By Martha R. Kelso and LaDonna L. Boeckman

Why All the Pressure About Pressure? The New Wound Care Regulations and How They May Impact the Defense of the Wound Case

With no standardized tool yet to point out and anticipate when skin failure may occur, we still have a lot of work to do in the healthcare space and fields of research on this subject.

Those who have spent any time litigating long-term care matters, serving in risk management for a long-term care facility, or working within a healthcare facility know that most lawsuits filed for injuries by residents fall into two categories: falls or wounds. Those who have spent time reviewing records repeatedly see that nearly every significant wound is documented and referred to by various interdisciplinary team members as a "pressure wound."

With the new Centers for Medicare and Medicaid Services (CMS) regulation implementation, this default of classifying and referring to the majority of wounds as a "pressure wound" within the healthcare setting (both long-term care facilities and hospitals) will now be highly problematic for defending wound cases. First, to the extent that the wound was caused by something other than pressure OR was a recurrence of a previously healed wound, CMS regulations now recognize these skin and wound types as having utterly different etiology from an in-house acquired pressure wound. Second, by not classifying the wound as caused by something other than pressure or counting the recurrence of a previously healed wound, the healthcare facility or individual practitioner will have difficulty utilizing and successfully proving the wound was caused by something other than negligent pressure. Finally, by not having the skin or wound issue classified correctly at the outset, the default assumption that all skin and wound issues are caused by pressure can raise the potential for new allegations, which may include abuse, negligence, failure to comply with statutory regulations, failure to assess correctly, failure to chart and document properly, failure to provide proper care planning, failure to provide appropriate interventions, failure to inform the patient or responsible party of correct diagnosis thereby preventing informed educated decisions to be made on the patient's care, and potentially raising concerns over fraudulent billing and reporting of correct diagnosis codes. These are significant before even addressing the ultimate problem that long-term care institutions face because of the change to CMS regulations. There is no adequate corresponding International Classification of Diseases (ICD) code to allow practitioners to identify skin or wound issues as skin failure, end-of-life, or potentially some similar causes unrelated to pressure.

Pressure injuries, also commonly known as pressure ulcers, pressure sores, decubitus ulcers, or bedsores, are signifi-

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cant healthcare concerns associated with prolonged pressure on the skin and underlying tissues. Centers for Medicare & Medicaid Services, State Operations Manual Appendix PP—Guidance to Surveyors for Long-Term Care Facilities (Rev. 211 Ed.). hereinafter CMS State Operations Manual Appendix PP). Pressure injuries can lead to severe complications and diminished quality of life for patients. However, misdiagnosing a pressure wound is surprisingly frequent, often with legal ramifications. Accurate diagnosis is crucial, as several conditions can mimic pressure wounds, leading to delayed or inappropriate treatment. Additionally, CMS updated its guidance and stance on end-of-life (EOL) skin and wound failure on October 1, 2023 (Centers for Medicare and Medicaid Services [CMS], 2023a), furthering the need for accurate assessment and diagnosis of non-pressure and pressure-related injuries. See Centers for Medicare and Medicaid Services, Long-Term Care Facility Resident Assessment Instrument 3.0 User's Manual (Version 1.18.11 ed.) (hereinafter CMS RAI). This article delves into the legal landscape surrounding the regulatory changes and challenges of misdiagnosing pressure injuries. It explores the potential grounds for litigation, the challenges associated with common mimics, and their clinical implications.

Some plaintiffs are seeking to exclude all evidence related to the informed consent process, including notes in the medical record documenting the informed consent process occurred and testimony elaborating on the same.

The Standard of Care and Its Breach

The changes in the CMS Resident Assessment Instrument (RAI) Manual, Section M come into play in two different contexts: First, a correctly identified and classified wound that develops as a result of skin changes at the end-of-life inherently (theoretically) protects and healthcare provider and institution from a claim that the wound was caused by failure to prevent a pressure wound from developing by either not have the proper care plan in place to prevent the development of a wound, or failing to follow, or failing to ensure that the care plan was followed as written. Second, if a claim is made that a resident developed a pressure wound, proper and consistent documentation that the wound is an end-of-life wound (or some other cause) will assist in defending the allegations of the claim. Finally, for causes of action based upon regulatory framework, rather than a deviation from the standard of care, proper classification and consistent documentation will prevent a second cause of action for failing to classify and chart or document correctly. Hence, the legal framework for end-of-life or other etiology wounds misdiagnosed and misclassified as pressure wounds can fall under two categories: failure to follow regulations and/or deviation from the standard of care.

The legal framework for misdiagnosed pressure injuries in the non-regulatory arena hinges on the concept of the standard of care. The definition of standard of care is typically what a reasonably careful practitioner would do under the same or similar circumstances. Typically, this can also be defined as the skill and knowledge a healthcare professional must possess and exercise in similar situations. In the case of pressure injuries, depending upon the totality of the circumstances, the standard of care may require healthcare providers to do the following:

- Conduct a thorough skin assessment upon admission and at regular intervals;
- Implement appropriate preventive measures based on individual risk factors;
- Review an individual's clinical condition;
- Regularly monitor and document any changes in skin integrity;
- Provide prompt and effective treatment upon identifying a pressure injury to prevent infection and promote healing (CMS, 2023b);

CMS State Operations Manual Appendix PP.

Registered nurses should document a thorough investigation, including a skin and wound assessment, identifying wound characteristics that allow identification of pressure injuries from other wounds. See American Nurse Association, "Is Diagnosis of Pressure Ulcers within an RN's Scope of Practice? American Nurse, January 11 (retrieved May 4, 2024 at ***https://www.myamericannurse.com/is-diagnosis-of-pressure-ulcers-within-an-rns-scope-of-practice/***). Once a wound is identified as a pressure injury, further wound assessment should be performed to properly stage the wound, utilizing the correct staging criteria for the various care sites. Pressure injury staging is not universal across care settings, so care should be taken to ensure the correct staging criteria are based on where the patient currently resides. Martha R. Kelso, Surviving Survey Across Post-Acute Settings [Conference Session] from Post-Acute Care Symposium (October 30-31, 2021).

Malpractice occurs when a healthcare professional deviates from this established standard of care. This deviation can manifest in various ways, including:

- Failure to properly assess a patient's risk factors for developing pressure injuries.
- Neglecting to implement preventive measures like pressure reduction or redistribution techniques.
- Misinterpreting skin changes as unrelated conditions, leading to delayed treatment.

Avoidable versus Unavoidable

These terms "Avoidable" versus "Unavoidable" are frequently misconstrued as a medical question when, in fact, they refer to whether specific processes were followed. Understanding the terminology in its correct inference can change the context of the case. Traditionally, two groups are referenced when defining these terms: CMS and the National Pressure Injury

Advisory Panel (NPIAP). CMS defines "Unavoidable" as meaning "that the resident developed a pressure ulcer/injury even though the facility had:

1. Evaluated the resident's clinical condition and risk factors;
2. Defined and implemented interventions that are consistent with resident needs, goals, and professional standards of practice;
3. Monitored and evaluated the impact of the interventions;
4. And revised the approaches as appropriate"

CMS State Operations Manual Appendix PP.

The NPIAP states an unavoidable pressure ulcer could develop "even though the provider:

1. Evaluated the individual's clinical condition and pressure ulcer risk factors;
2. Defined and implemented interventions consistent with individual needs, goals, and recognized standards of practice;
3. Monitored and evaluated the impact of the interventions;
4. And revised the approaches as appropriate"

See J.M. Black, L. E., Baharestani, M. M., Langemo, D., Goldberg, M., McNichol, L., Cuddigan, J., & National Pressure Ulcer Advisory Panel, Pressure Ulcers: Avoidable or Unavoidable? Results of the National Pressure Ulcer Advisory Panel consensus conference. Ostomy Wound Management, 57(2), 24–37 (2011) (Retrieved May 4, 2024 from ***https://doi.org/10.1097/WON.0000000000000050***).

Following a decision tree to determine if the wound meets the criteria of Avoidable versus Unavoidable can be handy. Martha R Kelso developed the following decision tree for use by facilities, surveyors, wound professionals, expert witnesses, and others who may need to know if the processes were properly followed and if a skin or wound issue is correctly labeled as Avoidable or Unavoidable (See Figure 1).

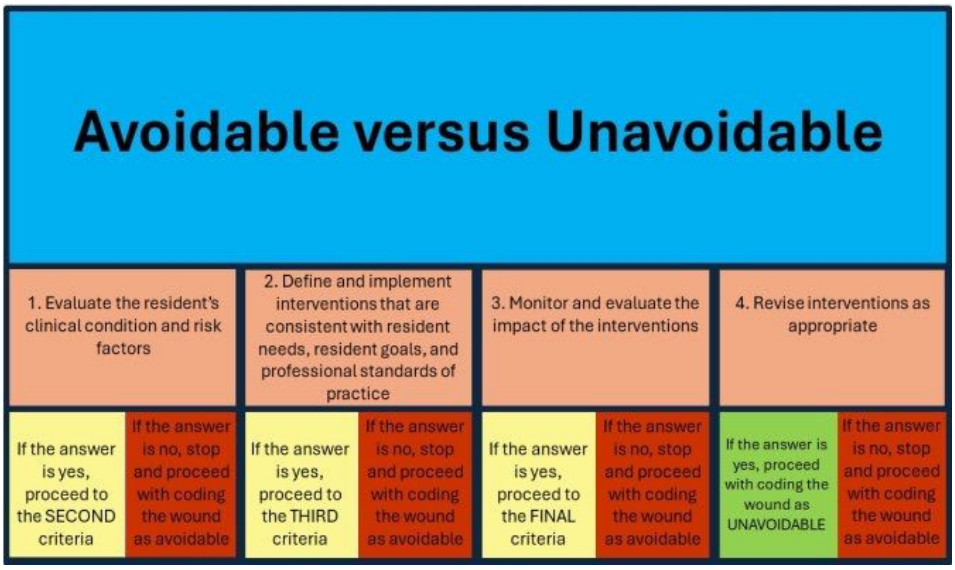

Fig 1: Decision Process Tree for Avoidable versus Unavoidable
Decision Process Tree developed by Martha R. Kelso. Shared with permission.

Updates for End-of-Life Skin and Wound Changes

At the end of 2017, CMS issued guidance regarding Kennedy Terminal Ulcers (KTUs), stating they are "considered to be pressure ulcers that generally occur at the end of life." CMS went on to list certain characteristics that may differentiate KTUs from other pressure ulcers. The differentiating characteristics are:

1. KTUs appear suddenly and within hours;
2. Usually appear on the sacrum and coccyx but can appear on the heels, posterior calf muscles, arms, and elbows;
3. Edges are usually irregular and are red, yellow, and black as the ulcer progresses, often described as pear-, butterfly- or horseshoe-shaped (Photo 1); and
4. Often appear as an abrasion, blister, or darkened area and may develop rapidly to a Stage 2, Stage 3, or Stage 4 injury.

By October 1, 2023, CMS issued new guidance regarding end-of-life skin and wound changes, stating, "Skin changes at the end of life (SCALE), also referred to as Kennedy Terminal Ulcers (KTUs) and skin failure, are not primarily caused by pressure and are not coded in Section M." See LTC Instrument at M-6. This update in regulatory guidance is a significant change in instructing how long-term care facilities should view end-of-life skin and wound failure in terms of how to code section M of the MDS and how the care plan, interventions, goals, and education to family or responsible parties should occur. However, CMS has instructed Long-Term Care Hospitals (LTCH) to follow this coding methodology since 2013 in the LTCH CARE Data Set or IRF-PAI. See Centers for Medicare & Medicaid Services, Long-Term Care Hospital (LTCH) Continuity Assessment Record & Evaluation (Care) Data Set (LCDs) & LCDs Manual. (retrieved July 13, 2024 from ***https://www.cms.gov/medicare/quality/long-term-care-hospital/ltch-care-data-set-ltch-qrp-manual***).

Understanding the causative factors of skin failure at the end-of-life is an unavoidable symptom that develops in some patients as part of the dying process. It is

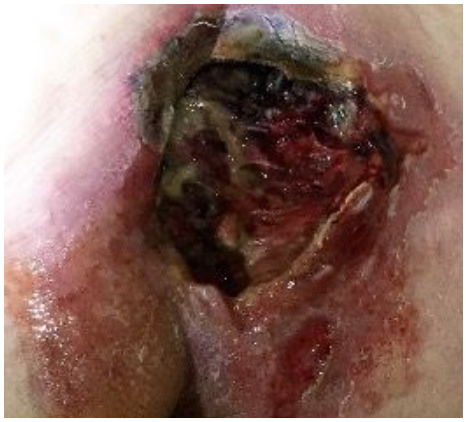

Photo 1: Example of Horseshoe Shaped Kennedy Terminal Ulcer (KTU)
Image provided by Wound Care Plus, LLC/Martha R Kelso

most likely a result of reduced skin and soft tissue perfusion (hypoperfusion), which may decrease resistance to external pressure or other processes related to death and dying. End-of-life skin and wound changes can occur shortly before death but may start to appear as far out as several months. While other common etiologies may play into skin and tissue integrity alterations like pressure, friction, shear, and moisture, the primary etiology is hypoperfusion or compromised perfusion associated with organ failure due to the dying process.

Examples (see below) of End-of-Life Skin Changes [skin intact] may include Kennedy Lesions (KL) (Photo 2), Trombley-Brennen Terminal Tissue Injury (TB-TTI) (Photo 3), Skin Changes at Life's End (SCALE) (Photo 4), and mottling (Photo 5). Examples of End-of-Life Wound Change(s) [open wound(s) or full thickness wound(s) with or without slough or eschar] may include Kennedy Terminal Ulcers (Photo 1), Skin Failure-End Stage (Photo 6), Skin Changes at Life's End Wounds (Photo 7); Open Fungating Wounds (Photo 8), and Open Malignant Wounds (Photo 9). These categories were first defined by the Post Acute Wound Skin Integrity Council (PAWSIC) in their proposal to the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) committee submitted on December 1, 2023. See Post Acute Wound Skin Integrity Council, Kelso, M.R., Kennedy-Evans, K.L., Krasner, D.L, & Maguire, J. PAWSIC ICD-10-CM Code Proposal from the Post-Acute Wound & Skin Integrity Council to the ICD-10 Coordination and Maintenance Committee. Both lists are not intended to be all-inclusive since end-of-life skin and wound phenomena are still being studied, and additional terms or phenomena may be elicited over time

Updated CMS Regulations

The changes made to CMS's RAI Version 3.0 Manual for Unhealed Pressure Ulcers/Injuries note the following:

- If an ulcer/injury arises from a combination of factors that are primarily caused by pressure, then the area should be included in this section as a pressure ulcer/injury.
- If a pressure ulcer is surgically closed with a flap or graft, it should be coded as a surgical wound and not as a pressure ulcer. If the flap or graft fails, continue to code it as a surgical wound until healed.
- Residents with diabetes mellitus (DM) can have a pressure, venous, arterial, or diabetic neuropathic ulcer. The primary etiology should be considered when coding whether a resident with DM has an ulcer/injury that is caused by pressure or other factors.
- If a resident with DM has a heel ulcer/injury from pressure and the ulcer/injury is present in the 7-day look-back period, code I and proceed to code items in M0300 as appropriate for the pressure ulcer/injury.
- If a resident with DM has an ulcer on the plantar (bottom) surface of the foot close to the metatarsals and the ulcer is pres-

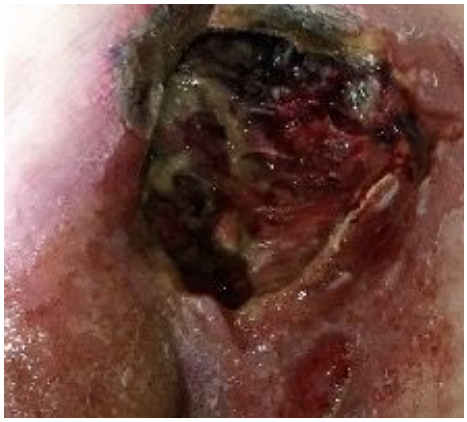

Photo 2: Example of a Kennedy Lesion
Image Provided by Dr. Diane L. Krasner

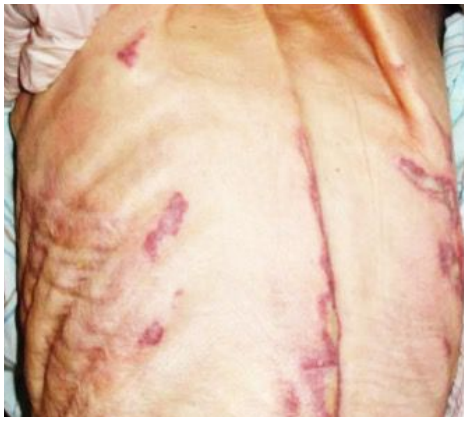

Photo 3: Example of a Trombley-Brennen Terminal Tissue Injury (TB-TTI)
Multiple linear areas of reddish purple tissue
Image from (Trombley et al., 2012)

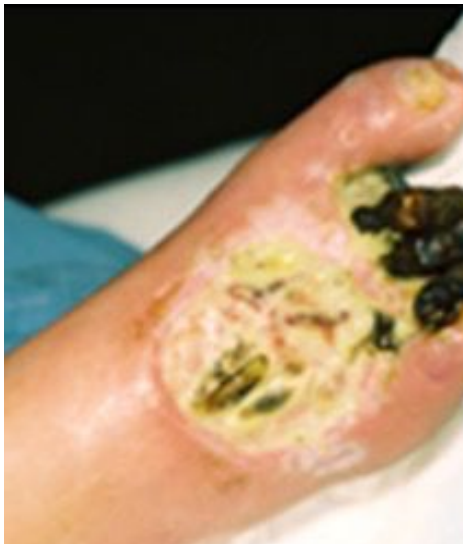

Photo 4: Example of a Skin Changes at Life's End (SCALE)
Image Provided by Dr. Diane L. Krasner

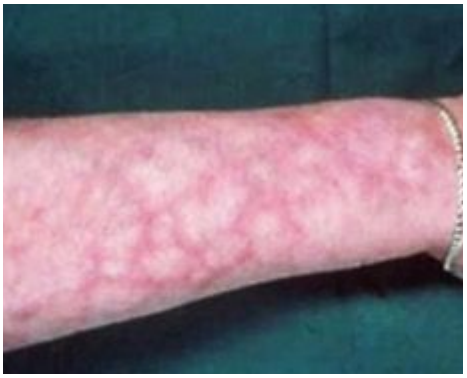

Photo 5: Example of mottling
Image Provided by Crossroads Hospice

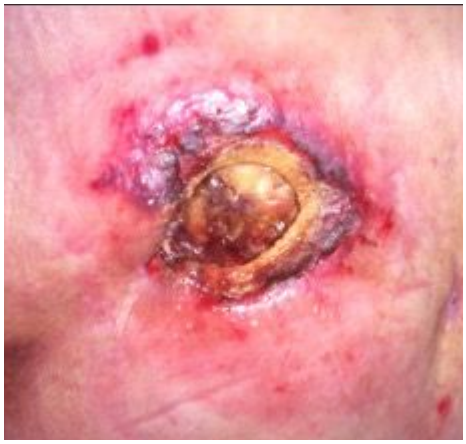

Photo 6: Example of Skin Failure-End Stage
Image Provided by Wound Care Plus, LLC/Martha R. Kelso

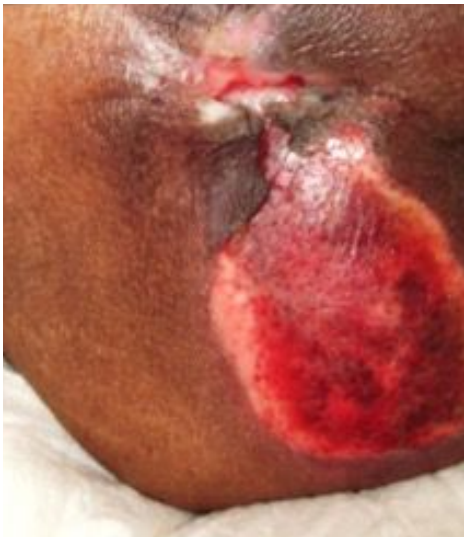

Photo 7: Skin Changes at Life's End Wounds (Skin tear evolving into an eschar at End-of-Life)

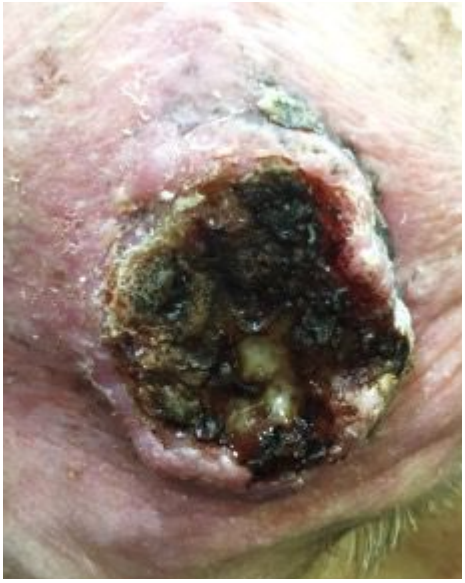

Photo 8: Open Fungating Wound
Image Provided by Wound Care Plus, LLC/ Martha R. Kelso

ent in the 7-day look-back period, code 0 and proceed to M1040 to code the ulcer as a diabetic foot ulcer. It is not likely that pressure is the primary cause of the resident's ulcer when the ulcer is in this location.

- Scabs and eschar are different both physically and chemically. Eschar is a collection of dead tissue within the wound that is flush with the surface of the wound. A scab is made up of dried blood cells and serum, sits on the top of the skin, and forms over exposed wounds such as wounds with granulating surfaces (like pressure ulcers, lacerations, evulsions, etc.). A scab is evidence of wound healing. A pressure ulcer that was staged as a 2 and now has a scab indicates it is a healing stage 2, and therefore, staging should not change. Eschar characteristics and the level of damage it causes to tissues is what makes it easy to distinguish from a scab. It is essential to have staff trained in wound assessment and able to distinguish scabs from eschar.
- If two pressure ulcers/injuries occur on the same bony prominence and are separated, at least superficially, by skin, then count them as two separate pressure ulcers/injuries. Stage and measure each pressure ulcer/injury separately.
- If a resident had a pressure ulcer/injury that healed during the look-back period of the current assessment, do not code the ulcer/injury in the evaluation.
- Skin changes at the end of life (SCALE), also referred to as Kennedy Terminal Ulcers (KTUs) and skin failure, are not primarily caused by pressure and are not coded in Section M.

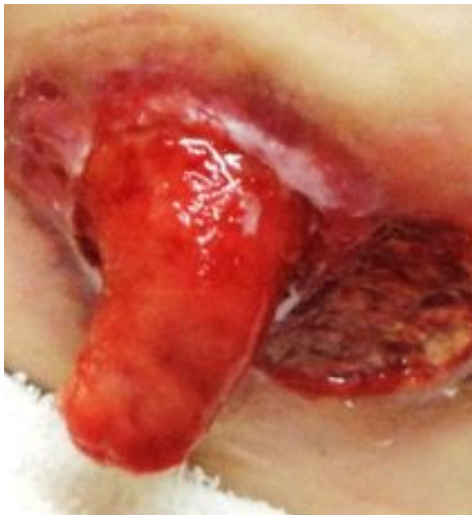

Photo 9: Open Malignant Wounds
Image Provided by Wound Care Plus, LLC/ Martha R. Kelso

See CMS Long-Term Care Facility Resident Assessment Instrument 3.0 User's Manual (Version 1.18.11 ed.).

Guidance for Now

With no end-of-life skin or wound change categories listed with diagnostic codes despite the regulatory changes, the current recommended diagnostic code by the Association of Clinical Documentation Integrity Specialists (ACDIS) is L98.9: Disorder of skin and subcutaneous tissue, unspecified. See Association of Clinical Documentation Integrity Specialists, Q & A: Skin Failure Due to Hypoperfusion (March 16, 2024) (retrieved May 4, 2024 from ***https://acdis.org/articles/qa-skin-failure-due-hypoperfusion#***:~:text=The%20documentation%20does%20need%20to,9.) Care plans should reflect the potential causative factors of end-of-life skin or wound changes, and approaches should reflect palliation instead of strategies focused on healing. Additionally, medical providers should support the etiology, document the potential causes, and reflect that the skin and wound changes are most likely due to hypoperfusion injuries. Goals of care should reflect comfort, and interventions should support and alleviate discomfort due to the death or dying process.

Healthcare professionals should educate family, loved ones, and other responsible parties on causation and what to expect. Educational guides exist focused on what patients, families, and caregivers need to know. Krasner, D.L, Skin Changes at Life's End (SCALE): A Guide for Patients, Families and Caregivers WoundSource & Kestrel Health Information, Inc. (2021). These guides can be helpful regarding expectations and symptoms to watch for and document. Palliative approaches should be paramount and may include decreased turning, repositioning, reduction in dressing changes, or other care that may increase discomfort or pain. Hospice would be appropriate at this phase if selected by the patient or responsible party.

Conclusion

While the changes listed are welcomed and respected, the updates to Section M of the MDS have created a veritable minefield for healthcare providers practicing in a long-term care setting. Those practicing

in the area must know CMS's recognition of end-of-life wounds. However, without the necessary diagnostic codes to appropriately categorize these conditions, alternative documentation strategies should be created and used facility-wide to protect against any claims of failure to assess correctly. The same approach will allow for the adoption and full-throated defense of the wound caused by end-of-life, and not pressure, as recognized by the recent CMS regulatory changes published in Section M of the RAI Manual.

Counselors for plaintiff and defense need to be aware of the changes and how they can affect the case's ownness, the standard of care, fact-finding, and, ultimately, potential outcomes. With CMS recognizing skin failure for some skin and wound etiologies, Plaintiff's firms can no longer dispute the validity of this phenomenon. Defense firms, however, must still show skin and wound failure was present using the assessment, complete records, notations, care planning, and adequate diagnosis and not treat these skin and wound types as an impenetrable shield.

As with any changes in healthcare, it will take time for all interdisciplinary teams and providers to get up to speed and adopt or create paradigm shifts in practice. It will take even longer for patients and responsible parties to understand, recognize, and feel informed about this condition and accept the typical fate of being at end-of-life or other causes of skin failure events in their loved ones. With no standardized tool yet to point out and anticipate when skin failure may occur, we still have a lot of work to do in the healthcare space and fields of research on this subject.

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