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Medical Malpractice

Decubitus Ulcers: An Update on Staging and The Impact of Never Events on Hospital Litigation

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Not so long ago, the vast majority of litigation surrounding the development of decubitus ulcers, or pressure ulcers, involved nursing home defendants. In more recent years, stand-alone hospital claims involving these ulcers have become much more prolific. While many commentators have noted that the increased litigation involving decubitus ulcers in nursing homes has lead to a decrease in their incidence in nursing homes, hospitals still struggle.

In response to ongoing problems with the development of decubitus ulcers at hospitals — which can be life threatening — the Centers for Medicare and Medicaid Services (CMS) has included decubitus ulcers on its list of never events. Never events are conditions that CMS states should not develop, and for which they will not pay. Through these relatively new guidelines, hospitals will be denied payment for extra costs attendant to treating skin breakdown that develops at a hospital when patients enter the hospital with intact skin. Perhaps the greater economic potential impact upon hospitals, though, may be the increased litigation and improved treatment, resulting from what many consider to be the new standard of care with regard to pressure ulcer prevention in the hospital.

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The New Staging of Skin Breakdown

Attorneys experienced with this area of litigation know well the traditional four stages of skin breakdown established in the medical literature, CMS guidelines and by the most prominent group addressing pressure ulcers, the National Pressure Advisory Panel (NPUAP). Through the years, additional approaches on both the medical and litigation front involve pressure sores developing from the external skin to the internal tissue, ranging from the least severe Stage I ulcer, through the most severe Stage IV ulcer.

New staging is similar to the past with some exceptions that may have a significant impact upon litigation overall, the plaintiff's strategy and defenses in these cases. The definitions as provided by NPUAP are as follows:

Suspected Deep Tissue Injury: Purple or maroon localized area of discolored intact skin or blood-filled due to damage of underlying soft tissue from pressure and/or shear. The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue.

Stage I: Intact skin with non-blanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have visible blanching; its color may differ from the surrounding area.

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

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

Stage IV: 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.

Through the years there have been a

significant number of articles on "deep tissue injury" (DTI). DTI can have a substantial impact upon attorneys who practice in this area. One of the most important issues in what can often be diagnosed as suspected DTI, is that DTI has been characterized as a type of wound that may develop from the internal tissue first to the external skin later — i.e., the damage may be present in the underlying tissue long before it is manifested on the skin. In effect, DTI develops the opposite way from a traditional pressure ulcer. Accordingly, when reviewing medical records, attorneys and experts may misidentify the appropriate parties believed to have caused skin breakdown to occur. Specifically, one theory behind DTI is that the damage may have been caused at an earlier day and time than the first presentation of the visual injury — based upon the fact that the deep tissue injury developed from the internal tissue first and is not immediately apparent. If a patient is being transferred from one type of facility to another, expert opinion may arise quite late in litigation suggesting that the earlier and seemingly innocent facility (be it a hospital or a nursing home) may have caused that injury to occur in the form of DTI.

An additional advent to the formal staging is that known as an "unstageable" ulcer. Although the diagnosis had existed in the medical community for some time, it has become a more formal diagnosis. An unstageable ulcer has been characterized by NPAUP as a full thickness tissue loss in which the base of the ulcer is covered by slough (yellow, tan, gray, green and/or brown) and or eschar (tan, brown or black) in the wound bed. The concept behind the unstageable diagnosis is that until the slough and eschar are removed, the clinician does not have enough visual information to properly stage the ulcer. That is, the stage of the wound at that juncture simply cannot be ascertained. Unstageable ulcers are an important diagnosis because they may often be very serious pressure ulcers, which have to be debrided to be correctly staged.

Hospitals, Ulcers and Never Events

Recently, Centers for Medicare and Medicaid Services (CMS) ruled that it would cease additional payments to hospitals for a number of conditions acquired in the hospital (i.e., not present upon admission) that CMS has deemed are avoidable and should not occur. CMS characterizes these Hospital Acquired Conditions (HAC) as never events. The concept is that hospitals should not be permitted to bill for conditions that they either caused or otherwise could have prevented. On this list are pressure ulcers. This decision by CMS is quite controversial and has met with significant resistance from a number of trade organizations and health care groups. They point to research that shows that some ulcers are unavoidable.

Another controversy regarding the CMS decision to list pressure ulcers as never events that it seemingly diverges from the stance CMS has taken with regard to pressure ulcers in nursing homes (although many commentators believe CMS will apply the same never events position towards nursing homes as it now has towards hospitals). F-Tag 314, the pressure ulcer component of the CMS guidelines and standard for nursing homes under the Omnibus Budget Reconciliation Act of 1987, states that it is regulation that:

> [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.

For nursing homes, CMS takes the position that under certain conditions, with some patients, skin breakdown is "unavoidable." Hospitals, however, have no such provision. Even though the never events language of the rule does not fully suggest that all pressure ulcers are avoidable, its import does not permit hospitals a means through which to obtain payment for treatment of HAC pressure ulcers even if there is clinical evidence that such pressure ulcers were unavoidable.

For attorneys practicing in this area of the law, the analysis turns to whether or not these particular never event standards enunciated by CMS give rise to a cause of action or establish the standard of care for hospital acquired pressure ulcers.

As may be expected, the answer is anything but simple. The health care industry has responded quickly and aggressively to these standards, releasing a number of position papers and articles suggesting that a significant number of bedsores that can and will arise are unavoidable. Nevertheless, this begs the question as to what type of environment hospitals operate, and of course the specific phraseology of never events.

Commentary abounds, primarily from the defense perspective, over concerns that the new CMS rule will have an impact on the following areas: (1) creating a new standard of care; (2) negligence per se litigation; and (3) res ipsa loquitur strategies by plaintiff attorneys.

In the end, it is too soon to tell whether the individual components of the never event rule can serve to establish the standard of care for a hospital, a negligence per se claim or advance re ipsa loquitor theories. Quite simply, hospitals have not operated under these new regulations long enough for that determination. Additionally, the term never event may or may not end up with sticking power. It is entirely possible that it may. It is a term chosen by the government after numerous studies and input by many respected non-profit groups based upon well-founded research. One can argue that after this significant level of investigation and research, CMS has rightly concluded that the conditions contained on the never event list are so avoidable that they absolutely do not warrant payments to hospitals when they occur. This may be persuasive in litigation as establishing them as conditions that truly are never events, and should indeed never occur. In those circumstances, in the absence of strong evidence to the contrary, res ipsa loquitur theories or negligence per se arguments may in fact survive. ■