and choices regarding feeding tubes;

6) **42 CFR §483.20(b), F272, Comprehensive Assessments.** Determine if the resident’s comprehensive assessment reflects the resident’s nutritional status, including factors that may have contributed to inadequate oral intake, and evaluates the resident’s response to the implementation of tube feeding, including nutritional and psychosocial aspects;

7) **42 CFR §483.20(g), F278, Accuracy of Assessments.** Determine whether the assessment accurately reflects the resident’s status;

8) **42 CFR §483.20(g), F278, Accuracy of Assessments.** Determine if the resident’s comprehensive care plan includes measurable objectives, time frames, and specific interventions consistent with the resident’s specific nutritional status, risks, needs, and current clinical standards of practice. This includes interventions prior to the insertion of the feeding tube to attempt to avoid tube feeding and after the insertion of the tube to prevent tube-related and tube-feeding related complications and restore, if possible, adequate oral intake;

9) **42 CFR §483.20(k)(2)(iii), F280, Comprehensive Care Plan Revision.** Determine if the care plan was periodically reviewed and revised by appropriate staff, in conjunction with the practitioner and with input from the resident or his/her legal representative, to try to meet the resident’s nutritional and hydration needs; reduce, prevent, or address potential complications; and attempt to restore normal eating skills, if possible;

10) **42 CFR §483.20(k)(3)(i), F281, Services Provided Meet Professional Standards of Quality.** Determine if staff provided care in accordance with accepted professional standards of quality to maintain or restore adequate oral intake, if possible, and to manage the feeding tube to maintain or improve nutrition and prevent complications, to the extent possible;

11) **42 CFR §483.20(k)(3)(ii), F282, Care Provided by Qualified Persons in Accordance with the Plan of Care.** Determine whether care of the resident with a feeding tube is being provided by qualified staff and/or whether the care plan is adequately and/or correctly implemented;

12) **42 CFR §483.25(i), F325, Nutrition.** Determine if the facility has managed the resident’s nutritional interventions to meet the resident’s nutritional needs, while using a feeding tube;

13) **42 CFR §483.25(l), F329, Unnecessary Drugs.** Determine if the facility has reviewed the resident’s medication regimen for medications that may have caused or contributed to a decline in oral intake, or ability to chew and/or swallow, that may have contributed to the decision to place a feeding tube or affected the efforts to restore normal eating;

14) **42 CFR §483.30, F353, Nursing Services.** Determine if the facility has sufficient nursing staff that is qualified to provide necessary care and services to the resident being fed by a feeding tube;

15) **42 CFR §483.40(a), F385, Physician Supervision.** Determine if a physician is supervising the medical aspects of the tube feedings including assessment of causes of impaired nutritional status, development of a treatment regimen...
consistent with current clinical standards of practice, monitoring, and response to notification of change in the resident’s medical status;

16) **42 CFR §483.60, F425, Pharmacy Services.** Determine if the policies were developed and implemented for the safe administration of medications for a resident with a feeding tube;

17) **42 CFR §483.65, F441, Infection Control.** Determine if the facility established and maintained an infection control policies for safe and sanitary care and services for a resident being fed by a tube;

18) **42 CFR §483.75(i), F501, Medical Director.** Determine whether the medical director helped the facility develop and implement policies addressing the assessment and management of individuals with impaired or at-risk nutrition and hydration status and recognizing, addressing, and preventing complications related to tube feedings;

19) **42 CFR §483.75(l), F514, Clinical Records** Determine whether the clinical record:
   - Accurately, completely and, in accordance with current clinical standards, documents: the resident's status (including changes in condition), care and services provided to the resident with a feeding tube, response to treatment and the resident's goals;
   - Provides the basis for determining the continued need for tube feeding and whether changes in treatment are necessary.

**DEFICIENCY CATEGORIZATION**

Once the team has completed its investigation, analyzed the data, reviewed the regulatory requirements, and determined that noncompliance exists, the team must determine the severity of each deficiency, based on the harm or potential for harm to the resident. The key elements for severity determination for F322 are as follows:

1. **Presence of harm/negative outcome(s) or potential for negative outcomes because of lack of appropriate care and services.** Actual or potential harm/negative outcomes for F322 may include but are not limited to:
   - Failure to adequately assess a resident’s nutritional status and the care and services needed to maintain or improve the resident’s nutritional status and/or to identify why the use of a feeding tube was medically unavoidable;
   - Failure to adequately identify nutritional requirements for a resident fed by a feeding tube and ensure that the tube feeding met those needs (if clinically feasible), resulting in the resident experiencing malnutrition and dehydration;
   - Failure to verify the location of the tube in accordance with current clinical standards, facility protocols, and resident condition; therefore increasing the risk for complications such as aspiration; and
   - Failure to use and monitor a feeding tube per facility protocol and current clinical standards of practice or to identify and manage feeding tube-related or tube-feeding related complications, thereby allowing the complication to continue without appropriate intervention.

2. **Degree of harm (actual or potential) related to the noncompliance.** Identify how the facility practices caused, resulted in, allowed, or contributed to the actual or potential for harm.

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• 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 the potential is for serious injury, impairment, death, compromise or discomfort to occur to the resident.

3. The immediacy of correction required. Determine whether the noncompliance 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. 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.

Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety

Immediate jeopardy is a situation in which the facility’s noncompliance with one or more requirements of participation:

• Has allowed, caused, or resulted in (or is likely to allow, cause, or result in) serious injury, harm, impairment, or death to a resident;
• Requires immediate correction as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.

NOTE: The death or transfer of a resident, who was harmed as a result of facility practices, does not remove a finding of immediate jeopardy. The facility is required to implement specific actions to correct the deficient practices which allowed or caused the immediate jeopardy.

Examples of avoidable actual or potential resident outcomes that demonstrate severity at Level 4 may include, but are not limited to:

• The facility failed to train staff about how to ensure proper placement of a feeding tube, and/or to ensure that staff were checking for tube placement consistently and correctly. As a result of staff failure to verify tube placement, a resident got peritonitis (infection of the lining of the abdominal cavity) and died following the administration of tube feeding;
• As a result of the facility routinely keeping a resident lying almost flat in bed while administering the resident’s tube feeding, the resident aspirated some of the tube feeding and got aspiration pneumonia.

NOTE: If Severity Level 4 (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 or the potential for more than minimal harm at Severity Level 2 exists.

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

Severity Level 3 indicates noncompliance that resulted in actual harm that is not immediate jeopardy. The negative outcome can include but may not be limited to clinical compromise, decline, or the resident’s inability to maintain and/or reach his/her highest practicable well-being.

Examples of avoidable actual resident outcomes that demonstrate severity at Level 3 may include, but are not limited to:

• The facility failed to monitor for complications related to a resident’s
feeding tube and tube feeding. As a result, the resident experienced significant but not life-threatening tube feeding-related complications;

- As a result of facility failure to assess the resident’s nutritional needs and to continue to administer, monitor, and adjust tube feeding accordingly, a resident experienced significant weight loss that cannot be otherwise attributed to a medically unavoidable cause.

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

Severity Level 2 indicates noncompliance that resulted in a resident outcome of no more than minimal discomfort and/or had 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 outcomes at Severity Level 2 include, but are not limited to:

- As a result of staff failure to anchor a feeding tube properly, the resident had leakage and irritation around the tube insertion site that required topical treatment and resolved without complications;
- As a result of staff failure to manage a tube feeding pump properly, the resident did not receive the calculated amount of tube feeding, without resulting in significant weight loss or other GI complications;
- As a result of staff failure to consistently flush a resident’s feeding tube as ordered, the tube clogged and had to be replaced, but there were no other complications.

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

The failure of the facility to provide appropriate care and services for feeding tubes, places the resident at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.
Tag F 325 Nutrition
Based on a resident’s comprehensive assessment, the facility must ensure that a resident--
(1) Maintains acceptable parameters of nutritional status, such as body weight and protein levels, unless the resident’s clinical condition demonstrates that this is not possible; and
(2) Receives a therapeutic diet when there is a nutritional problem.

INTENT: Nutritional Status. The intent of this requirement is that the resident maintains, to the extent possible, acceptable parameters of nutritional status and that the facility:

• Provides nutritional care and services to each resident, consistent with the resident’s comprehensive assessment;
• Recognizes, evaluates, and addresses the needs of every resident, including but not limited to, the resident at risk or already experiencing impaired nutrition;
• Provides a therapeutic diet that takes into account the resident’s clinical condition, and preferences, when there is a nutritional indication.

DEFINITIONS
Definitions are provided to clarify clinical terms related to nutritional status.

Acceptable parameters of nutritional status refers to factors that reflect that an individual's nutritional status is adequate, relative to his/her overall condition and prognosis.

Albumin is the body’s major plasma protein, essential for maintaining osmotic pressure and also serving as a transport protein.

Anemia refers to a condition of low hemoglobin concentration caused by decreased production, increased loss, or destruction of red blood cells.

Anorexia refers to loss of appetite, including loss of interest in seeking and consuming food.

Artificial nutrition refers to nutrition that is provided through routes other than the usual oral route, typically by placing a tube directly into the stomach, the intestine or a vein.

Avoidable/Unavoidable failure to maintain acceptable parameters of nutritional status:

Avoidable means that the resident did not maintain acceptable parameters of nutritional status and that the facility did not do one or more of the following: evaluate the resident’s clinical condition and nutritional 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 did not maintain acceptable parameters of nutritional status even though the facility had evaluated the resident’s clinical condition and nutritional 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.

**Clinically significant** refers to effects, results, or consequences that materially affect or are likely to affect an individual's physical, mental, or psychosocial well-being either positively by preventing, stabilizing, or improving a condition or reducing a risk, or negatively by exacerbating, causing, or contributing to a symptom, illness, or decline in status.

**Current standards of practice** refers to approaches to care, procedures, techniques, treatments, etc., that are based on research or expert consensus and that are contained in current manuals, textbooks, or publications, or that are accepted, adopted or promulgated by recognized professional organizations or national accrediting bodies.

**Dietary supplements** refers to nutrients (e.g., vitamins, minerals, amino acids, and herbs) that are added to a person’s diet when they are missing or not consumed in enough quantity.

**Insidious weight loss** refers to a gradual, unintended, progressive weight loss over time.

**Nutritional Supplements** refers to products that are used to complement a resident’s dietary needs (e.g., total parenteral products, enteral products, and meal replacement products).

**Parameters of nutritional status** refers to factors (e.g., weight, food/fluid intake, and pertinent laboratory values) that reflect the resident’s nutritional status.

**Qualified dietitian** refers to one who is qualified based upon either registration by the Commission on Dietetic Registration of the American Dietetic Association or as permitted by State law, on the basis of education, training, or experience in identification of dietary needs, planning, and implementation of dietary programs.

**Therapeutic diet** refers to a diet ordered by a health care practitioner as part of the treatment for a disease or clinical condition, to eliminate, decrease, or increase certain substances in the diet (e.g., sodium or potassium), or to provide mechanically altered food when indicated.

**Usual body weight** refers to the resident’s usual weight through adult life or a stable weight over time.

**OVERVIEW**

Nutrients are essential for many critical metabolic processes, the maintenance and repair of cells and organs, and energy to support daily functioning. Therefore, it is important to maintain adequate nutritional status, to the extent possible. Other key factors in addition to intake can influence weight and nutritional status. For example, the body may not absorb or use nutrients effectively. Low weight may also pertain to: age-related loss of muscle mass, strength, and function (sarcopenia), wasting (cachexia) that occurs as a consequence of illness and inflammatory processes, or disease causing changes in mental status. Changes in the ability to taste food may accompany later life.

Impaired nutritional status is not an expected part of normal aging. It may be associated with an increased risk of mortality and other negative outcomes such as impairment of anticipated wound healing, decline in function, fluid and electrolyte imbalance/dehydration, and unplanned weight change. The early identification of residents with, or at risk for, impaired nutrition, may allow the interdisciplinary team
to develop and implement interventions to stabilize or improve nutritional status before additional complications arise. However, since intake is not the only factor that affects nutritional status, nutrition-related interventions only sometimes improve markers of nutritional status such as body weight and laboratory results. While they can often be stabilized or improved, nutritional deficits and imbalances may take time to improve or they may not be fully correctable in some individuals.

A systematic approach can help staff’s efforts to optimize a resident’s nutritional status. This process includes identifying and assessing each resident’s nutritional status and risk factors, evaluating/analyzing the assessment information, developing and consistently implementing pertinent approaches, and monitoring the effectiveness of interventions and revising them as necessary.

**ASSESSMENT**

According to the American Dietetic Association, “Nutritional assessment is a systematic process of obtaining, verifying and interpreting data in order to make decisions about the nature and cause of nutrition-related problems.” The assessment also provides information that helps to define meaningful interventions to address any nutrition-related problems.

The interdisciplinary team clarifies nutritional issues, needs, and goals in the context of the resident’s overall condition, by using observation and gathering and considering information relevant to each resident’s eating and nutritional status. Pertinent sources of such information may include interview of the resident or resident representative, and review of information (e.g., past history of eating patterns and weight and a summary of any recent hospitalizations) from other sources.

The facility identifies key individuals who should participate in the assessment of nutritional status and related causes and consequences. For example, nursing staff provide details about the resident’s nutritional intake. Health care practitioners (e.g., physicians and nurse practitioners) help define the nature of the problem (e.g., whether the resident has anorexia or sarcopenia), identify causes of anorexia and weight loss, tailor interventions to the resident’s specific causes and situation, and monitor the continued relevance of those interventions. Qualified dietitians help identify nutritional risk factors and recommend nutritional interventions, based on each resident’s medical condition, needs, desires, and goals. Consultant pharmacists can help the staff and practitioners identify medications that affect nutrition by altering taste or causing dry mouth, lethargy, nausea, or confusion.

Although the Resident Assessment Instrument (RAI) is the only assessment tool specifically required, a more in-depth nutritional assessment may be needed to identify the nature and causes of impaired nutrition and nutrition-related risks. Completion of the RAI does not remove the facility’s responsibility to document a more detailed resident assessment, where applicable. The in-depth nutritional assessment may utilize existing information from sources, such as the RAI, assessments from other disciplines, observation, and resident and family interviews. The assessment will identify usual body weight, a history of reduced appetite or progressive weight loss or gain prior to admission, medical conditions such as a cerebrovascular accident, and events such as recent surgery, which may have affected a resident’s nutritional status and risks. The in-depth nutritional

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assessment may also include the following information:

**Assessment Items**

**General Appearance** - General appearance includes a description of the resident’s overall appearance (e.g., robust, thin, obese, or cachectic) and other findings (e.g., level of consciousness, responsiveness, affect, oral health and dentition, ability to use the hands and arms, and the condition of hair, nails, and skin) that may affect or reflect nutritional status.

**Height** - Measuring a resident’s height provides information that is relevant (in conjunction with his or her weight) to his/her nutritional status. There are various ways to estimate height if standing height cannot be readily measured. A protocol for determining height helps to ensure that it will be measured as consistently as possible.

**Weight** - Weight can be a useful indicator of nutritional status, when evaluated within the context of the individual’s personal history and overall condition. When weighing a resident, adjustment for amputations or prostheses may be indicated. Significant unintended changes in weight (loss or gain) or insidious weight loss may indicate a nutritional problem.

Current standards of practice recommend weighing the resident on admission or readmission (to establish a baseline weight), weekly for the first 4 weeks after admission and at least monthly thereafter to help identify and document trends such as insidious weight loss. Weighing may also be pertinent if there is a significant change in condition, food intake has declined and persisted (e.g., for more than a week), or there is other evidence of altered nutritional status or fluid and electrolyte imbalance. In some cases, weight monitoring is not indicated (e.g., the individual is terminally ill and requests only comfort care).

Obtaining accurate weights for each resident may be aided by having staff follow a consistent approach to weighing and by using an appropriately calibrated and functioning scale (e.g., wheelchair scale or bed scale). Since weight varies throughout the day, a consistent process and technique (e.g., weighing the resident wearing a similar type of clothing, at approximately the same time of the day, using the same scale, either consistently wearing or not wearing orthotics or prostheses, and verifying scale accuracy) can help make weight comparisons more reliable.

A system to verify weights can help to ensure accuracy. Weights obtained in different settings may differ substantially. For example, the last weight obtained in the hospital may differ markedly from the initial weight upon admission to the facility, and is not to be used in lieu of actually weighing the resident. Approaches to improving the accuracy of weights may include reweighing the resident and recording the current weight, reviewing approaches to obtaining and verifying weight, and modifying those approaches as needed.

Examples of other factors that may impact weight and the significance of apparent weight changes include:

- The resident’s usual weight through adult life;
- Current medical conditions;
- Calorie restricted diet;
- Recent changes in dietary intake;
- Edema.

**Food and fluid intake** - The nutritional assessment includes an estimate of
calorie, nutrient and fluid needs, and whether intake is adequate to meet those needs. It also includes information such as the route (oral, enteral or parenteral) of intake, any special food formulation, meal and snack patterns (including the time of supplement or medication consumption in relation to the meals), dislikes, and preferences (including ethnic foods and form of foods such as finger foods); meal/snack patterns, and preferred portion sizes.

Fluid loss or retention can cause short term weight change. Much of a resident’s daily fluid intake comes from meals; therefore, when a resident has decreased appetite, it can result in fluid/electrolyte imbalance. Abrupt weight changes, change in food intake, or altered level of consciousness are some of the clinical manifestations of fluid and electrolyte imbalance. Laboratory tests (e.g., electrolytes, BUN, creatinine and serum osmolality) can help greatly to identify, manage, and monitor fluid and electrolyte status.

**Altered nutrient intake, absorption, and utilization.** Poor intake, continuing or unabated hunger, or a change in the resident’s usual intake that persists for multiple meals, may indicate an underlying problem or illness. Examples of causes include:

- The inability to consume meals provided (e.g., as a result of the form or consistency of food/fluid, cognitive or functional decline, arthritis-related impaired movement, neuropathic pain, or insufficient assistance);
- Insufficient availability of food and fluid (e.g., inadequate amount of food or fluid or inadequate tube feedings);
- Environmental factors affecting food intake or appetite (e.g., comfort and level of disruption in the dining environment);
- Adverse consequences related to medications;
- Diseases and conditions such as cancer, diabetes mellitus, advanced or uncontrolled heart or lung disease, infection and fever, liver disease, hyperthyroidism, mood disorders, and repetitive movement disorders (e.g., wandering, pacing, or rocking).

The use of diuretics and other medications may cause weight loss that is not associated with nutritional issues, but can also cause fluid and electrolyte imbalance/dehydration that causes a loss of appetite and weight.

Various gastrointestinal disorders such as pancreatitis, gastritis, motility disorders, small bowel dysfunction, gall bladder disease, and liver dysfunction may affect digestion or absorption of food. Prolonged diarrhea or vomiting may increase nutritional requirements due to nutrient and fluid losses. Constipation or fecal impaction may affect appetite and excretion.

Pressure ulcers and some other wounds and other health impairments may also affect nutritional requirements. A hypermetabolic state results from an increased demand for energy and protein and may increase the risk of weight loss or under-nutrition. Examples of causes include advanced chronic obstructive pulmonary disease (COPD), pneumonia and other infections, cancer, hyperthyroidism, and fever.

Early identification of these factors, regardless of the presence of any associated weight changes, can help the facility choose appropriate interventions to minimize any subsequent complications. Often, several of these factors affecting nutrition coexist.
**Chewing abnormalities** - Many conditions of the mouth, teeth, and gums can affect the resident’s ability to chew foods. For example, oral pain, dry mouth, gingivitis, periodontal disease, ill-fitting dentures, and broken, decayed or missing teeth can impair oral intake.

**Swallowing abnormalities** - Various direct and indirect causes can affect the resident’s ability to swallow. These include but are not limited to stroke, pain, lethargy, confusion, dry mouth, and diseases of the oropharynx and esophagus. Swallowing ability may fluctuate from day to day or over time. In some individuals, aspiration pneumonia can complicate swallowing abnormalities.

**NOTE:** Swallowing studies are not always required in order to assess eating and swallowing; however, when they are indicated, it is essential to interpret any such tests in the proper context. A clinical evaluation of swallowing may be used to evaluate average daily oral function.

**Functional ability** - The ability to eat independently may be helped by addressing factors that impair function or by providing appropriate individual assistance, supervision, or assistive devices. Conditions affecting functional ability to eat and drink include impaired upper extremity motor coordination and strength or reduced range of motion (any of which may be hampered by stroke, Parkinson’s disease, multiple sclerosis, tardive dyskinesia, or other neuromuscular disorders or by sensory limitations (e.g., blindness)). Cognitive impairment may also affect a resident’s ability to use a fork, or to eat, chew, and swallow effectively.

**Medications** - Medications and nutritional supplements may affect, or be affected by, the intake or utilization of nutrients (e.g., liquid phenytoin taken with tube feedings or grapefruit juice taken with some antihyperlipidemics). Medications from almost every pharmaceutical class can affect nutritional status, directly or indirectly; for example, by causing or exacerbating anorexia, lethargy, confusion, nausea, constipation, impairing taste, or altering gastrointestinal function. Inhaled or ingested medications can affect food intake by causing pharyngitis, dry mouth, esophagitis, or gastritis. To the extent possible, consideration of medication/nutrient interactions and adverse consequences should be individualized.

**Goals and prognosis** - Goals and prognosis refer to a resident’s projected personal and clinical outcomes. These are influenced by the resident’s preferences (e.g., willingness to participate in weight management interventions or desire for nutritional support at end-of-life), anticipated course of a resident’s overall condition and progression of a disease (e.g., end-stage, terminal, or other irreversible conditions affecting food intake, nutritional status, and weight goals), and by the resident’s willingness and capacity to permit additional diagnostic testing, monitoring and treatment.

**Laboratory/Diagnostic Evaluation** Laboratory tests are sometimes useful to help identify underlying causes of impaired nutrition or when the clinical assessment alone is not enough to define someone’s nutritional status.

Abnormal laboratory values may, but do not necessarily, imply that treatable clinical problems exist or that interventions are needed. Confirmation is generally desirable through additional clinical evaluation and evidence such as food intake, underlying medical condition, etc. For example, serum albumin may help establish prognosis but is only sometimes helpful in identifying impaired nutrition or guiding interventions. Serum albumin may drop significantly during an acute illness for...
reasons unrelated to nutrition; therefore, albumin may not improve, or may fall further, despite consumption of adequate amounts of calories and protein.

The decision to order laboratory tests, and the interpretation of subsequent results, is best done in light of a resident’s overall condition and prognosis. Before ordering laboratory tests it is appropriate for the health care practitioner to determine and indicate whether the tests would potentially change the resident’s diagnosis, management, outcome or quality of life or otherwise add to what is already known. Although laboratory tests such as albumin and pre-albumin may help in some cases in deciding to initiate nutritional interventions, there is no evidence that they are useful for the serial follow-up of undernourished individuals.

**NOTE:** If laboratory tests were done prior to or after admission to the facility and the test results are abnormal, the physician or other licensed health care practitioner, in collaboration with the interdisciplinary team, reviews the information and determines whether to intervene or order additional diagnostic testing.

**Analysis.** Analysis refers to using the information from multiple sources to include, but not limited to, the Resident Assessment Instrument (RAI), and additional nutritional assessments as indicated to determine a resident’s nutritional status and develop an individualized care plan.

Resultant conclusions may include, but are not limited to: a target range for weight based on the individual's overall condition, goals, prognosis, usual body weight, etc.; approximate calorie, protein, and other nutrient needs; whether and to what extent weight stabilization or improvement can be anticipated; and whether altered weight or nutritional status could be related to an underlying medical condition (e.g., fluid and electrolyte imbalance, medication-related anorexia, or an infection).

Suggested parameters for evaluating significance of unplanned and undesired weight loss are:

<table>
<thead>
<tr>
<th>Interval</th>
<th>Significant Loss</th>
<th>Severe Loss Greater than</th>
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<tbody>
<tr>
<td>1 month</td>
<td>5%</td>
<td>Greater than 5%</td>
</tr>
<tr>
<td>3 months</td>
<td>7.5%</td>
<td>Greater than 7.5%</td>
</tr>
<tr>
<td>6 months</td>
<td>10%</td>
<td>Greater than 10%</td>
</tr>
</tbody>
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The following formula determines percentage of weight loss: \( \frac{\text{usual weight} - \text{actual weight}}{\text{usual weight}} \times 100 \). Based on analysis of relevant information, the facility identifies a clinically pertinent basis for any conclusions that a resident could not attain or maintain acceptable parameters of nutritional status.

**Specification of the Nutritional Concern** A clear statement of the nature of the nutritional concern provides the basis for resident-specific interventions. Many residents have multiple coexisting issues. For example:

- **Poor food and fluid intake:** The resident has poor intake, is not consuming specific food groups, and has increased nutritional needs specific to clinical conditions. The resident also has lost significant weight over a few days while taking medications that may affect appetite.
- **Specific clinical conditions:** The resident has an infection with fever and is in a hyper-metabolic state associated with an increased demand for energy.

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and protein. The resident also has a neuromuscular disorder affecting the ability to eat or swallow, and has impaired cognition affecting attention and appetite.

**Care planning and interventions** The management of nutrition in nursing homes involves various medical, psychosocial, ethical, and functional considerations. Based on information generated by the comprehensive assessment and any pertinent additional nutritional assessment, the interdisciplinary team (including a physician or other licensed health care practitioner and the resident or the resident’s representative) develops an individualized care plan. The care plan addresses, to the extent possible, identified causes of impaired nutritional status, reflects the resident’s goals and choices, and identifies resident-specific interventions and a time frame and parameters for monitoring. The care plan is updated as needed; e.g., as conditions change, goals are met, interventions are determined to be ineffective, or as specific treatable causes of nutrition-related problems (anorexia, impaired chewing, etc.) are identified. If nutritional goals are not achieved, different or additional pertinent approaches are considered and implemented as indicated. Pertinent documentation can help identify the basis (e.g., current resident status, comorbid conditions, prognosis, and resident choices) for nutrition-related goals and interventions.

**Resident Choice** A resident or resident representative has the right to make informed choices about accepting or declining care and treatment. The facility can help the resident exercise those rights effectively by discussing with the resident (or the resident’s representative) the resident’s condition, treatment options (including related risks and benefits, and expected outcomes), personal preferences, and any potential consequences of accepting or refusing treatment. If the resident declines specific interventions, the facility must address the resident’s concerns and offer relevant alternatives.

The facility’s care reflects a resident’s choices, either as offered by the resident directly or via a valid advance directive, or based on a decision made by the resident’s surrogate or representative in accordance with state law. The presence of care instructions, such as an advance directive, declining some interventions does not necessarily imply that other support and care was declined or is not pertinent. When preferences are not specified beforehand, decisions related to the possible provision of supplemental or artificial nutrition should be made in conjunction with the resident or resident’s representative in accordance with state law, taking into account relevant considerations such as condition, prognosis, and a resident’s known values and choices.

**NOTE:** The presence of a “Do Not Resuscitate” (DNR) order does not by itself indicate that the resident is declining other appropriate treatment and services. It only indicates that the resident has chosen not to be resuscitated if cardiopulmonary functions cease.

**Meeting Nutritional Needs** The scope of interventions to meet residents’ nutritional needs depends on many factors, including, but not limited to a resident’s current food intake, the degree of nutritional impairment or risk, resident choices,
the response to initial interventions, and the feasibility of addressing underlying conditions and causes. Basic energy needs can generally be met by providing a diet that includes enough calories to stabilize current body weight. Adjustments may be necessary when factors exist such as those discussed within this document. For example, limits on dairy products may be desirable in individuals with lactose intolerance, and additional amounts of nutrients and calories may be needed for individuals with hypermetabolic states (e.g., fever, hyperthyroidism, acute wounds, or heart or lung disease), to try to keep the body from using lean body mass for energy and wound repair.

Diet Liberalization

Research suggests that a liberalized diet can enhance the quality of life and nutritional status of older adults in long-term care facilities. Thus, it is often beneficial to minimize restrictions, consistent with a resident’s condition, prognosis, and choices before using supplementation. It may also be helpful to provide the residents their food preferences, before using supplementation. This pertains to newly developed meal plans as well as to the review of existing diets.

Dietary restrictions, therapeutic (e.g., low fat or sodium restricted) diets, and mechanically altered diets may help in select situations. At other times, they may impair adequate nutrition and lead to further decline in nutritional status, especially in already undernourished or at-risk individuals. When a resident is not eating well or is losing weight, the interdisciplinary team may temporarily abate dietary restrictions and liberalize the diet to improve the resident’s food intake to try to stabilize their weight.

Sometimes, a resident or resident’s representative decides to decline medically relevant dietary restrictions. In such circumstances, the resident, facility and practitioner collaborate to identify pertinent alternatives.

Weight-Related Interventions

For many residents (including overweight individuals), the resident’s usual body weight prior to decline or admission is the most relevant basis for weight-related interventions. Basing interventions on ideal body weight can be misleading, because ideal body weight has not been definitively established for the frail elderly and those with chronic illnesses and disabilities.

The care plan includes nutritional interventions that address underlying risks and causes of weight loss (e.g., the need for eating assistance, reduction of medication side effects, and additional food that the resident will eat) or unplanned weight gain. It is important that the care plan address insidious, abrupt, or sudden decline in intake or insidious weight loss that does not trigger review of the Nutritional Status Resident Assessment Protocol (RAP); for example, by intensifying observation of intake and eating patterns, monitoring for complications related to poor intake, and seeking underlying cause(s).

Many risk factors and some causes of weight loss can be addressed, at least partially, while others may not be modifiable. In some cases, certain interventions may not be indicated or appropriate, based on individual goals and prognosis. Weight stability, rather than weight gain, may sometimes be the most pertinent short-term or long-term objective for the nutritionally at-risk or compromised resident. After an acute illness or as part of an advanced or end-stage medical condition, the resident’s weight and other nutritional parameters may not return to previous levels and may stabilize at a lower level, sometimes indefinitely.
**NOTE:** There should be a documented clinical basis for any conclusion that nutritional status or significant weight change are unlikely to stabilize or improve (e.g., physician’s documentation as to why weight loss is medically unavoidable).

**Weight gain.** Unplanned weight gain in a resident may have significant health implications. Rapid or abrupt increases in weight may also indicate significant fluid excess. After assessing the resident for the cause of the weight gain, care plan interventions may include dietary alterations based on the resident’s medical condition, choices, and needs. If the resident exercises his/her right to choose and declines dietary restrictions, the facility discusses with the resident the benefits of maintaining a lower weight and the possible consequences of not doing so. A health care practitioner can help inform the resident about the rationale for the recommended plan of care.

**Environmental factors.** Appetite is often enhanced by the appealing aroma, flavor, form, and appearance of food. Resident-specific facility practices that may help improve intake include providing a pleasant dining experience (e.g., flexible dining environments, styles and schedules), providing meals that are palatable, attractive and nutritious (e.g., prepare food with seasonings, serve food at proper temperatures, etc.), and making sure that the environment where residents eat (e.g., dining room and/or resident’s room) is conducive to dining.

**Anorexia.** The facility, in consultation with the practitioner, identifies and addresses treatable causes of anorexia. For example, the practitioner may consider adjusting or stopping medications that may have caused the resident to have dyspepsia or become lethargic, constipated, or confused, and reevaluate the resident to determine whether the effects of the medications are the reasons for the anorexia and subsequent weight loss.

Where psychosis or a mood disorder such as depression has been identified as a cause of anorexia or weight change, treatment of the underlying disorder (based on an appropriate diagnostic evaluation) may improve appetite. However, other coexisting conditions or factors instead of, or in addition to, depression, may cause or contribute to anorexia. In addition, the use of antidepressants is not generally considered to be an adequate substitute for appropriately investigating and addressing modifiable risk factors or other underlying causes of anorexia and weight loss.

**Wound Healing.** Healing of acute (e.g., postoperative) and chronic (e.g., pressure ulcer) wounds requires enough calories and protein so that the body will not use lean body mass (muscle) for energy and wound repair. However, to date, no routinely beneficial wound-specific nutritional measures have been identified. Care plan interventions for a resident who has a wound or is at risk of developing a wound may include providing enough calories to maintain a stable weight and a daily protein intake of approximately 1.2-1.5 gm protein/Kg body weight. The recommended daily protein intake may be adjusted according to clinical need and standards of clinical practice for situations in which more calories and protein are indicated. Sometimes, it may be most appropriate to try to encourage the resident to eat as many calories and as much protein as tolerated, because he/she does not desire or cannot tolerate more aggressive nutritional interventions.

Additional strategies for wound healing may be considered when indicated. A multivitamin/mineral supplement may be prescribed, however current evidence...
does not definitively support any specific dietary supplementation (e.g., Vitamin C and Zinc) unless the resident has a specific vitamin or mineral deficiency.

**Functional factors.** Based on the comprehensive interdisciplinary assessment, the facility provides the necessary assistance to allow the resident to eat and drink adequately. A resident with functional impairment may need help with eating. Examples of such interventions may include, but are not limited to: ensuring that sensory devices such as eyeglasses, dentures, and hearing aids are in place; providing personal hygiene before and after meals, properly positioning the individual, providing eating assistance where needed, and providing the assistive devices/utensils identified in the assessment.

**Chewing and Swallowing.** In deciding whether and how to intervene for chewing and swallowing abnormalities, it is essential to take a holistic approach and look beyond the symptoms to the underlying causes. Pertinent interventions may help address the resident’s eating, chewing, and swallowing problems and optimize comfort and enjoyment of meals. Examples of such interventions may include providing proper positioning for eating; participation in a restorative eating program; use of assistive devices/utensils; and prompt assistance (e.g., supervision, cueing, hand-over-hand) during every meal/snack where assistance is needed.

Treating medical conditions (e.g., gastroesophageal reflux disease and oral and dental problems) that can impair swallowing or cause coughing may improve a chewing or swallowing problem. Examples of other relevant interventions include adjusting medications that cause dry mouth or coughing, and providing liquids to moisten the mouth of someone with impaired saliva production.

Excessive modification of food and fluid consistency may unnecessarily decrease quality of life and impair nutritional status by affecting appetite and reducing intake. Many factors influence whether a swallowing abnormality eventually results in clinically significant complications such as aspiration pneumonia. Identification of a swallowing abnormality alone does not necessarily warrant dietary restrictions or food texture modifications. No interventions consistently prevent aspiration and no tests consistently predict who will develop aspiration pneumonia. For example, tube feeding may be associated with aspiration, and is not necessarily a desirable alternative to allowing oral intake, even if some swallowing abnormalities are present.

Decisions to downgrade or alter the consistency of diets must include the resident (or the resident’s representative), consider ethical issues (such as the right to decline treatment), and be based on a careful review of the resident’s overall condition, correctable underlying causes of the risk or problem, the benefits and risks of a more liberalized diet, and the resident’s preferences to accept risks in favor of a more liberalized food intake.

**Medications.** When a resident is eating poorly or losing weight, the immediate need to stabilize weight and improve appetite may supersede long-term medical goals for which medications were previously ordered. It may be appropriate to change, stop, or reduce the doses of medications (e.g., antiepileptics, cholinesterase inhibitors, or iron supplements) that are associated either with anorexia or with symptoms such as lethargy or confusion that can cause or exacerbate weight loss. The medical practitioner in collaboration with the staff and

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the pharmacist reviews and adjusts medications as appropriate. (For additional Guidance related to medications, refer to 42 CFR 483.25(l)(1), F329, Unnecessary Drugs.)

**Food fortification and supplementation.** With any nutrition program, improving intake via wholesome foods is generally preferable to adding nutritional supplements. However, if the resident is not able to eat recommended portions at meal times or to consume between-meal snacks/nourishments, or if he/she prefers the nutritional supplement, supplements may be used to try to increase calorie and nutrient intake. Since some research suggests that caloric intake may increase if nutritional supplements are consumed between meals, and may be less effective when given with meals, the use of nutritional supplements is generally recommended between meals instead of with meals. Taking a nutritional supplement during medication administration may also increase caloric intake without reducing the resident’s appetite at mealtime. Examples of interventions to improve food/fluid intake include:

- Fortification of foods (e.g., adding protein, fat, and/or carbohydrate to foods such as hot cereal, mashed potatoes, casseroles, and desserts);
- Offering smaller, more frequent meals;
- Providing between-meal snacks or nourishments;
- Increasing the portion sizes of a resident’s favorite foods and meals;
- Providing nutritional supplements.

**Maintaining fluid and electrolyte balance** If a resident has poor intake or abnormal laboratory values related to fluid/electrolyte balance, the care plan addresses the potential for hydration deficits. Examples of interventions include adjusting or discontinuing medications that affect fluid balance or appetite; offering a variety of fluids (water, fruit juice, milk, etc.) between meals, and encouraging and assisting residents as appropriate. Serving (except to those with fluid restrictions) additional beverages with meals will also help increase fluid intake. Examples of ways to encourage fluid intake include maintaining filled water pitchers and drinking cups easily accessible to residents (except those with fluid restrictions) and offering alternate fluid sources such as popsicles, gelatin, and ice cream.

**Use of appetite stimulants.** To date, the evidence is limited about benefits from appetite stimulants. While their use may be appropriate in specific circumstances, they are not a substitute for appropriate investigation and management of potentially modifiable risk factors and underlying causes of anorexia and weight loss.

**Feeding Tubes.** Feeding tubes have potential benefits and complications, depending on an individual’s underlying medical conditions and prognosis, and the causes of his or her anorexia or weight loss. Possible feeding tube use, especially for residents with advanced dementia or at the end-of-life, should be considered carefully. The resident’s values and choices regarding artificial nutrition should be identified and considered. The health care practitioner should be involved in reviewing whether potentially modifiable causes of anorexia, weight loss, and eating
or swallowing abnormalities have been considered and addressed, to the extent possible. For residents with dementia, studies have shown that tube feeding does not extend life, prevent aspiration pneumonia, improve function or limit suffering.

**End-of-Life.** Resident choices and clinical indications affect decisions about the use of a feeding tube at the end-of-life. A resident at the end of life may have an advance directive addressing his or her treatment goals (or the resident’s surrogate or representative, in accordance with State law, may have made a decision). Decreased appetite and altered hydration are common at the end of life, and do not require interventions other than for comfort. Multiple organ system failure may impair the body’s capacity to accept or digest food or to utilize nutrients. Thus, the inability to maintain acceptable parameters of nutritional status for someone who is at the end-of-life or in the terminal stages of an illness may be an expected outcome.

Care and services, including comfort measures, are provided based on the resident’s choices and a pertinent nutritional assessment. The facility can help to support intake, to the extent desired and feasible, based on the information from the assessment and on considering the resident’s choices.

If individualized approaches for end-of-life care are provided in accordance with the care plan and the resident’s choices, then the failure to maintain acceptable parameters of nutritional status may be an expected outcome for residents with terminal conditions.

**Monitoring** Monitoring after care plan implementation is necessary for residents with impaired or at-risk nutritional status, as well as for those whose current nutritional status is stable. Monitoring includes a review of the resident-specific factors identified as part of the comprehensive resident assessment and any supplemental nutrition assessment.

Identifying and reporting information about the resident’s nutritional status and related issues such as level of consciousness and function are obtainable through various staff observations. For example, nursing assistants may be most familiar with the resident’s habits and preferences, symptoms such as pain or discomfort, fluctuating appetite, and nausea or other gastrointestinal symptoms. More intensive and frequent monitoring may be indicated for residents with impaired or at-risk nutritional status than for those who are currently nutritionally stable. Such monitoring may include, but is not limited to, observing for and recognizing emergence of new risk factors (e.g., acute medical illness, pressure ulcers, or fever), evaluating consumption of between-meal snacks and nutritional supplements, and reviewing the continued relevance of any current nutritional interventions (e.g., therapeutic diets, tube feeding orders or nutritional supplements).

Evaluating the care plan to determine if current interventions are being followed and if they are effective in attaining identified nutritional and weight goals allows the facility to make necessary revisions. Subsequent adjustment of interventions will depend on, but are not limited to, progress, underlying causes, overall condition and prognosis. The resident’s current nutritional and medical status helps the staff determine the frequency of reweighing the resident. For example, reweighing a resident within a week of initiating or substantially revising...
nutritional interventions to address anorexia or weight loss assists in monitoring responses to interventions. Monitoring residents who experience unplanned weight loss, including reweighing at least weekly until weight is stable or increasing and then routinely thereafter, helps clarify his/her responses to interventions. However in some residents, subsequent weight monitoring may not be clinically indicated (e.g., palliative care resident).

Nutrition-related goals may need to be modified, depending on factors such as further clarification of underlying causes (e.g., when evidence suggests that unmodifiable factors may prevent improved or stabilized nutritional status) and responses to current interventions. In some cases, the current plan of care may need to be modified and new or additional interventions implemented. The facility explains any decisions to continue current interventions when the resident’s nutritional status continues to decline. For example, because the goal of care for someone with a terminal, advanced, or irreversible condition has changed to palliation.

**INVESTIGATIVE PROTOCOL**

**Objectives**

- To determine if the facility has practices in place to maintain acceptable parameters of nutritional status for each resident based on his/her comprehensive assessment.
- To determine if failure to maintain acceptable parameters of nutritional status for each resident was avoidable or unavoidable (the resident’s clinical condition demonstrates that maintaining acceptable parameters is not possible).
- To determine if the resident has received a therapeutic diet when there is a nutritional indication.

**Use** Use this protocol for each sampled resident to determine through interview, observation and record review whether the facility is in compliance with the regulation, specifically:

- To determine if residents maintained acceptable parameters of nutritional status, relative to his/her comprehensive assessment;
- For a resident who did not maintain acceptable parameters of nutritional status, to determine if the facility assessed and intervened (e.g., therapeutic diet) to enable the resident to maintain acceptable parameters of nutritional status, unless the resident’s clinical condition demonstrated that this was not possible;
- For a resident who is at nutritional risk, to determine if the facility has identified and addressed risk factors for, and causes of, impaired nutritional status, or demonstrated why they could not or should not do so.

**Procedures** Briefly review the RAI, care plan, and any additional relevant nutritional assessment information that may be available to identify facility evaluations, conclusions, and interventions to guide subsequent observations.

**NOTE:** For the purposes of this investigation, conduct record reviews prior to meal observations to note the resident’s therapeutic diet, food texture and level of

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required assistance with meals.

1. Observation  Observe residents during the initial tour of the facility and throughout the survey process. To facilitate the investigation, gather appropriate information (e.g., dining style, nourishment list, schedules, and policies). During observations, surveyors may see non-traditional or alternate approaches to dining services such as buffet, restaurant style or family style dining. These alternate dining approaches may include more choices in meal options, preparations, dining areas and meal times. Such alternate dining approaches are acceptable and encouraged.

While conducting the resident dining observations:

- Observe at least two meals during the survey;
- Observe a resident’s physical appearance for signs that might indicate altered nutritional status (e.g., cachectic) and note any signs of dental and oral problems;
- Observe the delivery of care (such as assistance and encouragement during dining) to determine if interventions are consistent with the care plan;
- Observe the serving of food as planned with attention to portion sizes, preferences, nutritional supplements, prescribed therapeutic diets and between-meal snacks to determine if the interventions identified in the care plan were implemented;
- Follow up and note differences between the care plan and interventions.
- Determine if staff responded appropriately to the resident’s needs (e.g., for assistance, positioning, and supervision).

2. Interview  Interview the resident, family or resident’s representative to identify:

- Whether staff are responsive to the resident’s eating abilities and support needs, including the provision of adaptive equipment and personal assistance with meals as indicated;
- Whether the resident’s food and dining preferences are addressed to the extent possible, e.g., whether the resident is offered substitutions or choices at meal times as appropriate and in accordance with his/her preferences;
- Whether pertinent nutritional interventions, such as snacks, frequent meals, and calorie-dense foods, are provided;
- If the resident refused needed therapeutic approaches, whether treatment options, related risks and benefits, expected outcomes and possible consequences were discussed with the resident or resident’s representative, and whether pertinent alternatives or other interventions were offered.

Interview interdisciplinary team members on various shifts (e.g., certified nursing assistant, registered dietitian, dietary supervisor/manager, charge nurse, social worker, occupational therapist, attending physician, medical director, etc.) to determine, how:

- Food and fluid intake, and eating ability and weight (and changes to any of these) are monitored and reported;
- Nutrition interventions, such as snacks, frequent meals, and calorie-dense foods are provided to prevent or address impaired nutritional status (e.g., unplanned weight changes);
- Nutrition-related goals in the care plan are established, implemented, and monitored periodically;
• Care plans are modified when indicated to stabilize or improve nutritional status (e.g., reduction in medications, additional assistance with eating, therapeutic diet orders);
• A health care practitioner is involved in evaluating and addressing underlying causes of nutritional risks and impairment (e.g., review of medications or underlying medical causes).

If the interventions defined, or the care provided, appear to be inconsistent with current standards of practice, interview one or more physicians or other licensed health care practitioners who can provide information about the resident’s nutritional risks and needs. Examples include, but are not limited to:
• The rationale for chosen interventions;
• How staff evaluated the effectiveness of current interventions;
• How staff managed the interventions;
• How the interdisciplinary team decided to maintain or change interventions;
• Rationale for decisions not to intervene to address identified needs.

3. Record Review

Review the resident’s medical record to determine how the facility:
• Has evaluated and analyzed nutritional status;
• Has identified residents who are at nutritional risk;
• Has investigated and identified causes of anorexia and impaired nutritional status;
• Has identified and implemented relevant interventions to try to stabilize or improve nutritional status;
• Has identified residents’ triggered Resident Assessment Instrument (RAI) for nutritional status;
• Has evaluated the effectiveness of the interventions;
• Has monitored and modified approaches as indicated.

Documentation

Documentation of findings and conclusions related to nutritional status may be found in various locations in the medical record, including but not limited to interdisciplinary progress notes, nutrition progress notes, the RAP summary, care plan, or resident care conference notes. Review of the documentation will help the surveyor determine how the facility developed approaches to meet each resident’s nutritional needs. This information will help the surveyor determine whether a resident’s decline or failure to improve his/her nutritional status was avoidable or unavoidable.

Assessment and Monitoring

Review information including the RAI, diet and medication orders, activities of daily living worksheets, and nursing, dietitian, rehabilitation, and social service notes. Determine if the resident’s weight and nutritional status were assessed in the context of his/her overall condition and prognosis, if nutritional requirements and risk factors were identified, and if causes of the resident’s nutritional risks or impairment were sought.

Determine:
• Whether the facility identified a resident’s desirable weight range, and identified weight loss/gain;
• Whether the facility identified the significance of any weight changes, and
what interventions were needed;
• Whether there have been significant changes in the resident’s overall intake;
• Whether the reasons for the change were identified and if appropriate interventions were implemented;
• Whether the facility has calculated nutritional needs (i.e., calories, protein and fluid requirements) and identified risk factors for malnutrition;
• Whether the facility met those needs and if not, why;
• Whether the resident’s weight stabilized or improved as anticipated;
• Whether a need for a therapeutic diet was identified and implemented, consistent with the current standards of practice;
• Whether the facility indicated the basis for dietary restrictions;
• Whether the reasons for dietary changes were identified and appropriate interventions implemented;
• Whether the facility accommodated resident choice, individual food preferences, allergies, food intolerances, and fluid restrictions and if the resident was encouraged to make choices;
• Whether the facility identified and addressed underlying medical and functional causes (e.g., oral cavity lesions, mouth pain, decayed teeth, poorly fitting dentures, refusal to wear dentures, gastroesophageal reflux, or dysphagia) of any chewing or swallowing difficulties to the extent possible;
• Whether the facility identified residents requiring any type of assistance to eat and drink (e.g., assistive devices/utensils, cues, hand-over-hand, and extensive assistance), and provided such assistance;
• Whether the facility has identified residents receiving any medications that are known to cause clinically significant medication/nutrient interactions or that may affect appetite, and determined risk/benefit;
• Whether the facility identified and addressed to the extent possible medical illnesses and psychiatric disorders that may affect overall intake, nutrient utilization, and weight stability;
• Whether the facility reviewed existing abnormal laboratory test results and either implemented interventions, if appropriate, or provided a clinical justification for not intervening (see note in Laboratory/Diagnostic Evaluation);
• Whether the resident’s current nutritional status is either at or improving towards goals established by the care team;
• Whether alternate interventions were identified when nutritional status is not improving or clinical justification is provided as to why current interventions continue to be appropriate.

Care Plan Review the comprehensive care plan to determine if the plan is based on the comprehensive assessment and additional pertinent nutritional assessment information. Determine if the facility developed measurable objectives, approximate time frames, and specific interventions to try to maintain acceptable parameters of nutritional status, based on the resident’s overall goals, choices, preferences, prognosis, conditions, assessed risks, and needs.

If care plan concerns, related to nutritional status are noted, interview staff responsible for care planning about the rationale for the current plan of care. If
questions remain after reviewing available information including documentation in the medical record, interview the resident’s attending physician or licensed health care practitioner or the facility’s medical director (e.g., if the attending physician or licensed health care practitioner is unavailable) concerning the resident’s plan of care.

**NOTE:** Because the physician may not be present in the facility and have immediate access to the resident’s medical record when the surveyor has questions, allow the facility the opportunity to first provide any pertinent information to the physician before responding to the interview.

**Care Plan Revision.** Determine if the staff has evaluated the effectiveness of the care plan related to nutritional status and made revisions if necessary based upon the following:

- Evaluation of nutrition-related outcomes;
- Identification of changes in the resident’s condition that require revised goals and care approaches;
- Involvement of the resident or the resident’s representative in reviewing and updating the resident’s care plan.

**Review of Facility Practices.** Related concerns may have been identified that would suggest the need for a review of facility practices. Examples of such activities may include a review of policies, staffing, and staff training, functional responsibilities, and interviews with staff (to include but not limited to management). If there is a pattern of residents who have not maintained acceptable parameters of nutritional status without adequate clinical justification, determine if quality assurance activities were initiated in order to evaluate the facility’s approaches to nutrition and weight issues.

**Interviews with Health Care Practitioners.** If the interventions defined, or the care provided, appear to be inconsistent with recognized standards of practice, interview one or more health care practitioners as necessary (e.g., physician, hospice nurse, dietitian, charge nurse, director of nursing or medical director). Depending on the issue, ask:

- How it was determined that chosen interventions were appropriate;
- Why identified needs had no interventions;
- How changes in condition that may justify additional or different interventions were addressed;
- How staff evaluated the effectiveness of current interventions.

**DETERMINATION OF COMPLIANCE**

**Synopsis of Regulation (Tag F325)** This regulation requires that, based on the resident’s comprehensive assessment, the facility ensures that each resident maintains acceptable parameters of nutritional status unless the resident’s clinical condition demonstrates that this is not possible, and that to the extent possible the resident receives a therapeutic diet when indicated.

**Criteria for Compliance**

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Compliance The facility is in compliance with Tag F325, Nutrition, if staff have:

- Assessed the resident’s nutritional status and identified factors that put the resident at risk of not maintaining acceptable parameters of nutritional status;
- Analyzed the assessment information to identify the medical conditions, causes and problems related to the resident’s condition and needs;
- Provided a therapeutic diet when indicated;
- Defined and implemented interventions to maintain or improve nutritional status that are consistent with the resident’s assessed needs, choices, goals, and recognized standards of practice, or provided clinical justification why they did not do so;
- Monitored and evaluated the resident’s response to the interventions; and revised the approaches as appropriate, or justified the continuation of current approaches.

If not, failure to maintain acceptable parameters of nutritional status is avoidable, cite at Tag F325.

Noncompliance After completing the investigative protocol, the survey team must analyze the data to determine whether noncompliance with the regulation exists. Noncompliance must be established before determining severity. A clear understanding of the facility’s noncompliance with requirements (i.e., deficient practices) is essential to determine how the deficient practice(s) relates to any actual harm or potential for harm to the resident.

Noncompliance with Tag F325 may include (but is not limited to) one or more of the following, including failure to:

- Accurately and consistently assess a resident’s nutritional status on admission and as needed thereafter;
- Identify a resident at nutritional risk and address risk factors for impaired nutritional status, to the extent possible;
- Identify, implement, monitor, and modify interventions (as appropriate), consistent with the resident’s assessed needs, choices, goals, and current standards of practice, to maintain acceptable parameters of nutritional status;
- Notify the physician as appropriate in evaluating and managing causes of the resident’s nutritional risks and impaired nutritional status;
- Identify and apply relevant approaches to maintain acceptable parameters of residents’ nutritional status;
- Provide a therapeutic diet when indicated.

Potential Tags for Additional Investigation If noncompliance with 42 CFR 483.25(i) has been identified, the survey team may have determined during the investigation of Tag F325 that concerns may also be present with related process and/or structure requirements. Examples of related process and/or structure requirements related to noncompliance with Tag F325 may include the following:

1) 42 CFR 483.10, Tag F150, Resident Rights Determine if the resident’s preferences related to nutrition and food intake were considered.

2) 42 CFR §483.20(b)(1), Tag F272, Comprehensive Assessments Determine if the facility assessed the resident’s nutritional status and the factors that put the resident at risk for failure to maintain acceptable parameters of nutritional status.
status.

3) 42 CFR §483.20(k), Tag F279, Comprehensive Care Plans Determine if the facility developed a comprehensive care plan for each resident that includes measurable objectives, interventions/services, and time frames to meet the resident’s needs as identified in the resident’s assessment and provided a therapeutic diet when indicated.

4) 42 CFR §483.20(k)(2)(iii), Tag F280, Comprehensive Care Plan Revision Determine if the care plan was periodically reviewed and revised as necessary by qualified persons after each assessment to maintain acceptable parameters of nutritional status and provided a therapeutic diet when indicated.

5) 42 CFR 483.20(k)(3)(ii), Tag F282, Provision of Care in Accordance with the Care Plan Determine if the services provided or arranged by the facility were provided by qualified persons in accordance with the resident’s written plan of care.

6) 42 CFR 483.25(j), Tag F327, Hydration Determine if the facility took measures to maintain proper hydration.

7) 42 CFR 483.25(k)(2), F328, Special Needs Determine if the facility took measures to provide proper treatment and care for Parenteral and Enteral Fluids.

8) 42 CFR 483.25, Tag F329, Unnecessary Medicines Determine if food and medication interactions are impacting the residents’ dietary intake.

9) 42 CFR 483.30(a), Tag F353, Sufficient Staff Determine if the facility had qualified staff in sufficient numbers to provide necessary care and services, including supervision, based upon the comprehensive assessment and care plan.

10) 42 CFR 483.35(a)(1)(2), F361, Dietary Services – Staffing Determine if the facility employs or consults with a qualified dietitian. If not employed full-time, determine if the director of food service receives scheduled consultation from the dietitian concerning storage, preparation, distribution and service of food under sanitary conditions.

11) 42 CFR 483.35(b), F362, Standard Sufficient Staff Determine if the facility employs sufficient support personnel competent to carry out the functions of the dietary service.

12) 42 CFR 483.40(a)(1)(2), Tag F385, Physician Services – Physician Supervision Determine if a physician supervised the medical aspects of care of each resident, as indicated, as they relate to medical conditions that affect appetite and nutritional status.

13) 42 CFR 483.75(h)(2)(ii), Tag F500, Use of Outsider resources If the facility does not employ a qualified dietitian, determine if the professional services of a dietitian are furnished by an outside resource, meet professional standards and principles, and are timely.

14) 42 CFR 483.75(i)(2)(i)(ii), Tag F501, Medical Director Determine if the medical director helped develop and implement resident care policies as they relate to maintaining acceptable parameters of nutritional status and the provision of therapeutic diets when indicated.

15) 42 CFR 483.75(o), Tag F520, Quality Assessment and Assurance
Related concerns may have been identified that would suggest the need for a review of facility practices. Such activities may involve a review of policies, staffing and staff training, contracts, etc. and interviews with management, for example. If there is a pattern of residents who have not maintained acceptable parameters of nutritional status without adequate clinical justification, determine if quality assurance activities address the facility’s approaches to nutrition and weight issues.

**DEFICIENCY CATEGORIZATION**

Once the team has completed its investigation, analyzed the data, reviewed the regulatory requirements, and determined that noncompliance exists, the team must determine the severity of each deficiency, based on the resultant effect or potential for harm to the resident.

The key elements for severity determination for Tag F325 are as follows:

1. Presence of harm/negative outcome(s) or potential for negative outcomes due to a failure of care and services. Actual or potential harm/negative outcomes for F325 may include, but are not limited to:
   - Significant unplanned weight change;
   - Inadequate food/fluid intake;
   - Impairment of anticipated wound healing;
   - Failure to provide a therapeutic diet;
   - Functional decline;
   - Fluid/electrolyte imbalance.

2. Degree of harm (actual or potential) related to the noncompliance. 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;
   - If harm has not yet occurred, determine how likely the potential is for serious injury, impairment, death, compromise or discomfort to occur to the resident.

3. The immediacy of correction required. Determine whether the noncompliance 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 F325. 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.

**Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety**

Immediate Jeopardy is a situation in which the facility’s noncompliance:

- 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;
- Requires immediate correction, as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.

**NOTE:** The death or transfer of a resident who was harmed as a result of facility

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practices does not remove a finding of immediate jeopardy. The facility is required to implement specific actions to correct the deficient practices which allowed or caused the immediate jeopardy.

Examples of avoidable actual or potential resident outcomes that demonstrate severity at Level 4 may include, but are not limited to:

- Continued weight loss and functional decline resulting from ongoing, repeated systemic failure to assess and address a resident’s nutritional status and needs, and implement pertinent interventions based on such an assessment;
- Development of life-threatening symptom(s), or the development or continuation of severely impaired nutritional status due to repeated failure to assist a resident who required assistance with meals;
- Substantial and ongoing decline in food intake resulting in significant unplanned weight loss due to dietary restrictions or downgraded diet textures (e.g., mechanic soft, pureed) provided by the facility against the resident’s expressed preferences;
- Evidence of cardiac dysrhythmias or other changes in medical condition due to hyperkalemia, resulting from the facility’s failure to provide a potassium restricted therapeutic diet that was ordered.

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 or the potential for more than minimal harm at Level 2 exists.

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

Level 3 indicates noncompliance that results in actual harm that is not immediate jeopardy. The negative outcome can include, but may not be limited to clinical compromise, decline, or the resident’s inability to maintain and/or reach his/her highest practicable level of well-being.

Examples of avoidable actual resident outcomes that demonstrate severity at Level 3 may include, but are not limited to:

- Significant unplanned weight change and impaired wound healing (not attributable to an underlying medical condition) due to the facility’s failure to revise and/or implement the care plan to address the resident’s impaired ability to feed him/herself;
- Loss of weight from declining food and fluid intake due to the facility’s failure to assess and address the resident’s use of medications that affect appetite and food intake;
- Unplanned weight change and declining food and/or fluid intake due to the facility’s failure to assess the relative benefits and risks of restricting or downgrading diet and food consistency or to obtain or accommodate resident preferences in accepting related risks;
- Decline in function related to poor food/fluid intake due to the facility’s failure to accommodate documented resident food dislikes and provide appropriate substitutes;
- A resident with known celiac disease (damage to the small intestine related to gluten allergy) develops persistent gastrointestinal symptoms including weight loss, chronic diarrhea, and vomiting, due to the facility’s failure to provide a gluten-free diet (i.e., one free of wheat, barley, and rye products)
as prescribed by the physician.

**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 Severity 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.

For Level 2 severity, the resident was at risk for, or has experienced the presence of one or more outcome(s) (e.g., unplanned weight change, inadequate food/fluid intake, impairment of anticipated wound healing, functional decline, and/or fluid/electrolyte imbalance), due to the facility’s failure to help the resident maintain acceptable parameters of nutritional status.

Examples of avoidable actual or potential resident outcomes that demonstrate severity at Level 2 may include, but are not limited to:

- Failure to obtain accurate weight(s) and to verify weight(s) as needed;
- Poor intake due to the facility’s intermittent failure to provide required assistance with eating, however, the resident met identified weight goals;
- Failure to provide additional nourishment when ordered for a resident, however, the resident did not experience significant weight loss;
- Failure to provide a prescribed sodium-restricted therapeutic diet (unless declined by the resident or the resident’s representative or not followed by the resident); however, the resident did not experience medical complications such as heart failure related to sodium excess.

**Severity Level 1: No Actual Harm with Potential for Minimal Harm** The failure of the facility to provide appropriate care and services to maintain acceptable parameters of nutritional status and minimize negative outcomes places residents at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

**Tag F 327 Hydration**

Hydration. The facility must provide each resident with sufficient fluid intake to maintain proper hydration and health

**Intent** The intent of this regulation is to assure that the resident receives sufficient amount of fluids based on individual needs to prevent dehydration.

Did the MDS trigger any CAAs for dehydration? What action was taken based on this information?

Consider whether assessment triggers CAAs and does the facility assess the causal factors for decline, potential for decline or lack of improvement.

**DEFINITIONS**

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Sufficient fluid means the amount of fluid needed to prevent dehydration (output of fluids far exceeds fluid intake) and maintain health. The amount needed is specific for each resident, and fluctuates as the resident’s condition fluctuates (e.g., increase fluids if resident has fever or diarrhea).

Risk factors for the resident becoming dehydrated are:
- Coma/decreased sensorium;
- Fluid loss and increased fluid needs (e.g., diarrhea, fever, uncontrolled diabetes);
- Fluid restriction secondary to renal dialysis;
- Functional impairments that make it difficult to drink, reach fluids, or communicate fluid needs (e.g., aphasia);
- Dementia in which resident forgets to drink or forgets how to drink;
- Refusal of fluids;

A general guideline for determining baseline daily fluids needs is to multiply the resident’s body weight in kg times 30cc (2.2 lbs = 1kg), except for residents with renal or cardiac distress. An excess of fluids can be detrimental for these residents.

Procedures
Identify if resident triggers any CAAs for dehydration/fluid maintenance, and cognitive loss.

Probes: Do sampled residents show clinical signs of possible insufficient fluid intake (e.g., dry skin and mucous membranes, cracked lips, poor skin turgor, thirst, fever), abnormal laboratory values (e.g., elevated hemoglobin and hematocrit, potassium, chloride, sodium, albumin, transferrin, blood urea nitrogen (BUN), or urine specific gravity)?

Special Needs The facility must ensure that residents receive proper treatment and care for the following special services Procedures §483.25(j)
- What care did the facility provide to reduce those risk factors and ensure adequate fluid intake (e.g., keep fluids next to the resident at all times and assisting or cuing the resident to drink)? Is staff aware of need for maintaining adequate fluid intake?
- Has the facility provided residents with adequate fluid intake to maintain proper hydration and health?
- If not:
  - Did the facility identify any factors that put the resident at risk of dehydration?
  - What care did the facility provide to reduce those risk factors and ensure adequate fluid intake (e.g., keep fluids next to the resident at all times and assisting or cuing the resident to drink)? Is staff aware of need for maintaining adequate fluid intake?

INVESTIGATIVE PROTOCOL
Objectives:
- To determine if the facility identified risk factors which lead to dehydration and developed an appropriate preventative care plan; and
To determine if the facility provided the resident with sufficient fluid intake to maintain proper hydration and health.

**Use:** Use this protocol for the following situations:

- A sampled resident who flagged for the sentinel event of dehydration on the Resident Level Summary;
- A sampled resident who has one or more QI conditions identified on the Resident Level Summary, such as:
  - #11 - Fecal impaction;
  - #12 - Urinary tract infections;
  - #13 - Weight loss;
  - #14 - Tube feeding;
  - #17 - Decline in ADLs;
  - #24 - Pressure Ulcer
- A sampled resident who was discovered to have any of the following risk factors: vomiting/diarrhea resulting in fluid loss, elevated temperatures and/or infectious processes, dependence on staff for the provision of fluid intake, use of medications including diuretics, laxatives, and cardiovascular agents, renal disease, dysphagia, a history of refusing fluids, limited fluid intake or lacking the sensation of thirst.

**Procedures:**

- Observations/interviews conducted as part of this procedure should be recorded on the Forms CMS-805 and/or the Form CMS-807.
- Determine if the resident was assessed to identify risk factors that can lead to dehydration, such as those listed above and also whether there were abnormal laboratory test values which may be an indicator of dehydration.

**NOTE:** A general guideline for determining baseline daily fluid needs is to multiply the resident’s body weight in kilograms (kg) x 30ml (2.2 lbs = 1 kg), except for residents with renal or cardiac distress, or other restrictions based on physician orders. An excess of fluids can be detrimental for these residents.

- Determine if an interdisciplinary care plan was developed utilizing the clinical conditions and risk factors identified, taking into account the amount of fluid that the resident requires. If the resident is receiving enteral nutritional support, determine if the tube feeding orders included a sufficient amount of free water, and whether the water and feeding are being administered in accordance with physician orders?
- Observe the care delivery to determine if the interventions identified in the care plan have been implemented as described.
- What is the resident’s response to the interventions? Does staff provide the necessary fluids as described in the plan? Do the fluids provided contribute to dehydration, e.g., caffeinated beverages, alcohol? Was the correct type of fluid provided with a resident with dysphagia?
- Is the resident able to reach, pour and drink fluids without assistance? Is the resident consuming sufficient fluids? If not, is staff providing the fluids according to the care plan?
- Is the resident’s room temperature (heating mechanism) contributing to dehydration? If so, how is the facility addressing this issue?
If the resident refuses water, are alternative fluids offered that are tolerable to the resident?

- Are the resident's beverage preferences identified and honored at meals?
- Does staff encourage the resident to drink? Are they aware of the resident's fluid needs? Is staff providing fluids during and between meals?
- Determine how the facility monitors to assure that the resident maintains fluid parameters as planned. If the facility is monitoring the intake and output of the resident, review the record to determine if the fluid goals or calculated fluid needs were met consistently.
- Review all related information and documentation to look for evidence of identified causes of the condition or problem. This inquiry should include interviews with appropriate facility staff and health care practitioners, who by level of training and knowledge of the resident, should know of, or be able to provide information about the causes of a resident's condition or problem.

**NOTE:** If a resident is at an end of life stage and has an advance directive, according to State law, (or a decision has been made by the resident’s surrogate or representative, in accordance with State law) or the resident has reached an end of life stage in which minimal amounts of fluids are being consumed or intake has ceased, and all appropriate efforts have been made to encourage and provide intake, then dehydration may be an expected outcome and does not constitute noncompliance with the requirement for hydration. Conduct observations to verify that palliative interventions, as described in the plan of care, are being implemented and revised as necessary, to meet the needs/choices of the resident in order to maintain the resident's comfort and quality of life. If the facility has failed to provide the palliative care, cite noncompliance with 42 CFR 483.25, F309, Quality of Care.

- Determine if the care plan is evaluated and revised based on the response, outcomes, and needs of the resident.

**Determination of Compliance 42 CFR 483.25(j), F 327 Hydration**

For this resident, the facility is compliant with this requirement to maintain proper hydration if they properly assessed, care planned, implemented the care plan, evaluated the resident outcome, and revised the care plan as needed. If not, cite at F327.

**Compliance Comprehensive Assessments:** For this resident in the area of hydration, the facility is compliant with this requirement if they assessed factors that put the resident at risk for dehydration, whether chronic or acute. If not, cite at F272.

**Compliance Comprehensive Care Plans:** For this resident in the area of hydration, the facility is compliant with this requirement if they developed a care plan that includes measurable objectives and timetables to meet the resident's needs as identified in the resident's assessment.

**Investigative Protocol - Dining and Food Service Objectives:**

- To determine if each resident is provided with nourishing, palatable, attractive meals that meet the resident’s daily nutritional and special dietary needs;
- To determine if each resident is provided services to maintain or improve eating skills;

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To determine if the dining experience enhances the resident’s quality of life and is supportive of the resident’s needs, including food service and staff support during dining.

**Use**

This protocol will be used for:

- All sampled residents identified with malnutrition, unintended weight loss, mechanically altered diet, pressure sores/ulcers, and hydration concerns;
- Food complaints received from residents, families and others.

**General Considerations:**

- Use this protocol at two meals during the survey, preferably the noon and evening meals.
- Record information on the Form CMS-805 if it pertains to a specific sampled resident, or on the Form CMS-807 if it relates to the general observations of the dining service/dining room.
- Discretely observe all residents, including sampled residents, during meals keeping questions to a minimum to prevent disruption in the meal service.
- For each sampled resident being observed, identify any special needs and the interventions planned to meet their needs. Using the facility’s menu, record in writing what is planned in writing to be served to the resident at the meal observed.
- Conduct observations of food preparation and quality of meals.

**Procedures:**

1. During the meal service, observe the dining room and/or resident’s room for the following:
   - Comfortable sound levels;
   - Adequate illumination, furnishings, ventilation; absence of odors; and sufficient space;
   - Tables adjusted to accommodate wheelchairs, etc.;
   - Appropriate hygiene provided prior to meals.

2. Observe whether each resident is properly prepared for meals. For example:
   - Resident’s eyeglasses, dentures, and/or hearing aids are in place;
   - Proper positioning in chair, wheelchair, gerichair, etc., at an appropriate distance from the table (tray table and bed at appropriate height and position);
   - Assistive devices/utensils identified in care plans provided and used as planned.

3. Observe the food service for:
   - Appropriateness of dishes and flatware for each resident. Single use disposable dining ware is not used except in an emergency and in other appropriate dining activities. Except those with fluid restriction, each resident has an appropriate place setting with water and napkin;
   - Whether meals are attractive, palatable, served at appropriate temperatures and are delivered to residents in a timely fashion.
   - Did the meals arrive 30 minutes or more past the scheduled mealtime?
   - If a substitute was needed, did it arrive more than 15 minutes after the request for a substitute?
   - Are diet cards, portion sizes, preferences, and condiment requests being honored?
4. Determine whether residents are being promptly assisted to eat or provided necessary assistance/cueing in a timely manner after their meal is served.

   **Note** whether residents at the same table or in resident rooms, are being served and assisted concurrently.

   - If you observe a resident who is being assisted by a staff member to eat or drink, and the resident is having problems with eating or drinking, inquire if the staff member who is assisting them is a paid feeding assistant. If so, follow the procedures at tag F373.

5. Determine if the meals served were palatable, attractive, nutritious and met the needs of the resident. **Note the following:**

   - Whether the resident voiced concerns regarding the taste, temperature, quality, quantity and appearance of the meal served;
   - Whether mechanically altered diets, such as pureed, were prepared and served as separate entree items (except when combined food, e.g., stews, casseroles, etc.);
   - Whether attempts to determine the reason(s) for the refusal and a substitute of equal nutritive value was provided, if the resident refused/rejected food served;
   - Whether food placement, colors, and textures were in keeping with the resident’s needs or deficits, e.g., residents with vision or swallowing deficits.
   - **Sample Tray Procedure** If residents complain about the palatability/temperature of food served, the survey team coordinator may request a test meal to obtain quantitative data to assess the complaints. Send the meal to the unit that is the greatest distance from the kitchen or to the affected unit or dining room. Check food temperature and palatability of the test meal at about the time the last resident on the unit is served and begins eating.

6. Observe for institutional medication pass practices that interfere with the quality of the residents’ dining experience. This does not prohibit the administration of medications during meal service for medications that are necessary to be given at a meal, nor does this prohibit a medication to be given during a meal upon request of a resident who is accustomed to taking the medication with the meal, as long as it has been determined that this practice does not interfere with the effectiveness of the medication.

   - Has the facility attempted to provide medications at times and in a manner to support the dining experience of the resident, such as:
     - Pain medications being given prior to meals so that meals could be eaten in comfort;
     - Foods served are not routinely or unnecessarily used as a vehicle to administer medications (mixing the medications with potatoes or other entrees).

7. Determine if the sampled resident consumed adequate amounts of food as planned.

   - Determine if the facility is monitoring the foods/fluids consumed. Procedures used by the facility may be used to determine percentage of food consumed, if available; otherwise, determine the percentage of food consumed using the following point system:
     - Each food item served except for water, coffee, tea, or condiments equals one point.

   **Example:** Breakfast: juice, cereal, milk, bread and butter, coffee (no points) equals four points. If the resident consumes all four items in the amount served, the resident
consumes 100% of breakfast. If the resident consumes two of the four food items served, then 50% of the breakfast would have been consumed.

- If three-quarters of a food item is consumed, give one point; for one-half consumed, give .5 points; for one-fourth or less, give no points. Total the points consumed x 100 and divide by the number of points given for that meal to give the percentage of meal consumed. Use these measurements when determining the amount of liquids consumed: Liquid measurements: 8 oz. cup = 240 cc, 6 oz. cup = 180 cc, 4 oz. cup = 120 cc, 1 oz. cup = 30 cc.
- Compare these findings with the facility’s documentation to determine if the facility has accurately recorded the intake. Ask the staff if these findings are consistent with the resident’s usual intake;
- Note whether plates are being returned to the kitchen with 75% or more of food not eaten.

B. If concerns are noted with meal service, preparation, quality of meals, etc., interview the person(s) responsible for dietary services to determine how the staff are assigned and monitored to assure meals are prepared according to the menu, that the meals are delivered to residents in a timely fashion, and at proper temperature, both in the dining rooms/areas and in resident rooms.

NOTE: If concerns are identified in providing monitoring by supervisory staff during dining or concerns with assistance for residents to eat, evaluate nursing staffing in accord with 42 CFR 483.30(a), F353, and quality of care at 42 CFR 483.25(a)(2) and (3). 5.73
MDS Section K Swallowing/ Nutritional Status

<table>
<thead>
<tr>
<th>Section K</th>
<th>Swallowing/Nutritional Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>K0100. Swallowing Disorder</td>
<td>Signs and symptoms of possible swallowing disorder</td>
</tr>
<tr>
<td>A. Loss of liquids/solids from mouth when eating or drinking</td>
<td></td>
</tr>
<tr>
<td>B. Holding food in mouth/cheeks or residual food in mouth after meals</td>
<td></td>
</tr>
<tr>
<td>C. Coughing or choking during meals or when swallowing medications</td>
<td></td>
</tr>
<tr>
<td>D. Complaints of difficulty or pain with swallowing</td>
<td></td>
</tr>
<tr>
<td>Z. None of the above</td>
<td></td>
</tr>
<tr>
<td>K0200. Height and Weight</td>
<td>While measuring, if the number is X.1 . X.4 round down, X.5 or greater round up</td>
</tr>
<tr>
<td>A. Height</td>
<td>in inches. Record most recent height measure since admission</td>
</tr>
<tr>
<td>B. Weight</td>
<td>in pounds. Base weight on most recent measure in last 30 days; measure weight consistently, according to standard facility practice (e.g., in a.m. after voiding, before meal, with shoes off, etc.)</td>
</tr>
<tr>
<td>K0300. Weight Loss</td>
<td>Loss of 5% or more in the last month or loss of 10% or more in last 6 months</td>
</tr>
<tr>
<td>Enter Code</td>
<td>0. No or unknown</td>
</tr>
<tr>
<td>1. Yes, on physician-prescribed weight-loss regimen</td>
<td></td>
</tr>
<tr>
<td>2. Yes, not on physician-prescribed weight-loss regimen</td>
<td></td>
</tr>
<tr>
<td>K0500. Nutritional Approaches</td>
<td>Check all that apply</td>
</tr>
<tr>
<td>A. Parenteral/IV feeding</td>
<td></td>
</tr>
<tr>
<td>B. Feeding tube - nasogastric or abdominal (PEG)</td>
<td></td>
</tr>
<tr>
<td>C. Mechanically altered diet - require change in texture of food or liquids (e.g., pureed food, thickened liquids)</td>
<td></td>
</tr>
<tr>
<td>D. Therapeutic diet (e.g., low salt, diabetic, low cholesterol)</td>
<td></td>
</tr>
<tr>
<td>Z. None of the above</td>
<td></td>
</tr>
<tr>
<td>K0700. Percent Intake by Artificial Route</td>
<td>Complete K0700 only if K0500A or K0500B is checked</td>
</tr>
<tr>
<td>Enter Code</td>
<td>A. Proportion of total calories the resident received through parenteral or tube feeding</td>
</tr>
<tr>
<td>1. 25% or less</td>
<td></td>
</tr>
<tr>
<td>2. 26-50%</td>
<td></td>
</tr>
<tr>
<td>3. 51% or more</td>
<td></td>
</tr>
<tr>
<td>Enter Code</td>
<td>D. Average fluid intake per day by IV or tube feeding</td>
</tr>
<tr>
<td>1. 500 cc/day or less</td>
<td></td>
</tr>
<tr>
<td>2. 501 cc/day or more</td>
<td></td>
</tr>
</tbody>
</table>
CMS REFERENCES Swallowing Nutritional Status


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Parenteral Nutrition Standardization. Journal of Parenteral and Enteral Nutrition, 31; 441-448. (http://pen.sagepub.com/content/31/5.toc)

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