

The Bulletin on

# LONG-TERM CARE LAW

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## *The Principle Of Unintended Consequences At Work*

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### **How Seemingly Reasonable Precautions Sparked Decades Of Litigation Over The Use Of Side Rails**

*By Robin Dale, J.D., Lane Powell Spears Lubersky*

The risks and benefits of side rails in acute care and long-term care settings continues to be the focus of considerable debate. A universally accepted tenant of this debate declares that the routine use of side rails resulted more from a fear of liability than from individual determinations of usefulness.

While generally accepted, there is little research supporting this universally accepted principle. This article attempts to verify this principle by documenting the genesis and evolution of the legal standards associated with the use of side rails through a thorough review of published court decisions. It concludes by determining that the side rail litigation of the last quarter century sprung directly from the wholesale, and possibly unwarranted, adoption of routine usage of side rails as a generally accepted standard of care in both acute and long-term care facilities.

Side rails are adjustable metal or rigid plastic bars that attach to beds and are available in a variety of shapes and sizes. Commonly used synonymous terms are bed rails, safety rails, side boards and cot sides. Side rails have been in use since at least the 1930s. The potential benefits of side rails are thought to include: (1) aid in turning and repositioning; (2) providing a ready hand hold for getting in and out of bed; (3) providing a feeling of comfort and security; and (4) reducing the risk of falling out of bed. In contrast, the potential risks of side rails are thought to include: (1) strangling or entrapment; (2) serious injuries from falls when a patient climbs over rails; (3) inducing agitated behavior when side rails are used as restraints; and (4) inducing feelings of isolation.

#### ***The 1940s: Evolution of a Standard of Care***

Both the benefits and risks of side rails have been recognized since their usage became accepted practice in the 1930s. However, it was not until the mid-1960s that the use of side rails was articulated as the legally accepted standard of care in case law. The slow evolution of this standard of care is best explained by medical providers' early reluctance to adopt the wholesale use of side rails due to the potential that the risks outweighed the benefits.

The five reported cases dealing with side rail usage from the 1940s show an early awareness of these risks and benefits. From the start of that decade, it was recognized that side rails were restraints whose primary function was to confine patients. In one of the earliest cases discussing the use of side rails, the Supreme Court of Utah noted that the standard of care did not entail the blanket application of side rails in all instances. Indeed, the Utah court noted the risks of side rails when it declared that:

“[T]he use of sideboards for conscious patients is often bad therapy; that conscious patients can, and often do, crawl over sideboards in which event any resulting fall occurs from a greater height and hence is likely to have more serious consequences.”

The Utah Court’s concerns were borne out two years later when a New York woman sued an acute care facility for injuries suffered from a fall when she attempted to climb over side rails. However, the New York facility was not found liable in this instance because the use of side rails was thought to be evidence of a reasonable precaution being taken by the facility.

Review of these early recorded cases shows that by the end of the 1940s, the medical community had yet to articulate an applicable standard of care with regard to side rails. However, this failure to successfully articulate a standard of care resulted in dismissal of only one of that decade’s five recorded cases addressing side rails. Three of these four cases were decided in plaintiff’s favor. In four of the five reported cases from the 1940s, facilities were accused of negligence for failing to use side rails. In the one recorded case in which injury was caused by a patient attempting to climb over side rails, the court decided in favor of the defendant acute care facility because the presence of side rails was thought to be a reasonable precautionary measure. Thus, by the end of the 1940s, the lesson to be learned by the reported case law was clear: facilities had a greater chance of success in litigation when side rails were in place. Given these results, it is not surprising that the following decades saw a dramatic increase in cases in which side rails were used.

### ***1950s: Stumbling Upon a Standard of Care***

The 1950s saw a near quadrupling of the number of reported cases involving the use of side rails. Almost all of these cases involved allegations of failure to use or provide side rails to patients who later fell from bed. Of the 17 reported cases from the decade of the 1950s, 14 involved allegations of failure to use or provide side rails. The outcome of these cases was slightly in favor of defendants over plaintiffs. Of the three remaining cases, one involved entrapment and two involved individuals injured while attempting to climb over the side rails.

Despite their limited success, throughout the 1950s plaintiffs were unable to consistently articulate a generally accepted standard of care. Indeed, most of the cases decided in favor of defendants throughout this decade were decided based upon plaintiffs’ failure to clearly articulate an applicable standard of care in their respective states. Conversely, plaintiffs’ greatest successes came when doctors had ordered side rails to be used and nursing staff failed to raise them. Plaintiffs were generally unsuccessful in claiming injury while climbing over side rails. In these cases, the defendant facilities successfully asserted that the patient was contributorily negligent. Thus, despite the failure to articulate a standard of care, courts accorded deference to facilities when there was evidence that side rails had been used. This deference encouraged facilities to err on the side of using side rails.

This pattern of litigation results was a driving force behind a 1957 report from James E. Ludlam, legal counsel for the California Hospital Association, which extolled the virtues of the regular use of side rails. The stated purpose of Ludlam’s article was to offer solutions to the growing problem of geriatric patients who were found “out of bed without permission.” Interestingly, Ludlam began his article by noting that side rails were the preferred option for confining patients because nets over the beds would be impractical and contrary to fire codes. In his report, Ludlam noted that in over 7,000 “out-of-bed incidents” between 1954 and 1956, two-thirds involved patients “who had gone over the rails or foot of the bed.” Ludlam ignored or downplayed evidence suggesting the injury rate rose when policies increasing the use of side rails were implemented. Instead, he focused on the smaller payouts and increased likelihood of a defense verdict when side rails were used. Ludlam noted that:

“[E]xperience shows that it is much easier to defend or settle a case when the rails are up than when they are down. The patient’s attitude toward the hospital is more friendly when he feels that the hospital has made an effort to protect him. The judge and jury are also impressed by this effort.”

Ludlam concluded his article by recommending that (1) side rails be permanently attached to all hospital beds, and (2) hospitals establish general standing orders for the use of side rails. Among the recommended standing orders was

the requirement to use side rails for the sedated, feverish, visually impaired, post-operative and all “elderly patients in a confused or in a known senile condition.” In addition, Ludlam recommended that “nurses be allowed to exercise their judgment in the application of bed rails for circumstances other than those covered in this list.”

Ludlam’s article is thought by experts to have marked a turning point in the way both acute care and long-term care facilities approached the issue of side rails. At the end of the 1950s, a medically sufficient standard of care had not been articulated by the courts or plaintiffs’ bar. In addition, acute care and long-term care facilities had achieved considerable success in defending lawsuits when they could show that they had provided side rails as a precaution. Taking their direction from Ludlam, acute care and long-term care facilities began to develop a patchwork of policies requiring side rails in most situations. In turn, these policies evolved into the accepted standard of care, which more often than not required the use of side rails. Thus, where there had been no generally accepted standard, a standard arose based upon the litigation victories of the past rather than an objective risk/utility analysis. Consistent with the principle of “unintended consequences,” these changes set in motion forces that were not envisioned at the time. The acute care and long-term care facilities’ reaction to the perceived benefits of side rails set the stage for the explosion of litigation that was to ensue in the next three decades over side rails —litigation that would ultimately result in the rejection of the standard arising from Ludlam’s pronouncements.

### ***1960s, 1970s and 1980s: The Slow March Toward a New Standard***

Despite Ludlam’s advice, some courts in the early 1960s continued to question the application of side rails. The New Hampshire Supreme Court went so far as to suggest the then novel —now generally accepted —position that proper patient assessment, not blanket administration of side rails, was the key to their successful usage. The New Hampshire court noted that:

“The evidence indicated that physical restraint of a patient is often undesirable, that bedrails are not always effective even when used, and that ‘each patient problem of this type has to be appraised on its own characteristics, and a procedure decided upon.’”

At about the same time, the Supreme Court of Washington refused to accept the proposition that the application of side rails in all cases was within the standard of care. Unfortunately, the tide had turned in favor of the use of side rails and these two cases represented the last efforts to question the use of bed rails for two decades.

By the close of the 1960s, the routine use of side rails had become standard nursing practice. This development was prompted by greater use of private and semi-private rooms in acute care and long-term care settings, a continued nursing shortage, and the insurance industry’s identification of the absence of side rails as a major liability issue. An increasing number of courts began to note that the use of side rails was a common and customary practice. By 1969, nursing school manuals directed that side rails always be applied to residents who were “restless, obese, sedated, or needed added protection.” Nurses were directed to get physician approval when not applying side rails. Indeed, the practice of using side rails became so accepted that some courts declared that lay jurors were capable of determining when restraints, like side rails, were properly provided without the testimony of expert witnesses.

Consistent with Ludlam’s earlier advice, acute care and long-term care facilities began to adopt criteria and policies governing the use of side rails. A number of facilities developed policies requiring the use of side rails based upon a patient’s age. It was not uncommon for facilities to require bed rails for patients over 50, over 60, or for “all elderly patients.” One state went so far as to adopt into law the requirement that “bed patients and disoriented patients” be provided side rails. Predictably, these policies were used against the facilities when they were not followed.

Not surprisingly, the number of injuries arising from side rail use dramatically increased. This sparked many new lawsuits decrying the overuse of side rails. In the decades from 1930 to 1960, there were only three reported cases alleging that acute care or long-term care facilities were at fault for using side rails. The first such case was reported in 1952 and involved a three-year-old boy who was placed in a full-sized hospital bed equipped with side rails. The boy was later found hanging by his neck from the side rails, dead of strangulation.

Predictably, with the increased use of side rails, allegations of injury while climbing over side rails became commonplace in the 1970s and 1980s. Allegations of entrapment began to rise in the 1980s. Health professionals and the public alike began to question whether the routine use of side rails was a wise practice.

### ***The 1990s: Another Change in the Standards of Care***

This heightened awareness of the dangers of side rails led to a number of changes in the later half of the 1990s. In addition to pressure from patients and their families, these changes were due to the influence of two federal agencies, the Health Care Financing Administration (HCFA) and the Food and Drug Administration (FDA). By the turn of the century, facilities could no longer rely upon the use of side rails as a defense, as it was the very use of these restraining devices that was being called into question.

Prior to the 1990s, the standard of care for the use and application of side rails had been the same for acute care and long-term care facilities. This changed with the adoption of the Omnibus Budget Reconciliation Act of 1987 (OBRA 87). The regulations implementing OBRA 87 severely restricted the use of side rails in nursing homes. In 1992, side rails were explicitly identified as restraints by HCFA. Concurrently, HCFA mandated documentation of the use of side rails and a doctor's authorization for use. These restrictions resulted in a dramatic reduction in the use of physical restraints in nursing homes in the 1990s.

In addition to changes in the long-term care settings, changes were also being implemented by the FDA under its authority to regulate medical devices. In 1995, the FDA issued a Safety Alert describing the hazards associated with side rail usage. The FDA report described 102 entrapment incidents resulting in 68 deaths and 22 injuries. In April 2003, the FDA issued its "Clinical Guidance For the Assessment and Implementation of Bed Rails." The guidance warns that the automatic use of side rails "may pose unwarranted hazards to patient safety." The FDA and the U.S. Department of Health and Human Services are currently in the process of finalizing a "Hospital Bed System Dimension Guidance to Reduce Entrapment" to provide recommendations to manufacturers of hospital beds. On March 22, 2005, the FDA initiated a seizure of all Vail Products Inc. Models 500, 1000 and 2000 bed systems due to an inordinate risk of entrapment. The notification urged all acute care and long-term care facilities to discontinue use of the beds.

### ***2000 and Beyond: A New Century — A New Standard — More Litigation***

Despite the federal government's leading role in attempting to resolve problems associated with side rails, the issue continues to be debated and litigation goes on. Lawsuits alleging the failure to use side rails show no sign of abating. In addition, there has been a marked increase in cases involving patients who injure themselves climbing over bed rails and/or become entrapped in the rails themselves.

### ***Conclusion***

A thorough review of the published case law confirms the longstanding, universally accepted principle that the practice of routine side rail usage sprang not from evidence-based medical practice but from an over cautious approach by acute care and long-term care facilities in attempt to avoid litigation or liability. Ironically, by adopting the routine use of side rails, these facilities unwittingly adopted a standard of care that put patients at risk of entrapment and increased injury, spawning the eventual adoption of a new standard and additional litigation.

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