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THE LEGAL AND MEDICAL ASPECTS OF PHYSICAL RESTRAINTS AND BED SIDERAILS AND THEIR RELATIONSHIP TO FALLS AND FALL-RELATED INJURIES IN NURSING HOMES

Julie A. Braun and Elizabeth A. Capezuti[*]

INTRODUCTION

Falls and fall-related injuries are a leading cause of lawsuits against nursing homes.[1] Historically, physical restraints and bed siderails were viewed as a risk-management tool to prevent or reduce falls and, consequently, the possibility of litigation.[2] However, no clinical study

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[1]*See* Laurence Z. Rubenstein, *Preventing Falls in the Nursing Home*, 278 JAMA 595, 596 (1997).

[2]Sandra H. Johnson, *The Fear of Liability and the Use of Restraints in Nursing Homes*, 18 LAW, MED. & HEALTH CARE 263, 264 (1990) ("There is no doubt that the legal system plays a role in risk aversion and the use of restraints in nursing homes."), Marshall B. Kapp, *Malpractice Liability in Long-Term Care: A Changing Environment*, 24 CREIGHTON L. REV 1235, 1242-43 (June 1991) ("Since the pervasive fear of liability based on patient falls . . . has, at least in part, fueled an excessive reliance over the years in American nursing homes on the

demonstrates that any intervention, including restraints, unequivocally prevents falls or fall-related injuries.[3] In fact, "one-half of all falls occur among restrained [residents]"[4] and "serious injury rates are higher in facilities that use restraints.[5] Further, physical restraints and siderails pose risks in addition to fall-related injuries.[6]

This article begins by presenting background information on physical restraints, siderails, and falls. Next, it considers the prevalence of restraint and siderail use in nursing homes[7] located in the United States and, for comparison purposes, other countries. A diverse selection of clinical studies examining restraint and bed siderail use and their relationship to falls and fall-related injuries follows. This section is supplemented by a review of interventions that replace siderails and prevent bedside falls and injuries.[8] Further, the article explains how physical restraints and siderails pose risks in addition to fall-related injuries. The article continues with a brief overview of the many physical and psychological consequences of physical restraint and siderail use.

Then attention shifts to restraint use within the context of direct, explicit regulation by the federal government and by each of the states. Highlights include the impact of professional standards of practice,

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use of physical (mechanical) . . . restraints in a purported attempt to assure resident safety, the liability implications of falls . . . and the practice of using restraints must logically be discussed together.") [hereinafter *Malpractice Liability in Long-Term Care*]; Julie A. Braun & Elizabeth Capezuti, *Siderail Use and Legal Liability in Illinois Nursing Homes*, 88 ILL. B.J. 324, 325 (June 2000) (discussing briefly the history of siderail usage from the 1930s to present).

[3]*See* Wayne A. Ray et al., *A Randomized Trial of a Consultation Service to Reduce Falls in Nursing Homes*, 278 JAMA 557, 557 (1997) ("Falls are a major health problem in nursing homes, but no interventions have been shown to prevent falls in nursing home residents.").

[4]Gerard S. Brungardt, *Patient Restraints: New Guidelines for a Less Restrictive Approach*, 49 GERIATRICS 43, 43 (1994).

[5]*Id.* at 48 *citing* Lois K. Evans et al., *Redefining a Standard of Care for Frail Older People: Alternatives to Routine Physical Restraint, in* ADVANCES IN LONG-TERM CARE 81, 81-108 (Paul R. Katz et al. eds., 1990).

[6]Joan Furlo Todd et al., *Injury and Death Associated with Hospital Bed Side-Rails: Reports to the US Food and Drug Administration from 1985 to 1995*, 87 AM. J. PUB. HEALTH 1675, 1675-77 (1997).

[7]As used herein, the term *nursing home* refers to facilities that meet the requirements for a state license "to provide, on a regular basis, health-related services to individuals who do not require hospital care, but whose mental or physical condition requires services that are above the level of room and board and can be made available only through institutional facilities." 42 C.F.R. § 440.155(a) (1999). As used herein, nursing home encompasses facilities that are freestanding or hospital-based. In addition, their ownership may be proprietary, nonprofit, or governmental.

[8]Brungardt, *supra* note 4, at 43-44 *citing* Evans, *supra* note 5 at 81-108.

major organizational positions on restraints, and voluntary accreditation standards on the evolving standard of care.

Overall, the article places the risk of liability in a realistic perspective, reasoning that, in most situations, an individualized assessment of fall risk best serves legal and nursing home resident[9] interests. It concludes by exploring risk management strategies that eliminate or substantially reduce the legal exposure of nursing homes.

WHAT ARE RESTRAINTS?

Physical restraints include "[a]ny manual method or physical or mechanical device, material, or equipment attached or adjacent to the resident's body that the individual cannot remove easily which restricts freedom of movement or normal access to one's body."[10] Examples include, but are not limited to, leg and arm restraints, hand mitts, lap cushions and lap trays the resident cannot remove, waist/belt restraints, pelvic restraints, chest/pelvic combination restraints commonly referred to as "Houdini" suits, and vest/chest/jacket restraints.[11] "Such inhibitions in mobility have most often been justified on the basis of perceived benefits in managing fall risk, treatment interference, or dementia-related behavioral symptoms such as agitation and wandering."[12] However, no scientific data supports the efficacy of restraints used in this manner.[13]

Nursing Home Practices as Restraints

Certain nursing home practices satisfy the definition of a restraint, such as: using bed rails to keep a resident from voluntarily getting out of bed as opposed to enhancing mobility while in bed; tucking in a sheet so tightly that a bed-bound resident cannot move; using wheelchair safety

[9]Following the terminology used in federal regulations, 42 C.F.R. § 483.10 (1999), the authors refer to individuals who have been admitted to nursing homes as *residents* rather than *patients*.

[10]U.S. DEP'T HEALTH & HUM. SERVS., HEALTH CARE FIN. ADMIN., GUIDANCE TO SURVEYORS—LONG-TERM CARE FACILITIES (Transmittal 274, June 1995), PP-44 [hereinafter HCFA GUIDANCE].

[11]*See id.* at PP-45.

[12]*See* Elizabeth Capezuti & Karen A. Talerico, *Physical Restraint Removal, Falls & Injuries*, *in* 2 RES. AND PRACTICE IN ALZHEIMER'S DISEASE 339, 339 (1999) [hereinafter Capezuti & Talerico].

[13]*See id.*

bars to prevent rising out of a chair; placing a resident in a chair that prevents rising; and placing a wheelchair-bound resident so close to a wall that the wall prevents the resident from rising.[14] Seclusion, the involuntary confinement of a nursing home resident alone in a unit or room that the person is physically prevented from leaving, may also be characterized as another form of restraint.[15]

Siderails as Restraints

Siderails are adjustable metal or rigid plastic bars that attach to a nursing home or hospital bed.[16] They come in a variety of sizes (full, half, and one-quarter length) and shapes.[17] Most nursing homes use two full-length siderails with wide vertical bars.[18] "Depending on their purpose, siderails may or may not be restraints."[19] Whether a siderail is a restraint depends on how it functions for the particular individual for whom it is being used, not on what type of rail, size rail, or time of use.[20] When siderails impede the resident's desired movement or activity (such as getting out of bed when that resident wants to get out of bed) they meet the definition of a restraint.[21] Siderails used on the bed of a completely immobile resident (for example, to prevent a comatose individual from falling out of bed), while not necessary, are not considered restraints because that person is not trying to leave the bed.[22] If a resident chooses to use siderails for enhancing mobility in

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[14]HCFA GUIDANCE, *supra* note 10, at PP-45.

[15]*See generally*, Frieda H. Outlaw & Barbara J. Lowery, *An Attributional Study of Seclusion and Restraint of Psychiatric Patients*, 8 ARCHIVES PSYCHIATRIC NURSING 69-77 (1994); U.S. GEN. ACCT. OFFICE, HEALTH, EDUC. & HUM. SERVS. DIV., *Improper Restraint or Seclusion Places People at Risk* (GAO/HEHS-99-176, Sept 7, 1999); Leslie G. Aronovitz, *Extent of Risk from Improper Restraint or Seclusion is Unknown*, U.S. GEN. ACCT. OFFICE, Testimony before the U.S. Senate Committee on Finance (GAO/T-HEHS-00-26, Oct. 26, 1999); NEW YORK STATE COMM'N ON QUALITY OF CARE FOR THE MENTALLY DISABLED, *Restraint and Seclusion Practices in New York State Psychiatric Facilities* (1994); Chadwick v. Al-Basha, 692 N.E.2d 390 (Ill. App. Ct. 1998) (alleging unlawful restraint and seclusion).

[16]Elizabeth A. Capezuti & William T. Lawson, III, *Falls and Restraint Liability Issues*, *in* NURSING HOME LITIGATION: INVESTIGATION AND CASE PREPARATION 205, 223 (Patricia W. Iyer ed., 1999).

[17]*See id.*

[18]*See id.*

[19]U.S. DEP'T OF HEALTH & HUM. SERVS., HEALTH CARE FIN. ADMIN., SIDERAILS INTERIM POL'Y (Feb. 4, 1997) [hereinafter SIDERAILS INTERIM POL'Y].

[20]*See id.*

[21]*See id.*

[22]*See id.*

and out of bed, then the siderails are not restraints.[23] Siderails must be evaluated as a restraint when they serve multiple purposes (that is, facilitating in-bed mobility and keeping the resident from getting out of bed when the resident wants to get out of bed).[24]

FALLS

A fall is defined as an event in which a person inadvertently or intentionally comes to rest on the ground or some other lower level (such as a chair, toilet or bed) after losing balance during walking or some other activity.[25] A fall-related serious injury may result in medical treatment including hospitalization, emergency department visit, physician visit, or on-site radiological examination. Serious injuries might include fractures; head injuries with altered consciousness; joint dislocations or sprains; or sutured lacerations.[26]

Nearly one third of people 65 years of age or older fall each year.[27] Fall risk increases with age and is much higher among nursing home residents than among older adults living in the community.[28] In a typical 100-bed nursing home, between 100 and 200 falls are reported

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[23] *See id.*

[24] SIDERAILS INTERIM POL'Y, *supra* note 19.

[25] MERCK MANUAL OF GERIATRICS 65, 65 (William B. Abrams et al. eds., 2d ed. 1995) ("Medical personnel usually define a fall as an event in which a person comes to rest on the ground or some other lower level after losing balance during walking or some other activity."), *available at* http://www.merck.com/pubs/mm_geriatrics (last visited Sept. 8, 2000).

[26] Mary E. Tinetti & Christianna S. Williams, *Falls, Injuries due to Falls, and the Risk of Admission to a Nursing Home*, 337 NEW ENG. J. MED. 1279, 1279-84 (1997) [hereinafter Tinetti & Williams]; Mary E. Tinetti et al., *Mechanical Restraint Use and Fall-Related Injuries among Residents of Skilled Nursing Facilities*, 116 ANNALS INTERNAL MED. 369, 370 (1992) [hereinafter *Mechanical Restraint Use*].

[27] *See* Steven R. Cummings & Michael C. Nevitt, Editorial, *Falls*, 331 N. ENG. J. MED 872, 872 (1994) [hereinafter Cummings & Nevitt]. For additional reference to nursing home fall injury rates, see Purushottam B. Thapa et al., *Injurious Falls in Nonambulatory Nursing Home Residents: A Comparative Study of Circumstances, Incidence, and Risk Factors*, 44 J. AM. GERIATRICS SOC'Y 273, 273-78 (1996); Clorinda M. Cali & Douglas P. Kiel, *An Epidemiologic Study of Fall-Related Fractures Among Institutionalized Older People*, 43 J. AM. GERIATRICS SOC'Y 1336, 1336-40 (1995); Jerry H. Gurwitz et al., *The Epidemiology of Adverse and Unexpected Events in the Long-Term Care Setting*, 42 J. AM. GERIATRICS SOC'Y 33, 33-38 (1994); P.O. Jantti, et al., *Falls Among the Elderly Nursing Home Residents*, 107 PUB. HEALTH 89, 89-96 (1993).

[28] *See* Cummings & Nevitt, *supra* note 27, at 872 *citing* Laurence Z. Rubenstein & Karen R. Josephson, *Causes of Falls in Elderly People*, *in* FALLS, BALANCE AND GAIT DISORDERS IN THE ELDERLY 21-38 (Bruno J. Vellas et al. eds., 1992).

each year; many more go unreported.[29] Dr. Rein Tideiksaar, a recognized authority on the topic of falls, estimates that more than 50 percent of nursing home residents fall annually; over 40 percent experience repeat fall occurrences.[30] About 11 percent of falls result in significant injury (such as hip fractures), often leading to hospitalization and further physical deterioration.[31] Falls are a major cause of death among older adults.[32] About 20 percent of all fall-related deaths occur in the five percent of elderly persons residing in nursing homes.[33]

The most commonly reported reason for the use of physical restraints and siderails is to protect a nursing home resident.[34] Specifically, restraints and siderails are used to safeguard residents from

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[29]*See* Rubenstein, *supra* note 1, at 596.

[30]*See* REIN TIDEIKSAAR, FALLS IN OLDER PERSONS: PREVENTION AND MANAGEMENT 1 (Health Professions Press 2d ed. 1998) [hereinafter Tideiksaar 1998]. This book discusses the consequences of falls (mortality, morbidity, family concerns and institutional effects); reviews the intrinsic and extrinsic causes of falls; identifies risk factors for falls and injury; considers environmental modifications (such as lighting, floor surfaces, hallways, beds, seating, tables and nightstands, and storage areas); details the clinical assessment and evaluation of fall risk and fall history; describes interventions that reduce fall risk including medical, rehabilitative, and environmental strategies as well as fall prevention programs; and evaluates reducing physical and chemical restraint use while decreasing fall risk. The appendix offers a performance-oriented environmental mobility screen; ambulation device measurement; ambulation device utilization; home fall prevention handouts; and case studies for self-study or training. For more information, write Health Professions Press, P.O. Box 10624, Baltimore, MD 21285-0624 or telephone toll-free (888) 337-8808. *See also* REIN TIDEIKSAAR, FALLS IN OLDER PERSONS: PREVENTION AND MANAGEMENT IN HOSPITALS AND NURSING HOMES 1 (Tactilitics 1st ed. 1993) [hereinafter Tideiksaar 1993]. This book advocates individual fall risk assessment and management. Chapter One reviews the consequences of falls in terms of outcomes for patients, families, and institutions. Chapter Two identifies the causes of falls including age-related physiological changes and pathological conditions, medications, and environmental factors. Chapter Three focuses on the clinical assessment and evaluation of falls and fall risk. Chapter Four discusses strategies for reducing fall risk. Chapter Five presents environmental modifications (such as lighting, ground surfaces, and furnishings) aimed at enhancing mobility and decreasing fall risk. Chapter Six educates the reader on the relationship between physical restraints and falls and fall-related injuries. For more information, write Tactilitics, Inc., 5595 Arapahoe Road, Suite B, Boulder, CO 80303 or telephone (800) 727-1868.

[31]*See* Rubenstein, *supra* note 1, at 596.

[32]*See* TABER'S CYCLOPEDIC MEDICAL DICTIONARY 708 (17th ed. 1993).

[33]*See* Rubenstein, *supra* note 1, at 596.

[34]*See* Linda M. Janelli et al., *Physical Restraints: Has OBRA Made A Difference?*, 20 J. GERONTOLOGICAL NURSING 17, 18 (1994).

falls and fall-related injury.[35] An additional reason for restraint and siderail use is the fear of liability should the resident fall and sustain injury.[36]

A research study of staff attitudes toward restraint use found that nurses ranked falling, violent behavior, interfering with treatment, confusion, and poor judgment as the most frequent rationales for restraining residents.[37] Moreover, study results demonstrated that falling was significantly more important than all other reasons.[38] As with other studies, the fear of lawsuits subsequent to resident falls remained a pivotal reason for applying restraints.[39] A review of restraint use in the practice of medicine concluded that the most common reason for restraint use was resident protection[40] including preventing falls, protecting medical devices (such as nasogastric tubes, Foley catheters, and endotracheal tubes), and controlling agitated behavior or wandering.[41] In another study, a questionnaire eliciting information regarding restraint use revealed that the most important reasons to restrain a resident included preventing self-injury, injury to

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[35] *See* Heather Bryant & Lori Fernald, *Nursing Knowledge and Use of Restraint Alternatives: Acute and Chronic Care*, 18 GERIATRIC NURSING 57, 60 (1997) ("In the chronic care setting the predominant reasons that [residents] were restrained was to prevent falls or self harm[.]"); Perla Werner, *Reducing Restraints: Impact on Staff Attitudes*, 20 J. GERONTOLOGICAL NURSING 19, 21 (1994) ("[R]easons for use of restraints that were cited as more important were protecting an older person from falling and preventing an older person from pulling out a catheter, feeding tube, or intravenous line."); *see* Tinetti, *Mechanical Restraint Use*, *supra* note 26, at 369 ("Prevention of fall-related injury and wandering are the most frequently cited reasons for restraining residents."); Johnson, *supra* note 2, at 263 ("Restraints are used in an attempt to protect the [resident] from avoidable injury caused by falling[.]").

[36] *See generally*, Johnson, *supra* note 2, at 263.

[37] *See* Sally B. Hardin, *Extended Care and Nursing Home Staff Attitudes Toward Restraints*, 20 J. GERONTOLOGICAL NURSING 23, 28 (1994).

[38] *See id.*

[39] *See* Hardin, *supra* note 37, at 30; Marshall B. Kapp, *Reducing Restraint Use in Nursing Homes: The Governing Board's Role*, 17 QUALITY REV. BULL. 22, 22-25 (1991) [hereinafter *Governing Board's Role*]; Marshall B. Kapp, *Nursing Home Restraints and Legal Liability: Merging the Standard of Care and Industry Practice*, 13 J. LEGAL MED., 1, 1-32 (1993) [hereinafter *Restraints & Legal Liability*]; Marshall B. Kapp, *Nursing Home Restraints and Legal Liability: Myths and Realities*, *in* LEGAL MED. 299, 299-336 (Cyril H. Wecht ed., 1993) [hereinafter *Myths & Realities*]; Marshall B. Kapp, *"But We'll Get Sued"- Confusing Restraints and Risk Management*, 6 UNTIE THE ELDERLY 1, 1-2 (1994).

[40] *See* Wayland Marks, *Physical Restraints in the Practice of Medicine: Current Concepts*, 152 ARCHIVES INTERNAL MED. 2203, 2204 (1992).

[41] *See id.*

others, and falls.[42] Similarly, a restraint reduction program examining perceptions of and knowledge about restraint use among staff members identified three important reasons for using restraints: preventing self-removal of (pulling on) an intravenous line, breaking open of sutures, and preventing a fall.[43] These reasons corroborate the work of other researchers.[44]

It is not unusual for a resident's family to express the fear of their loved one falling and insist on physical restraints and/or siderails to prevent this occurrence.[45] Family members of nursing home residents who fall (are single fallers, that is, those who would not be likely to fall again, or multiple fallers, that is, those who fall more than once) may feel guilty about the fall event and blame themselves for not preventing it.[46] Alternatively, they may blame the nursing home for allowing the fall to happen, sometimes even accusing the staff of neglect.[47]

In March 1999, the Council on Scientific Affairs of the American Medical Association issued recommendations that encourage "physicians to communicate the consequences, risks, and potential benefits of restraint use with family members of residents who ask for restraints."[48] In addition, nursing home staff, physical/occupational therapists, and social workers should educate family members about safety measures and fall prevention.[49] For example, instruction on how to identify environmental hazards that cause falls (such as poor lighting, highly polished floor or wet flooring) and interventions staff are using to address the resident's fall risk should be discussed. Family members are more

[42]*See* Janelli, *supra* note 34, at 19.

[43]*See* Terry L. Terpstra et al., *Reducing Restraints: Where to Start*, 29 J. CONTINUING EDUC. IN NURSING 10, 10, 12 (1998).

[44]*See id.* at 13; Diane Stratmann et al., *The Effects of Research on Clinical Practice: The Use of Restraints*, 10 APPLIED NURSING RES. 39 (1997) (relating the reasons for restraining residents at extended care and nursing home units in a Southeastern Veterans Affairs facility including preventing falls and fall-related injury (58%); preventing tube removal (22%), wandering (13%) and resident positioning (4%)).

[45]*See* Janelli, *supra* note 34, at 20; Johnson, *supra* note 2, at 264 (noting that family members may expect that restraints should be used and that their absence reflects bad care.)

[46]*See* Janelli, *supra* note 34, at 20.

[47]*See* Johnson, *supra* note 2, at 264.

[48]Rosalie Guttman et al., *Report of the Council on Scientific Affairs: Use of Restraints for Patients in Nursing Homes*, 8 ARCHIVES FAMILY MED. 101, 105 (1999).

[49]*See id.* at 104-05.

accepting of restraint removal when staff assures them that their family member's fall risk will be addressed with other interventions.[50]

TRENDS IN RESTRAINT PREVALENCE

Prevalence of Physical Restraint Use in the United States

The Health Care Financing Administration's ("HCFA") Online Survey Certification and Reporting ("OSCAR") system compiles data from resident census surveys.[51] All states are included.[52] The numbers reflect the subjective judgment of the reporting nursing homes.[53] For example, some facilities may not report siderails used as restraints or fail to include restraints that they believe are used for resident safety.[54] Conversely, there may be overreporting by some facilities that include every siderail as a restraint, even when not functioning as such.[55] Analysis of this statistical information reveals restraint use at the national, regional, and state level.[56] In addition, the data identifies trends in restraint prevalence.[57]

Recent OSCAR statistics show that the number of restrained nursing home residents nationwide has been reduced to 13.5 percent from 20 percent in 1996, and 40 percent in the early 1990s.[58] This

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[50]*See id.* at 102, 104.

[51]Eric M. Carlson, LONG-TERM CARE ADVOCACY FORM 10.302 (Sept. 1999) (providing a sample OSCAR report summarizing information from a federally certified nursing facility) [hereinafter Carlson]. Facility-specific data regarding federally certified nursing homes is *available at* http://www.medicare.gov/NHCompare/home.asp (last visited Sept. 9, 2000). The data from the Internet is considerably less detailed than the data contained in an OSCAR report.

[52]*See, e.g.*, OSCAR Resident Census Data (June 4, 1998) (copy on file with authors) (detailing restraint rates for all states) [hereinafter OSCAR CENSUS DATA]. An OSCAR report is available from the appropriate HCFA regional office upon submission of a Freedom of Information Act (5 U.S.C. § 552) request and payment of the required fee.

[53]HEALTH CARE FIN. ADMIN., *Restraint Reduction Newsletter* (Jerry Arzt ed., Win. 1997), *available at* http://www.hcfa.gov/pubforms/rrwin97.htm (visited Sept. 9, 2000) (discussing regional and national restraint rates for Jan. 1998).

[54]*See id.*

[55]*See id.*

[56]*See, e.g.*, OSCAR CENSUS DATA, *supra* note 52 (conveying national, regional, and state restraint rates).

[57]*Id.* (showing state restraint rates sorted by rate, the highest 20 state restraint rates, percent of residents restrained regionally, and the top 10 state increases and decreases as compared to an earlier OSCAR report).

[58]*See* HEALTH CARE FIN. ADMIN., *HCFA National Restraint Reduction Newsletter* (Jerry Arzt ed., Win. 1999), *available at*

seems to reflect a perennial national resolve to reduce restraint prevalence to the lowest possible level. Although, it is important to note considerable variation exists when comparing state restraint rates.[59] The authors are not aware of any empirical studies identifying the reasons for such broad variations among the states.

Siderail Use in the United States

No national figures for siderail prevalence exist due in part to the OSCAR and Minimum Data Set[60] reporting systems that rely on the subjective judgment of the nursing homes in relating their use of siderails as restraints.[61] Two studies report prevalence rates of 62 percent to 64.1 percent of bilateral full-length siderail usage in samples of nursing home residents collected between 1990 and 1992.[62] Data from an ongoing study of siderail use in three nursing homes found in 1999 bilateral siderails are used with approximately 40 to 70 percent of nursing home residents.[63]

Physical Restraint and Siderail Use in Other Countries

Restraint use in long-term and acute care environments varies among countries and institutions. Research conducted in Scotland and Sweden demonstrated that restraints are rarely employed and yet the incidence of injurious falls in these settings is no greater than in settings where restraints are regularly employed.[64]

A study conducted in a British hospital found that no physical restraints were used; however, 8.4 percent of patients had full-length

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http://www.hcfa.gov/publications/newsletters/restraint/1999/rrwin99.htm (last visited Sept. 10, 2000) [hereinafter *Restraint Reduction Newsletter*].

[59]*See* Karen Schoeneman & David R. Graber, *Trends in Restraint Prevalence in US Nursing Homes, 1990 through 1994*, 86 AM. J. PUB. HEALTH 1480, 1480-81 (1996).

[60]*See generally* JANET I. FELDMAN & R.W. BAKER, A STEP-BY-STEP GUIDE TO COMPLETING THE MDS 73-74 (1999) (discussing recordation of bed rail usage on the MDS reporting form).

[61]*Restraint Reduction Newsletter*, *supra* note 58.

[62]Mary E. Tinetti et al., *Mechanical Restraint Use Among Residents of Skilled Nursing Facilities: Prevalence, Patterns, and Predictors*, 265 JAMA 468, 470 (1991) [hereinafter *Restraint Prevalence, Patterns, and Predictors*].

[63]Elizabeth Capezuti et al., Abstract, *Siderail Use and Nighttime Falls among Nursing Home Residents*, 38 GERONTOLOGIST 226 (1998).

[64]*See* Elizabeth A. Capezuti et al., *Individualized Interventions to Prevent Bed-Related Falls and Reduce Siderail Use*, 25 J. GERONTOLOGICAL NURSING 26 (Nov. 1999) [hereinafter *Interventions to Prevent Bed-Related Falls and Reduce Rail Use*].

siderails raised.[65] Despite such low usage compared to American hospitals, the researchers questioned the appropriateness of bedrails.[66] A British medical journal editorial described the "absurd" and "distasteful" use of siderails in the United States.[67] The British aversion toward siderails is traced to a 1975 policy established by the Joint Working Party of the British Geriatrics Society and the Royal College of Nursing that clearly discourages routine bedrail use.[68]

A series of surveys conducted in four areas of Australia uncovered regional differences in physical restraint and siderail usage.[69] The restraint prevalence among a sample of 36,000 nursing home residents ranged from 15.3 percent to 26 percent.[70] Of those restrained, the most frequently used restraints were siderails.[71] Australian nurses, like those in the United States, frequently restrained residents due to fear of legal liability.[72] Interestingly, such fears are not raised in the British literature.

A study compared restraint type and prevalence in Denmark, France, Ireland, Italy, Japan, Spain, Sweden, and the United States finding trunk restraints are more prevalent in Sweden and the United States than other restraint types.[73] In other countries, a chair that prevents rising is the most common form of restraint, while limb restraint is the least common.[74] In general, the study found a very low

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[65] *See* Shaun O'Keefe et al., *Use of Restraints and Bedrails in a British Hospital*, 44 J. AM. GERIATRICS SOC'Y 1086, 1086-88 (1996).

[66] *See id.*

[67] *See* Editorial, *Cotsides: Protecting Whom Against What?*, 35 LANCET 383, 383-84 (1984) [hereinafter *Cotsides*].

[68] *See* Vivian Everitt & Jane Bridel-Nixon, *The Use of Bed Rails: Principles of Patient Assessment*, 12 NURSING STANDARDS 44, 44-47 (*quoting* Joint Working Party of the British Geriatrics Society and the Royal College of Nursing (1975)).

[69] *See* Andrew Retsas & Heather Crabbe, *The Use of Physical Restraints in Western Australia Nursing Homes*, 14 AUSTRALIAN J. ADVANCED NURSING 33, 33-39 (1997); Andrew Retsas & Heather Crabbe, *Breaking Use: Use of Physical Restraints in Nursing Homes in Queensland, Australia*, 4 COLLEGIAN 14, 14-21 (1998); Andrew Retsas, *Use of Physical Restraints in Nursing Homes in New South Wales, Australia*, 35 INT'L J. NURSING STUD. 177, 177-83 (1998); Andrew Retsas, *Survey Findings Describing the Use of Physical Restraints in Nursing Home in Victoria, Australia*, 35 INT'L J. NURSING STUD. 184, 184-91 (1998).

[70] *See id.*

[71] *See id.*

[72] *See id.*

[73] Gunnar Ljunggren et al., *Comparisons of Restraint Use in Nursing Homes in Eight Countries*, 26 SUPPL. AGE & AGEING 43, 43-44 (1997).

[74] *See id.*

prevalence of restraint use in Denmark, Iceland, and Japan with less than 9 percent of residents restrained at any time.[75] Between 15 and 17 percent of the residents surveyed were restrained in France, Italy, Sweden, and the United States.[76] In contrast, almost 40 percent were restrained in Spain.[77] Restraint practice patterns were attributed to cultural backgrounds and ethical positions.[78]

RESEARCH STUDIES: PHYSICAL RESTRAINTS

At present, there is no scientific basis to support the efficacy of restraints in preventing injury to nursing home residents.[79] Most research studies conclude that using physical restraints and siderails does not reduce the risk or incidence of falls, other accidents, or disruption of medical care when appropriate alternative interventions are provided.[80] In fact, research findings unequivocally suggest that restraints and siderails cause more problems than they prevent.[81]

Restrained Residents Still Fall

Physical restraint use is based on a general belief that restriction of a body part will prevent movement that could lead to falls.[82] However, numerous studies report a significant incidence of falls and injury among restrained older persons.[83] A study exploring the relationship

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[75] *See id.*
[76] *See id.*
[77] *See id.*
[78] *See* Ljunggren, *supra* note 73, at 46.
[79] *See* Guttman, *supra* note 48, at 103.
[80] *See* Guttman, *supra* note 48, at 105.
[81] *See id.*
[82] *See* Capezuti & Talerico, *supra* note 12, at 341.
[83] *See, e.g.*, Joyce Colling & Della Park, *Home, Safe Home*, 9 J. GERONTOLOGICAL NURSING 174, 179, 192 (1983); Yukie T. Gross et al., *Why do They Fall? Monitoring Risk Factors in Nursing Homes*, 16 J. GERONTOLOGICAL NURSING 20, 20-25 (1990); Cynthia Lund & Marian L. Sheafor, *Is Your Patient About to Fall?*, 11 J. GERONTOLOGICAL NURSING 37, 37-41 (1985); Lorraine C. Mion et al., *Falls in the Rehabilitation Setting: Incidence and Characteristics*, 14 REHABILITATION NURSING 17, 17-22 (1989); M. Misener & Mary Ann Matteson, *Fall-Related Injury in Nursing Home Residents*, 33 GERONTOLOGIST 276 (1993); Richard R. Neufeld et al., *A Multidisciplinary Falls Consultation Service in a Nursing Home*, 31 GERONTOLOGIST 120, 120-23 (1991) [hereinafter *Falls Consultation*]; Richard R. Neufeld et al., *Effects of Restraint Removal on Nursing Home Residents*, 31 GERONTOLOGIST 248 (1991); Mary E. Tinetti, *Factors Associated with Serious Injury During Falls by Ambulatory Nursing Home Residents*, 35 J. AM. GERIATRICS SOC'Y 644, 648 (1987); Tinetti, *Mechanical Restraint*

between restraint use and falls among 332 confused ambulatory residents in three Philadelphia-area skilled and intermediate care nursing homes over 9.5 months found that restraints were not associated with a significantly lower risk of falls or fall-related injuries.[84] These findings support individualized assessment of fall risk rather than routine restraint use for fall prevention.[85] This study provides further "compelling evidence that restrained residents still experience falls"[86] and challenges the effectiveness of restraints in preventing falls and fall-related injuries.[87]

Physical Restraints Exacerbate Falls and Fall-Related Injuries

A one-year study evaluating restraint use among previously unrestrained ambulatory nursing home residents at 12 skilled nursing home facilities in southern Connecticut revealed that restraints were used most frequently, according to nurses' reports, to prevent falls and injuries.[88] Ironically, study results associated restraints with continued, and perhaps increased, occurrence of serious injurious falls.[89] These results question the effectiveness of restraints in preventing falls and fall-related injuries.[90]

Restraint Removal Does Not Increase Falls or Fall-Related Injuries

Providing evidence that restraint reduction does not lead to a significant increase in falls and injuries is crucial to changing beliefs about restraint use and the practice of prolonged physical restraint. In the last decade, several empirically based studies of restraint reduction have

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Use, *supra* note 26, at 369-74; Ann Walshe & Harry Rosen, *A Study of Patient Falls from Bed* 9 J. NURSING ADMIN. 31 (1979); Henry M. Wieman & Mary E. Obear, *Falls and Restraint Use in a Skilled Nursing Facility*, 34 J. AM. GERIATRICS SOC'Y 907 (1986)

[84] *See* Elizabeth Capezuti et al., *Physical Restraint Use and Falls in Nursing Home Residents*, 44 J. AM. GERIATRICS SOC'Y 627, 627, 632 (1996) [hereinafter *Restraint Use & Falls*].

[85] *See id.* at 627.

[86] John F. Schnelle & Rick L. Smith, Editorial, *To Use Physical Restraints or Not?*, 44 J AM. GERIATRICS SOC'Y 727, 727 (1996) *discussing* Capezuti, *Restraint Use & Falls*, *supra* note 84, at 627-63.

[87] *See id.*

[88] *See* Tinetti, *Mechanical Restraint Use*, *supra* note 26, at 372, Tinetti, *Restraint Prevalence, Patterns, and Predictors*, *supra* note 62.

[89] *See* Tinetti, *Mechanical Restraint Use*, *supra* note 26, at 369, 372

[90] *See id.* at 372.

demonstrated that restraints can be removed without negative consequences.[91]

A clinical trial tested the relationship between restraint removal and falls and fall-related injuries using two different statistical designs.[92] First, multiple logistic regression was used to compare fall/injury rates in a sample of nursing home residents who had restraints removed to those who continued to be restrained.[93] Restraint removal was associated with a significantly lower fall and minor injury rate.[94] Second, researchers compared fall/injury rates among three homes with varying rates of restraint reduction.[95] Restraint removal was associated with a significantly lower fall rate.[96] Removal also significantly decreased the chance of minor fall-related injuries.[97] In contrast, the nursing home experiencing the least restraint reduction (11 percent) had a 50 percent higher fall rate and more than twice the rate of fall-related minor injuries when compared to the homes with 23 and 56 percent restraint reduction, respectively.[98] Additionally, researchers examined the effect of nighttime (that is, in bed) restraint removal and found no difference in fall rates between a subsample of 51 nursing home residents with restraints removed compared to 11 who continued to be restrained in bed.[99] Both studies strongly concluded that removing restraints does not increase resident falls or subsequent fall-related injury.[100]

Several other studies have confirmed these findings. A clinical nurse specialist successfully implemented a restraint reduction program

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[91]*See, e.g.*, Capezuti & Talerico, *supra* note 12, at 338-55; Guttman, *supra* note 48, at 101-05; Nicholas G. Castle & Vincent Mor, *Physical Restraints in Nursing Homes: A Review of the Literature Since the Nursing Home Reform Act of 1987*, 55 MED. CARE RES. & REV. 139, 139-70 (1998).

[92]Lois K. Evans, et al., *A Clinical Trial to Reduce Restraints in Nursing Homes*, 45 J. AM. GERIATRICS SOC'Y 675, 675-81 (1997) [hereinafter *Clinical Trial to Reduce Restraint Use*].

[93]*See id.*

[94]*See id.*

[95]*See id.*

[96]*See id.*

[97]*See* Evans, *supra* note 92, at 676-81.

[98]*See id.*

[99]*See* Elizabeth Capezuti et al., *Outcomes of Nighttime Physical Restraint Removal for Severely Impaired Nursing Home Residents*, 14 AM. J. ALZHEIMER'S DISEASE 157, 157-64 (1999) [hereinafter *Outcomes of Nighttime Restraint Removal*].

[100]*See id.*

at a 250-bed Baltimore nursing home where staff voiced their concerns about "falls and personal and professional liability for resident injury and wandering."[101] The fall rate decreased by nearly half during the first three months of restraint reduction efforts while the rate of serious injuries remain unchanged.[102] After one year, the restraint rate declined from 57 to 10 percent while the fall rate remained stable.[103] Similarly, a study conducted in a 816-bed academic nursing facility reported a reduction in physical restraint prevalence from 39 percent to 4 percent over three years, without any increase in fall or injury rates.[104]

A series of studies examining restraint use in extended care and nursing home units in a Southeastern veterans' facility revealed that decreasing the number of restrained residents did not increase falls.[105] Restraint use decreased by almost half (from 25 to 14 percent) following policy change and in-service education programs.[106] For example, to comply with the Joint Commission on Accreditation of Healthcare Organization's ("JCAHO") long-term care standards, facility policy was changed to require a physician's prescription before applying restraints.[107] Additional changes required discussing the decision to restrain with the resident and family.[108] Educational efforts concentrated on the negative effects of restraints, the importance of resident autonomy, and restraint alternatives.[109]

Serious Injuries Do Not Increase Upon Restraint Removal

A two-year restraint-reduction project involved 16 skilled nursing facilities in California, Michigan, New York, and North Carolina.[110] All had restraint rates above the national average with an aggregate

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[101] Joan D. Kramer, *Reducing Restraint Use in a Nursing Home*, 8 CLINICAL NURSE SPECIALIST 158, 160 (1994).

[102] *See id.* at 161.

[103] *See id.*

[104] *See* Jeffrey M. Levine et al., *Progress Toward a Restraint-Free Environment in a Large Academic Nursing Facility*, 41 J. AM. GERIATRICS SOC'Y 914, 914-18 (1995).

[105] *See* Stratmann, *supra* note 44, at 39.

[106] *See id.* at 41.

[107] *See id.*

[108] *See id.*

[109] *See id.* at 40.

[110] *See* Richard R. Neufeld et al., *Restraint Reduction Reduces Serious Injuries Among Nursing Home Residents*, 47 J. AM. GERIATRICS SOC'Y 1202 (1999).

restraint rate of 41 percent when the project began.[111] At the end of the study, the aggregate restraint rate had declined to 4.05 percent.[112] Like other studies, this one found that restraints did not prevent fall-related injuries.[113] In fact, moderate (injuries requiring medical attention) and serious injuries (those requiring immediate medical attention including lacerations requiring sutures, all fractures and injuries requiring transfer to the hospital) declined significantly after restraint removal.[114] At the same time, minor injuries (such as bruises or skin tears) increased minimally.[115]

Similarly, incident reports documenting falls were examined over a one-year period (six months before and after restraint removal) in two large (over 150 beds) non-profit skilled nursing facilities in Ohio.[116] While non-serious (no treatment, first aid, bruise or cut, or X-ray) falls increased, serious (hematoma, unconsciousness, stitches, fracture, hospital evaluation or admission, or death) falls did not.[117] Researchers recommend fall management programs while restraint reduction is being implemented.[118]

Individualized, Multifactorial Intervention Reduces Falls

Most falls in the elderly are due to both intrinsic (health problems, frailty, and sensory deficits such as poor vision/hearing) and extrinsic factors (environment such as slippery floors, uncomfortable seating, bed height).[119] In the last decade, several fall intervention studies have demonstrated the effectiveness of employing an individualized, multifactorial intervention to reduce falls among both community-residing and institutionalized older adults.[120] These fall prevention

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[111]*See id.* at 1205.

[112]*See id.*

[113]*See id.* at 1205-06.

[114]*See id.*

[115]*See* Neufeld, *supra* note 110, at 1205-06.

[116]*See* Farida K. Ejaz et al., *Restraint Reduction: Can It Be Achieved?*, 34 GERONTOLOGIST 694, 694 (1994).

[117]*See id.* at 698.

[118]*See id.*

[119]*See generally* Tideiksaar 1998, *supra* note 30, at 16; Tideiksaar 1993, *supra* note 30, at 19.

[120]*See, e.g.*, Ray, *supra* note 3, at 557; Mary E. Tinetti, et al., *A Multifactorial Intervention to Reduce the Risk of Falling among Elderly People Living in the Community*, 331 NEW ENG. J. MED. 821, 821-27 (1994).

programs identify each individual's risk factors (assessment) and then target the intervention(s) to correct, or at least compensate for the problem(s).[121] In general, effective fall prevention programs address medication side effects; demand appropriate observation of the restrained resident; facilitate safe mobility and transfer with human and/or device assistance as well as restorative/rehabilitative programs; consider a resident's pain/comfort needs; and create comfortable, individualized seating and bed environments.[122]

Research supports interventions to promote activity, not immobilization, a complication of restraint use. Unfortunately, clinical trials of exercise with falls as an outcome have not targeted persons over 75 years of age. However, evidence exists that exercise programs are effective in improving strength and balance, and thus reducing the risk factors for falls, among older individuals. The Frailty and Injuries: Cooperative Studies of Intervention Techniques ("FICSIT") demonstrated, in a nursing home population whose mean age was 87 years, that a progressive resistance exercise training intervention significantly increased muscle strength, gait velocity, the ability to climb stairs, and the general level of physical activity.[123] Individualized care plans, which address risk factors specific to each nursing home resident, are the best way to prevent falls and fall-related injury.[124] Changing embedded practices such as use of physical restraints, requires intensive re-education of staff and consultation by gerontology experts (physicians, nurses, and physical or occupational therapists, for example) to assist nursing home staff with residents that pose difficult clinical challenges.

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[121]*See* Tinetti, *supra* note 120, at 821-27.

[122]*See* Capezuti, *Interventions to Prevent Bed-Related Falls and Reduce Rail Use*, *supra* note 64, at 26-34; Amy Mosley et al., *Initiation and Evaluation of a Research-Based Fall Prevention Program*, 13 J. NURSING CARE QUALITY 38, 38-44 (1998); Ray, *supra* note 3, at 557-62; Rubenstein, *supra* note 1, at 595-96; Laurence Z. Rubenstein et al., *Falls in the Nursing Home*, 121 ANNALS INTERNAL MED. 442, 442-51 (1994) [hereinafter *Falls in the Nursing Home*].

[123]*See* Maria A. Fiatrone et al., *Exercise Training and Nutritional Supplementation for Physical Frailty in Very Elderly People*, 330 N. ENGL. J. MED. 1769, 1769-75 (1994).

[124]*See* Elizabeth Capezuti et al., *The Relationship between Physical Restraint Removal and Falls and Injuries among Nursing Home Residents*, 53 AM. J. GERONTOLOGY MED. SCIENCES M47, M47-M53 (1998) [hereinafter *Relationship between Restraint Removal and Falls and Injuries*]; Steven H. Miles & Roberta Meyers, *Untying the Elderly 1989 to 1993 Update*, 10 CLINICS IN GERIATRIC MED. 513, 513-25 (1994).

Fall Intervention Programs Best Incorporated into Practice if Introduced by Education and Consultation

Evans, Strumpf and their colleagues at the University of Pennsylvania School of Nursing are responsible for the first controlled clinical trial testing the effects of interventions to reduce restraints.[125] A one-year trial involving three Philadelphia-based skilled and intermediate care nursing homes concluded that a six-month educational program combined with unit-based, resident centered consultation effectively and safely reduces restraint use.[126]"[C]linically relevant and statistically significant levels of restraint reduction can be achieved without . . . serious [fall-related] injuries."[127] Restraint education combined with consultation resulted in an average reduction in restraint use of 56 percent.[128]

Other restraint reduction and fall prevention projects have successfully employed this education-consultation model.[129] For example, a consultation program designed to prevent falls and injuries in high-risk nursing home residents yielded optimistic results.[130] Fourteen Tennessee nursing homes were randomly assigned as intervention or control sites.[131] At the intervention sites, residents with a high fall risk were given interdisciplinary assessments of their living environment, mobility and assistive devices, medication regimens, and personal safety activities.[132] Then, recommendations were developed and implemented. Residents in the intervention homes experienced significantly fewer (19 percent) recurrent falls (defined as two or more) as well as (50 percent) fewer injurious falls at the end of the follow-up

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[125] *See* Evans, *Clinical Trial to Reduce Restraint Use*, *supra* note 92, at 680.

[126] *See id.* at 675-76.

[127] *See id.* at 680.

[128] *See id.* at 675, 677.

[129] *See, e.g.*, Neufeld, *Falls Consultation*, *supra* note 83, at 120-23; Lorraine C. Mion & Anne T. Mercurio, *Methods to Reduce Restraints: Process, Outcomes, and Future Direction*, 18 J. GERONTOLOGICAL NURSING 5, 5-11 (1992); Joanne Rader et al., *Restraint Strategies: Reducing Restraints in Oregon's Long-Term Care Facilities*, 18 J. GERONTOLOGICAL NURSING 49-56 (1992); Paula Werner et al., *Individualized Care Alternatives Used in the Process of Removing Physical Restraints in the Nursing Home*, 42 J. AM. GERIATRICS SOC'Y 321, 321-25 (1994) [hereinafter *Individualized Care Alternatives for Restraint Removal*]; Joanne E. Patterson et al., *Nursing Consultation to Reduce Restraints in a Nursing Home*, 9 CLINICAL NURSE SPECIALIST 231, 231-35 (1995).

[130] *See* Ray, *supra* note 3, at 558.

[131] *See id.*

[132] *See id.* at 557-58.

year.[133] The consultation program results demonstrated that "[t]he high rate of falls and related injuries in nursing homes should not be viewed as inevitable, but as outcomes that can be substantially improved through structured safety programs."[134]

Restraint Reduction Program Decreases Bedrail Use

A restraint-reduction program in a 265-bed private, non-profit nursing home located in Dallas, Texas achieved a 30.8 percent decrease in the number of restrained residents over a 14-month period.[135] The program emphasized the benefits of restraint removal over the risks of resident falls reasoning that restraint use is ineffective in preventing falls and produces negative psychological and physical effects.[136] Bedrails were the most commonly used restraint[137] and represented the greatest decrease in restraint use.[138] Because bedrails were attached to most beds in the facility, the possibility existed for their inappropriate and frequent use.[139]

RESEARCH STUDIES: SIDERAILS

As with other types of restraints, bed siderail use is based on the mistaken belief that siderails prevent falls and fall-related injuries. Another misconception is that siderails are an effective and/or benign safety device.[140] Ironically, the most common form of injury to persons enclosed by siderails occurs when the resident climbs over an elevated rail and falls at the bedside.[141] University of Minnesota research indicates that vest restraints increase the likelihood that a falling resident will be suspended and suffocate.[142] This research also finds an

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[133] *See id.* at 561.

[134] *See id.* at 562.

[135] *See* Martin Sundel et al., *Restraint Reduction in a Nursing Home and Its Impact on Employee Attitudes*, 42 J. AM. GERIATRICS SOC'Y 381, 383 (1994).

[136] *See id.* at 386.

[137] *See id.* at 383.

[138] *See id.* at 385.

[139] *See id.*

[140] *See* SIDERAILS INTERIM POL'Y, *supra* note 19.

[141] *See id.*

[142] Steven H. Miles & Patrick Irvine, *Deaths Caused by Physical Restraints*, 32 GERONTOLOGIST 762, 765 (1992); Steven H. Miles, *A Case of Death by Physical Restraint*

entrapment hazard.[143] Finally, siderails pose the same adverse effects of other restraints including, but not limited to, increasing immobility, deleterious psychological effects, urinary incontinence, and infections.[144] From a risk management perspective, siderails cannot be viewed as inconsequential attachments to nursing home beds. Their clinical efficacy has never been demonstrated.[145]

Effect of Siderails on Falls and Injuries

As early as 1983, Rubenstein and colleagues of Harvard University questioned the efficacy of siderails in preventing falls from bed.[146] While design of numerous other studies of falls and injuries did not include siderails as a risk factor, the researchers noted in their findings a surprisingly significant incidence of falls and injuries where siderails were used.[147] Several editorials and reviews of the falls literature also

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New Lessons from a Photograph, 44 J. AM. GERIATRICS SOC'Y 291, 291 (1996) [hereinafter *Death by Physical Restraint*].

[143]*See id.*

[144]*See id.*

[145]*See* Capezuti, *Interventions to Prevent Bed-Related Falls and Reduce Rail Use*, *supra* note 64, at 26-34; Elizabeth Capezuti et al., *Individualized Assessment and Intervention in Bilateral Siderail Use*, 19 GERIATRIC NURSING 322, 322-30 (1998) [hereinafter *Assessment and Intervention in Rail Use*]; Capezuti, *Relationship between Restraint Removal and Falls and Injuries, supra* note 124, at M52 *citing* Maggie Donius & Joanne Rader, *Use of Siderails: Rethinking a Standard of Practice*, 20 J. GERONTOLOGICAL NURSING 23, 23-27 (1994); Todd, *supra* note 6, at 1675-77 (reviewing FDA database for entrapment cases involving beds from January 1995 to August 1995 finds 111 entrapments, 65 percent associated with death; 23 percent with injury).

[146]*See* Howard S. Rubenstein et al., *Standards of Medical Care Based on Consensus Rather Than Evidence: The Case of Routine Bedrail Use for the Elderly*, 11 LAW, MED. & HEALTH CARE 271, 271-76 (1983).

[147]*See* Ellen B. Barbieri, *Patient Falls are not Patient Accidents*, 9 J. GERONTOLOGICAL NURSING 165, 165-172 (1983); Patricia P. Barry, *Iatrogenic Disorders in the Elderly Preventive Techniques*, 41 GERIATRICS 42, 42-47 (1986); Capezuti, *Outcomes of Nighttime Physical Restraint, supra* note 99, at 157-64; Harvey Catchen, *Repeaters Inpatient Accidents Among the Hospitalized Elderly*, 23 GERONTOLOGIST 273, 273-76 (1983); Jacob Dimant, *Accidents in the Skilled Nursing Facility*, 85 N.Y. STATE J. MED. 202, 202-05 (1985); Else M. Innes & William G. Turman, *Risk Management: Evaluation of Patient Falls*, 9 QUALITY REV. BULLETIN 30, 30-35 (1983); Klaus A. Jarvinen & Paivi H. Jarvinen, *Falling from Bed as a Complication of Hospital Treatment*, 21 J. CHRONIC DISEASES 375, 375-78 (1968); Margaret J. Kustaborder & Marilyn Rigney, *Interventions for Safety*, 9 J. GERONTOLOGICAL NURSING 159, 162, 173, 182 (1983); G. M. Tinker, *Accidents in a Geriatric Department*, 8 AGE & AGEING 196, 196-98 (1979); Walshe & Rosen, *supra* note 83, at 31.

discourage siderail use.[148] It is well recognized among physicians and nurses working in British geriatric facilities that siderails lack any known benefit in fall prevention[149] and British researchers report a low fall rate in institutions that do not use siderails.[150] A study conducted in a New Zealand hospital found a decrease in falls and injuries following a policy to reduce siderail use.[151]

Since siderails do not necessarily prevent older persons from transferring out of bed unassisted, they can lead to even more serious fall-related injuries due to the increased distance (siderails may add up to 2 feet) of a fall.[152] Capezuti and colleagues compared fall and injury rates among 188 nursing home resident using 0/1 full-length siderail to 131 residents with bilateral siderail use during a one-year data collection period.[153] After controlling for cognition, functional and behavioral status, there was no indication of a decreased risk of falls or recurrent falls with bilateral siderail use.[154] Three residents among the 131 with bilateral siderail use (1.6 percent) experienced a serious injury while two among the 188 subjects with 0/1 siderail (1.5 percent) were seriously injured.[155] Thus, bilateral siderails usage does not appear to significantly reduce the likelihood of falls, serious injuries or recurrent falls.[156]

There have been only a few studies documenting the fall outcomes related to siderail reduction.[157] In a New Zealand hospital, the reduction of full-length siderails did not change the fall rate while the

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[148] *See, e.g.*, J. Dermot Frengley, *Bedrails: Do They Have A Benefit?*, 47 J. AM. GERIATRICS SOC'Y 627, 627-28 (1999); Laurence Z. Rubenstein et al., *Falls in the Nursing Home*, 121 ANNALS INTERNAL MED. 442, 442-51 (1994); Mary E. Tinetti & Mark Speechley, *Prevention of Falls Among the Elderly*, 320 N. ENGL. J. MED. 1055, 1055-59 (1989); Beatrice Turkoski et al., *Clinical Nursing Judgment Related to Reducing the Incidence of Falls by Elderly Patients*, 22 REHABILITATION NURSING 124, 124-29 (May/June 1997).

[149] *See* Vivian Everitt & Jane Bridel-Nixon, *supra* note 68, at 44-47.

[150] *See Cotsides, supra* note 67, at 383-84; E.V. Morris & Bernard Isaacs, *The Prevention of Falls in a Geriatric Hospital*, 9 AGE & AGEING 181, 181-85 (1980).

[151] *See, e.g.*, H.C. Hanger et al., *An Analysis of Falls in the Hospital: Can We Do Without Bedrails?*, 47 J. AM. GERIATRICS SOC'Y 529, 529-31 (1999).

[152] *See* Capezuti, *Interventions to Prevent Bed-Related Falls and Reduce Rail Use*, *supra* note 64, at 26-34 *citing* Donius & Rader, *supra* note 145, at 23-27.

[153] *See* Capezuti, *Outcomes of Nighttime Physical Restraint Removal*, *supra* note 99, at 157-64.

[154] *See id.*

[155] *See id.*

[156] *See id.*

[157] *See, e.g.*, Hanger, *supra* note 151, at 529-31.

number of serious injuries were significantly reduced.[158] Half rails, compared to full-length rails, may reduce the risk of climbing over or around the rails; however, their use is not without risk.[159] Further, some rails, even when not raised, may cause problems with transferring out of bed. A study observed 20 older rehabilitation patients getting out of a bed with rails lowered compared to a bed without a rail attached.[160] It took significantly longer to get out of bed with lowered, attached rails due to the physical barrier of rail extending beyond the width of the bed, problems with getting feet under the bed or with lowering the bed to a comfortable height for standing.[161]

American researchers have only recently begun testing the effectiveness of alternatives to siderails.[162] Two groups of researchers have provided preliminary findings to support the use of very low height (that is, 7 to 13 inches above the floor) beds.[163] New products to deter falls from bed are being developed.[164] Development and testing of individualized interventions to replace siderails and reduce falls and injuries is especially important, considering the potential entrapment problem associated with siderails.

Entrapment Problems

From 1990 through 1994, the FDA received 102 reports of head and body entrapment incidents involving bedrails.[165] The 68 deaths, 22 injuries, and 12 entrapments without injury occurred in hospitals, long-

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[158] *See id.* at 530.

[159] *See* Fred M. Feinsod et al., *Eliminating Full-Length Bed Side Rails from Long-Term Care Facilities*, 5 NURSING HOME MED. 257, 260-62 (July 1997); Kara Parker & Steven H. Miles, *Deaths Caused by Bedrails*, 45 J. AM. GERIATRICS SOC'Y 797, 797-802 (1997) [hereinafter Parker & Miles].

[160] *See* M.C. Ball et al., *Bed Rails: A Barrier to Independence?*, 11 CLINICAL REHABILITATION 347, 347-49 (1997).

[161] *See id.*

[162] *See id.*

[163] *See* Elizabeth Capezuti et al., *The Effect of a Low-Height Bed Intervention on Night Falls among Frail Nursing Home Residents*, 39 GERONTOLOGIST 196 (1999); Richard R. Neufeld & Joan Dunbar, Abstract, *Siderails and Injuries in Nursing Homes*, 39 GERONTOLOGIST 500, 500 (1999); Richard R. Neufeld & Joan Dunbar, *Attitudes of Staff and Residents to Siderails in Nursing Homes*, 38 GERONTOLOGIST 226, 226-27 (1998).

[164] *See* Stephen Lane & Elizabeth Capezuti, *Deterrent for Escapes from Bed*, NAT'L INST. OF NURSING RES., Grant # 2 R 43 NR04369 (1999-2001) (on file with authors).

[165] *See* DEP'T OF HEALTH & HUM. SERVS., FOOD & DRUG ADMIN., *FDA Safety Alert: Entrapment Hazards with Hospital Bed Siderails* (Aug. 23, 1995) [hereinafter FDA ENTRAPMENT ALERT].

term care facilities, and private homes.[166] Entrapments occurred through the siderail bars; through the space between split siderails; between the siderail and mattress; or between the head or footboard, siderail, and mattress.[167] All deaths involved entrapment of the head, neck, or thorax, while most injuries involved fractures, cuts, and abrasions.[168] The majority of the deaths and injuries involved older adults.[169] Persons at high risk for entrapment include those with pre-existing conditions such as altered mental status (organic or medication related), confusion, restlessness, lack of muscle control, or a combination of these factors.[170]

Dr. Steven H. Miles, Center for Biomedical Ethics at the University of Minnesota, and Kara Parker, Department of Geriatric Medicine at St. Paul Ramsey Medical Center, and the Center for Biomedical Ethics at the University of Minnesota chronicled adult deaths and injuries attributable to bedrails from 1993 to 1996 and categorized the deaths into three types: asphyxiation; rail and in-bed entrapment; and rail and off-bed entrapment.[171]

Of the deaths, 70 percent were caused by the resident becoming trapped between the side of the mattress and a rail or in the triangular space created by the right angle of the rail and headboard where the mattress corner curves.[172] The face presses against the mattress as the body slips downwards.[173] Usually, the resident's arm was pinned beneath their body so that they were unable to pull themselves up.[174]

In 18 percent of the cases, the residents died from rail and in-bed entrapment.[175] Struggling to escape triggers rail latch failure collapsing the widely spaced vertical bars on the resident's neck.[176] Parker and Miles attribute these deaths to design flaws -- excess spacing of vertical bars and latch failure during shaking.[177] In a few cases, the person who

[166] *See id.*
[167] *See id.*
[168] *See id.*
[169] *See id.*
[170] *See* FDA ENTRAPMENT ALERT, *supra* note 165.
[171] *See* Parker & Miles, *supra* note 159, at 798.
[172] *See id.*
[173] *See id.*
[174] *See id.*
[175] *See id.*
[176] *See* Parker & Miles, *supra* note 159, at 798.
[177] *See id.*

climbed over the rail slipped and their head and neck landed on the rail.[178] Asphyxiation followed unless the person had the strength to raise their head from the rail.[179]

The remaining 12 percent of deaths were caused by rail and off-bed entrapment.[180] A composite scenario for rail and off-bed entrapment might involve an 83-year-old, 97-pound woman suffering from Alzheimer's who is wearing a vest restraint to prevent her from falling out of bed.[181] She exhibits risk factors for restraint asphyxiation including cognitive and physical disability, documented restlessness while restrained, and a recent history of being found suspended in a restraint.[182] The woman becomes suspended and struggles.[183] The restraint gathers around her upper thorax, concentrating compressing pressure on her chest.[184] Her weight is conveyed through the vest preventing her chest wall from expanding.[185] Typically, her vest catches under her arms, lifting them so that she cannot use them.[186] Her elbow jams into the bedding preventing her from using her arms to pull herself up safety or reach for a call button.[187] Medical evidence suggests that she was alive and capable of suffering as she died.[188]

In *Trew v. Smith & Davis Manufacturing Company*, a nursing home resident suffering from advanced stages of Alzheimer's disease died following rail and in-bed entrapment.[189] Suit was brought against the facility and the siderail manufacturer.[190] Discovery revealed that the manufacturer had known of the entrapment danger, but failed to take corrective measures.[191] The manufacturer sold 300,000 of this siderail model despite reports of entrapment, some of which resulted in

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[178]*See id.*
[179]*See id.*
[180]*See id.*
[181]*See* Miles & Irvine, *supra* note 142, at 765.
[182]*See* Miles, *Death by Physical Restraint*, *supra* note 142, at 291.
[183]*See id.*
[184]*See id.*
[185]*See id.*
[186]*See id.*
[187]*See* Miles, *Death by Physical Restraint*, *supra* note 142.
[188]*See id.*
[189]Trew v. Smith & Davis Manufacturing Company No. SF 95-354, 1996 WL 935336 (ATLA), at *1 (Santa Fe Cty. Jud. Dist. Ct. N.M. Aug. 1996); 16 No. 10 VERDICTS, SETTLEMENTS & TACTICS 456 (Oct. 1996).
[190]*See id.*
[191]*See id.*

death.[192] The facility settled for $900,000, the largest recovery in a New Mexico nursing home case.[193] The settlement agreement required restraint reduction and certification, in writing, to the plaintiff's attorneys, of a 90 percent restraint reduction from lawsuit inception until settlement.[194] During mediation, the manufacturer offered a $70,000 settlement.[195] The case proceeded to trial resulting in a $4.5M verdict, the largest wrongful death award in New Mexico involving a nursing home resident and the largest personal injury award recovered in Santa Fe County.[196]

Siderail Design Change

No universal standards exist for bed siderail design. Deaths from bedrails are under-recognized, preventable clinical events occurring in any medical setting, including nursing homes.[197] Researchers advocate a unified re-design of the relationship between rails, mattresses, and beds, which are now often assembled and used as separate products.[198] In April 1999, February 2000, and October 2000, the federal Food and Drug Administration ("FDA") convened representatives from government agencies, resident and patient advocacy organizations, bed manufacturers, research institutions and health care provider organizations to address the issue of bed design, among other items.[199] A task force reviewed, among other objectives, evidence-based equipment design guidance.[200] Meanwhile, eliminating or minimizing use of restraints and confirming the proper relationship between beds, rails and mattresses may prevent many of these deaths.[201]

Consider, for example, plaintiff's successful argument in *Trew v. Smith and Davis Manufacturing Company*, that the rail was negligently

[192] *See id.*
[193] *See id.*
[194] *See Trew*, *supra* note 189.
[195] *See id.*
[196] *See id.*
[197] *See* Parker & Miles, *supra* note 159, at 797.
[198] *See id.* at 800.
[199] *See* Anonymous, *Tell the FDA: Bedrails are Restraints Too! Advocates Fight to Stop Future Injuries and Deaths*, 14 QUALITY CARE ADVOCATE 6, 6-7 (1999).
[200] *See id.*
[201] *See* Parker & Miles, *supra* note 159, at 797.

designed to allow a nursing home resident's head to fit between the bars and that the defendant should have redesigned them.[202]

SIDERAIL ALTERNATIVES

Use of siderails often replaces the assessment process of unraveling the complex multifactorial etiology of an individual's fall risk. Effective bed-fall reduction projects emphasize the importance of a comprehensive assessment process.[203]

Siderails are used as restraints when they function to deter an older person from transferring out of bed.[204] They also remind the person to call for assistance; however, most persons for whom siderails are used lack the cognitive ability to correctly interpret their intended use.[205] Instead, many respond to siderails as a barrier to go over or around. Thus, because siderails add two feet to the potential fall height, likelihood of injury is increased.[206] Alternatives include bed bumpers on mattress edges, full body pillows, pillows, or rolled blankets under the mattress edge; each remind residents of the bed's edge without adding height to a fall.[207]

Most falls from bed occur when a resident is transferring in or out of bed.[208] For shorter (less than 5 feet) residents, the standard nursing home bed (usually 21 inches from the floor) may be too high for safe transfer.[209]Low beds that can be manually, hydraulically or electrically adjusted to promote safe transfer are available.[210] A non-skid mat

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[202]*See Trew*, *supra* note 189.

[203]*See* Capezuti, *Assessment and Intervention in Rail Use*, *supra* note 145, at 322-30; Elizabeth Capezuti et al., *Individualized Interventions to Prevent Bed-Related Falls and Reduce Siderail Use*, 25 J. GERONTOLOGICAL NURSING 26, 26-34 (Nov. 1999) (detailing the clinical decision-making process in choosing interventions to prevent bed falls) [hereinafter *Individualized Interventions to Prevent Bed-Related Falls and Reduce Siderail Use*].

[204]*See* SIDERAILS INTERIM POL'Y, *supra* note 19.

[205]*See* Capezuti, *Individualized Interventions to Prevent Bed-Related Falls and Reduce Siderail Use*, *supra* note 203, at 27.

[206]*See* O'Keefe, *supra* note 65, at 1075-77.

[207]*See* Capezuti, *Individualized Interventions to Prevent Bed-Related Falls and Reduce Siderail Use*, *supra* note 203, at 26-34.

[208]*See id.*

[209]*See id.* at 29.

[210]*See* Capezuti, *Assessment and Intervention in Rail Use*, *supra* note 145, at 322-30; Capezuti, *Individualized Interventions to Prevent Bed-Related Falls and Reduce Siderail Use*, *supra* note 203, at 26, 29.

placed at the side of the bed and/or toilet can reduce the likelihood of slipping.[211] Securely fastened grab bars as well as a toilet seat individually adjusted to the resident's height will reduce falls in the bathroom.[212] Additionally, many residents need a device to enable or assist them in safe transfer and promote stability when standing.[213] Transfer enablers include a trapeze, transfer pole or bar, or raised 1/4 or 1/2 length siderail directly attached to or adjacent to the top of the bed.[214] For residents with a history of climbing around or over siderails, especially those at high risk of injury (for example, persons with osteoporosis), reducing the risk of injury is essential.[215] For those residents unable to stand safely, but who may accidentally roll out of or attempt to unsafely exit from bed, a very low bed height (6 to 13 inches from the floor) is recommended.[216] Falling onto hard surfaces increases the likelihood of serious injury.[217] Thus, a bedside cushion such as an exercise mat or an eggcrate foam mattress is useful for those at risk of fall-related injury. Hip pads have also been shown to reduce the risk of hip fracture in fallers.[218] Developing an effective individualized care plan requires creative approaches, best achieved with input from the entire clinical care team. Most likely this will require staff education and administrative support as staff try interventions other than siderails.[219] Residents and their families must be informed and involved in the process.[220]

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[211] *See* Capezuti, *Individualized Interventions to Prevent Bed-Related Falls and Reduce Siderail Use*, *supra* note 203, at 29.

[212] *See id.* at 30.

[213] *See id.* at 27.

[214] *See id.*

[215] *See id.* at 30.

[216] *See id.*

[217] *See* Michael C. Nevitt & Steven R. Cummings, *Type of Fall and Risk of Hip and Wrist Fractures: The Study of Osteoporotic Fractures*, 41 J. AM. GERIATRICS SOC'Y 1226, 1226-34 (1993).

[218] *See* J.B. Lauritzen et al., *Effect of External Hip Protectors on Hip Fractures*, 341 LANCET 11, 11-13 (1993); S.N. Robinovitch et al., *Energy-Shunting Hip Padding System Attenuates Femoral Impact Force in a Simulated Fall*, 117 J. BIOMECHANICAL ENGINEERING 409, 409-13 (1995).

[219] *See* Donius, *supra* note 145, at 23-27.

[220] *See* Sarah G. Burger, *Working with Families and Residents*, 38 GERONTOLOGIST 227 (1998).

OTHER ADVERSE EFFECTS OF RESTRAINTS

For older persons, restraint use worsens deconditioning, gait, and balance abnormalities, thereby increasing a nursing home resident's fall and injury risk.[221] Other complications of prolonged immobilization include joint contractures; chronic constipation; incontinence; pressure sores; cardiopulmonary deconditioning; increased agitation and confusion; loss of autonomy and dignity; an increased likelihood of contusions, neurovascular compromise, and nosocomial infection; serious biochemical and physiologic effects; abnormal changes in body chemistry, basal metabolic rate and blood volume; orthostatic hypotension; lower extremity edema; bone demineralization; overgrowth of opportunistic organisms; and EEG changes.[222]

Burns

Poor posture control, hand dexterity or confusion can increase the chances of an accident among restrained nursing home residents who smoke.[223] Also, visitors and other residents unaware of a potential fire hazard may give smoking materials to the resident without staff knowledge.[224] Further, many residents use oxygen, or are in close proximity to other residents who use oxygen, thereby increasing the danger of fire.[225] The deliberate or accidental igniting of restraints may result in death or injury.[226] For example,

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[221] *See* Schnelle & Smith, *supra* note 86, at 727; Rubenstein, *Preventing Falls in the Nursing Home*, *supra* note 1, at 596; *see also* Rubenstein, *Falls in the Nursing Home*, *supra* note 122, at 442-51.

[222] *See* Kathleen Fletcher, *Use of Restraints in the Elderly*, 7 AACN CLINICAL ISSUES 611, 613-14 (1996); Kathy A. Gorski, *Myths & Facts . . . About Physical Restraints and the Elderly*, 25 NURSING 25 (1995); Brungardt, *supra*, note 4, at 43-44; 57 Fed. Reg. 27,397, 27,398 (1992) (associating restraint use with numerous negative outcomes, such as emotional desolation, agitation, fractures, chafing, burns, nerve damage, circulatory impairment, decubitus ulcers, strangulation and death); Tinetti, *Restraint, Prevalence, Patterns, and Predictors*, *supra* note 62, at 468; Lois K. Evans & Neville E. Strumpf, *Tying Down the Elderly: A Review of the Literature on Physical Restraint*, 37 J. AM. GERIATRICS SOC'Y 65, 69 (1989).

[223] *See* 61 Fed. Reg. 8,432, 8,438 (1996).

[224] *See id.*

[225] *See id.*

[226] *See* 61 Fed. Reg. 8,432, 8,437 (1996); *see also* Miles & Irvine, *supra* note 142, at 763 (analyzing 122 deaths caused by vest and strap restraints from 1983 through 1990 finding three persons who died trying to escape restraint by setting their restraints on fire and one person receiving oxygen by nasal cannula who died from a fire accidentally started by a cigarette).

> A 76-year-old nursing home resident diagnosed with dementia died two days after suffering third degree burns over 56 percent of his body when his clothing caught fire. Allegedly, the resident was found standing and ablaze from the waist up after facility staff responded to screams. In a subsequent negligence lawsuit, the decedent's surviving heir claimed that the resident had been placed in a vest restraint without a physician's order in violation of federal and state regulatory rules and procedures. She also claimed that the facility administrator had instructed employees to restrain the resident when his family members left the premises after visiting. The plaintiff also alleged that the facility had an ineffective smoking policy despite knowledge that some residents had cigarettes and lighters. She theorized that the resident's roommate, who also suffered from dementia, either lit a cigarette for the decedent or tried to help him use a cigarette lighter to burn off the restraining vest's straps. The resident's room was cleaned and painted at night immediately after the fire. A fire investigator allegedly found a trash bag in a dumpster containing the decedent's clothing and the remains of the vest. The administrator denied the allegations. A Texas Department of Human Services investigation prompted the establishment of an involuntary trusteeship to operate the facility and return it to compliance with federal and state regulations. A $1,350,000 settlement ended the negligence suit.[227]

It is important for every nursing home to have a smoking policy or risk a similarly large settlement following resident death from self-inflicted burns. Risk managers are advised to review their facility's smoking policy and compare it to actual smoking practices within the facility.

There have been reports of restraints with ash and cigarette burns in them, indicating a safety problem with flammable materials.[228] Although the FDA does not require flame-resistant materials for all restraints, the agency recommends that health care institutions.

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[227] *See Restraints: Resident Death from Burns*, 5 ISSUES IN CONTINUING CARE RISK MGMT. 15, 15-16 (ECRI) (June 1999) *citing* 15 MED. MALPRACTICE 29 (1999)

[228] *See* 61 Fed. Reg. 8,432, 8,437 (1996).

including nursing homes, develop and implement policies using flame-retardant restraints for residents who smoke while restrained.[229]

Agitation

"For years, uncooperative and agitated [residents] have been physically restrained in order to manage their behavior."[230] However, various observational studies have found that restrained residents exhibit the same, or more, agitated behaviors than unrestrained residents.[231] This suggests that restraints intensify rather than improve behavior among agitated older residents. For example, a resident's daughter related that her mother had been in a concentration camp during World War II and was agitated and frightened by restraints.[232] Upon restraint removal, her mother stopped screaming and became a much calmer person.[233]

Residents may describe a "prison-like feeling" when their bed rails are in the up position.[234] Residents already restless and agitated, fearful of soiling their bed, are at increased risk of falling while attempting to climb over siderails.[235] Other agitated residents risk injury while attempting to escape the confines of siderails.[236]

In *Kildron v. Shady Oaks Nursing Home*, physician's orders permitted physical (and chemical) restraint "as needed" for a 59-year-old resident with Alzheimer's disease.[237] The facility's director of nurses "testified that the staff did not use restraints on [this resident] unless absolutely necessary because they made him hostile and

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[229]*See id.*

[230]James T. O'Donnell et al., *Appropriate Use of Chemical and Physical Restraints with Elderly Nursing Home Residents*, 9 J. PHARMACY PRAC. 144, 144 (1996); Perla Werner et al., *Physical Restraints and Agitation in Nursing Home Residents*, 37 J. AM. GERIATRICS SOC'Y 1122, 1124 (1989) (reporting that the imposition of physical restraints increases manifestations of agitation).

[231]*See* Susan Dodds, *Exercising Restraint: Autonomy, Welfare and Elderly Patients*, 22 J. MED. ETHICS 160, 161 (1996); Werner, *supra*, note 230, at 1124; *see also* Goldberg v. Plaza Nursing Home Co., Inc., 222 A.D.2d 1082-83 (N.Y. App. Div. 1995) (describing nursing home resident's death due to either cardiac arrest triggered by agitation over being restrained or strangulation in a vest restraint).

[232]*See* Ejaz, *supra* note 116, at 697.

[233]*See id.*

[234]*See, e.g.*, Hanger, *supra* note 151, at 530.

[235]*See* Wendy Jehan, *Restraint or Protection? The Use of Bedside Rails*, 6 NURSING MGMT. 9, 10 (1999).

[236]*See id.* at 11.

[237]Kildron v. Shady Oaks Nursing Home, 549 So.2d 395, 396 (La. Ct. App. 1989).

agitated."[238] Instead, the facility let him wander and assigned an aide to watch him during the day.[239] One evening, the unattended resident fell and fractured his hip.[240] The appellate court affirmed the trial court's judgment "that the nursing home was not negligent in failing either to restrain or personally supervise and assist plaintiff at all times."[241] The court held that failure to use physical restraints was not a breach of the nursing home's duty of care.[242]

Resident Autonomy and Dignity

Restraints threaten resident personal autonomy and dignity. For example, a 72-year-old man said: "I felt like I was a dog and cried all night. It hurt me to have to be tied up. I felt like I was nobody, that I was dirt. It makes me cry to talk about it[.]"[243] Evans and Strumpf, nurse researchers at the University of Pennsylvania School of Nursing who have studied restraints for over a decade and are among the nation's leading advocates of restraint reduction, report that many residents express feelings of anger, fear, and abandonment long after the restraint experience.[244] Many are uninformed about why they are restrained, some even mistaking it for punishment. For example, an 84-year old woman recalls her experience:

> I don't remember misbehaving, but I may have been deranged from all the pills they gave me. Normally, I am spirited, but I am also good and obedient. Nevertheless, the nurse tied me down, like Jesus on the cross, by bandaging both wrists and ankles . . . it felt awful. I hurt and I worried, 'What if I get leg cramps; what will I do then if I can't move?' It was miserable . . . and an awful shock . . . Because I am a cooperative person. I felt so resentful. Callers, including men friends, saw me like that and I lost something; I lost a little personal prestige. I was embarrassed, like a child

[238] *See id.*
[239] *See id.*
[240] *See id.*
[241] *See id.* at 397.
[242] *See id.*
[243] Dodds, *supra* note 231, at 160.
[244] *See* Evans & Strumpf, *supra* note 222, at 69.

placed in a corner for being bad . . . I haven't forgotten the pain and indignity of being tied.[245]

FEDERAL LAW AND REGULATION

In practice, courts examine statutory and regulatory requirements as evidence of the appropriate professional standard of care.[246] Compliance with these legal standards is considered minimally adequate conduct, while deviation is negligence *per se* or a strong presumption of negligence.[247] The legal standard of care in nursing

[245]Dodds, *supra* note 231, at 160.

[246]Carlson, *supra* note 51, at § 10.08 (determining the standard of care in nursing home cases); LAWRENCE A. FROLIK & RICHARD L. KAPLAN, ELDER LAW IN A NUTSHELL 171 (2d ed. 1999) ("look to the various Federal and state certification standards to provide a proper standard of care"); Angela Snellenberger Quin, Comment, *Imposing Federal Criminal Liability on Nursing Homes: A Way of Deterring Inadequate Health Care and Improving the Quality of Care Delivered?*, 43 ST. LOUIS U. L.J. 653, 658 (Spring 1999) ("OBRA 87 provided a national standard of care applicable to all nursing homes participating in Medicare or Medicaid[.]"); Steven M. Levin et al., *Protecting the Rights of Nursing Home Residents Through Litigation*, 84 ILL. B.J. 36, 36 (Jan. 1996) ("OBRA and its regulations establish a national standard of care applicable to nursing homes which affects all nursing home cases"); Catherine Hawes, *Assuring Nursing Home Quality: The History and Impact of Federal Standards in OBRA-1987*, New York: Commonwealth Fund (Dec. 1996); Lorraine C. Mion et al., *Physical Restraint Use in the Hospital Setting: Unresolved Issues and Directions for Research*, 74 MILBANK Q. 411, 425 (1996); Marilyn Askin, *Nursing Home Residents as Clients*, 164 N.J. LAW. 30, 31 (Oct. 1994) (highlighting remarks presented at a National Academy of Elder Law Attorneys symposium that reference attorney use of the "copious standards set forth in the [Nursing Home Reform Act] and states' nursing home licensing laws as the basis for the standard of care."); Kapp, *Malpractice Liability in Long-Term Care, supra* note 2, at 1244 ("The courts . . . relied on the facility's compliance with applicable federal and state regulations regarding the safeguarding of resident welfare in holding that the facility had satisfied the legal standard of care, even if resident injury unfortunately took place anyway.").

[247]*See, e.g.*, Abrahams v. King Street Nursing Home, Inc., 664 N.Y.S.2d 479 (1997), *leave to appeal denied*, 671 N.Y.S.2d 715 (N.Y. 1998) (finding no evidence that the nursing home's failure to restrain a resident without physician order (as required by law and facility policy) was negligent); Klein v. BIA Hotel Corp., 49 Cal. Rptr. 2d 60, 64 (Cal. Ct. App. 1996) (relying on state licensing regulations in establishing the appropriate standard of care); Dusine v. Golden Shores Convalescent Ctr., 249 So.2d 40, 41 (Fla. Dist. Ct. App. 1971) (approving the admission of a regulation providing that "during provisions of restraint, the patient shall be observed vigilantly"); *cf.* Makas v. Hillhaven, 589 F. Supp. 736, 742 (M.D. N.C. 1984) (finding state nursing home patients' bill of rights provisions "so general and nebulous that a trier of fact could not determine whether the standard had been violated"); Stogsdill v. Manor Convalescent Home, 343 N.E.2d 589, 611-12 (Ill. App. Ct. 1976) (ruling that certain state nursing home regulations did not establish a standard of care); MO. REV. STAT. § 198.093(4) (1994 & Supp. 1998) (allowing a facility to be exempt from liability by simply showing that it "exercised all care reasonably necessary to prevent the deprivation and injury for which liability is

homes incorporates a strengthened presumption against restraint use unless identifiable alternatives have been investigated and found impossible.[248]

Nursing Home Reform Act

The minimum standard of care that nursing homes are expected to meet appears in the Nursing Home Reform Act (NHRA)[249] enacted by Congress as part of the Omnibus Budget Reconciliation Act of 1987 (OBRA)[250] and its implementing regulations.[251]

> Although the nursing home industry as a whole reacted favorably to the statutory and regulatory antipathy of restraints, a substantial number of long-term care professionals expressed anxiety about the potential malpractice liability implications for them and their facilities associated with radically reducing the use of restraints, particularly physical [restraints], for residents at risk of falling and/or wandering.[252]

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asserted."); *see also* Daniel M. Gitner, *Nursing the Problem: Responding to Patient Abuse in New York State*, 28 COLUM. J.L. & SOC. PROBS. 559, 598 (discussing New York's civil redress statute which provides nursing homes with an affirmative defense if they can prove that they "exercised all care reasonably necessary to prevent and limit the deprivation and injury"); Lori Owen, *Rights of Long-Term Care Facility Residents, in* THE ELDER LAW PORTFOLIO SERIES 12-5, 12-30 (Feb. 1996) ("Violation of the standards set forth in the [Nursing Home Reform Act] may be prima facie evidence of negligence or, in some instances, negligence per se."); Susan J. Hemp, Note, *The Right to a Remedy: When Should an Abused Nursing Home Resident Sue?*, 2 ELDER L.J. 195, 206 (Fall 1994) (opining that "[t]he exact standard of care may be established in several ways[.]" for example, "if a nursing home violates a federal or state regulation or deviates from statute, this is prima facie evidence of negligence.").

[248] *See* Marshall B. Kapp, *Physical Restraint Use in Critical Care: Legal Issues*, 7 AACN CLINICAL ISSUES 570, 570-85 (Nov. 1996) [hereinafter *Legal Issues*].

[249] The Nursing Home Reform Act was included in the Omnibus Budget Reconciliation Act of 1987, codified at 42 U.S.C. §§ 1395r-i(3) (a)-(h) (1994 & Supp. III 1997) [Medicare] & 1396r(a)-(h) (1994) [Medicaid]. Its content was based on INSTITUTE OF MEDICINE, IMPROVING THE QUALITY OF NURSING HOME CARE (1986). For background on this legal overhaul, *see, e.g.*, Mary Kathleen Robbins, Comment, *Nursing Home Reform: Objective Regulation or Subjective Decisions?* 11 T.M. COOLEY L. REV. 185 (1994).

[250] 42 U.S.C. §§ 1395i & 1396 *et seq.*; *see also* H.R. Rep. No. 100-391, 100th Cong., 1st Sess., pts. 1 & 2 (1987), *reprinted in* 1987 U.S.C.C.A.N. 2313-1; and H.R. Conf. Rep. No. 100-495, 100th Cong., 1st Sess. (1987), *reprinted in* 1987 U.S.C.C.A.N. 2313-1245 (confirming the intent of Congress to implement major reforms in nursing home care and to create a resident-centered, outcome-oriented survey process).

[251] 42 C.F.R. Pt. 483 (1999).

[252] Marshall B. Kapp, *Restraint Reduction and Legal Risk Management*, 47 J. AM. GERIATRICS SOC'Y 375, 375 (1999).

The NHRA imposes stringent standards for nursing homes participating in the Medicare/Medicaid programs, the primary funders of long-term care.[253] The discussion below, although not exhaustive, highlights many significant NHRA provisions.

Right to be Free from Restraints

All Medicaid- and Medicare-certified facilities must adhere to a Resident Bill of Rights as detailed in the federal regulatory scheme that includes the general right to be free from restraints, with some qualifications.[254] In *O'Gorman v. Pleasant Valley Extended Care*, a 78-year-old resident diagnosed with chronic obstructive pulmonary disease, arterial sclerosis, left side hemiplegia and an aneurysm refused the use of a restraint to prevent recurrent falls and signed an order prohibiting same.[255] The facility notified the resident's family and physician each time she fell.[256] In spite of such notifications, the resident maintained her right to be free from restraint.[257] The resident died following cerebral hemorrhage allegedly resulting from a blow to the head received after a fall from her wheelchair.[258] The jury unanimously agreed that the facility was not negligent in failing to prevent the resident's fall.[259]

Residents also have the right to be free from restraints imposed for discipline or convenience, and not required to treat medical symptoms which must be documented in the resident's chart and incorporated into the resident's assessment and care planing.[260] Consider, for example, *Nielsen v. Basit*, where a 29-year-old patient at a state mental institution "died, after a nurse dragged him down the hall in a chokehold, put him

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[253]42 U.S.C. §§ 1395r-i(3) (a)-(h) [Medicare] & 1396r(a)-(h) [Medicaid].

[254]*See* 42 C.F.R. § 483.10 (1999); *see generally* JOAN M. KRAUSKOPF ET AL., ELDER LAW: ADVOCACY FOR THE AGING (2d ed. 1993) (providing overview of the federal Bill of Rights).

[255]O'Gorman v. Pleasant Valley Hosp. Extended Care, No. 115287, 1996 WL 526084, at *1 (Ventura Cty. Super. Ct., May 1, 1996).

[256]*Id.* at *1.

[257]*Id.* at *2.

[258]*Id.* at *1, 2.

[259]*Id.* at *2.

[260]*See* 42 U.S.C. §§ 1396r(c)(1)(A)(ii) (Supp. IV 1998) [Medicaid] & § 1395i-3(c)(1)(A)(ii) (Supp. IV 1998) [Medicare]; 42 C.F.R. § 483.13(a) (1999); Bremenkamp v. Beverly Enters. Kansas, Inc., CIV. A. Nos. 89-2006-O, 89-2060-O, 1991 WL 126771, at *1 (D. Kan. June 10, 1991) (involving a resident who fell after being left improperly restrained and unattended in a bathroom perhaps because of staff shortage).

in restraints, and then left him in unattended seclusion."[261] A wrongful death suit is resulted in a $2,800,000 verdict.[262]

Quality of Life

Nursing homes accepting Medicare or Medicaid payments must care for residents "in such a manner and in such an environment as will promote maintenance or enhancement of the quality of life of each resident."[263] Restrained residents feel socially isolated, fearful, demoralized, humiliated, angry, uncomfortable, and confused.[264] These feelings remain months or years after restraint removal.[265]

Further, the nursing home must provide "services and activities to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each [nursing home] resident in accordance with a written plan of care[.]"[266] The facility must demonstrate how restraint and/or siderail use assists the resident in reaching his or her highest level of physical, mental, and emotional well being.[267]

Resident Assessment and Care Planning

Nursing homes are required to conduct a comprehensive resident assessment within 14 days of a resident's admission, "promptly after a significant change in physical and/or mental condition," and at least annually.[268] The assessment gathers information about a resident's ability to perform daily life functions such as walk, talk, eat, dress,

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[261]Nielsen v. Basit, No. 83C-1683, 1992 WL 740296, at *1 (Cook Cty. Cir. Ct. Ill. 1992).

[262]*Id.*

[263]42 U.S.C. §§ 1395i-3(b)(1)(A) (Supp. IV 1998) [Medicare] & 1396r(b)(1)(A) (Supp. IV 1998) [Medicaid]; 42 C.F.R. § 483.15 (1999) (featuring slightly different language -- "A facility must care for its residents in a manner and in an environment that promotes maintenance or enhancement of each resident's quality of life.")

[264]*See* Gorski, *supra* note 222, at 25.

[265]*Id.*

[266]42 U.S.C. §§ 1395i-3(b)(2) & (4)(A)(i) (Supp. IV 1998) [Medicare]; 42 U.S.C. §§ 1396r(b)(2) & (4)(A)(i) (Supp. IV 1998) [Medicaid]; 42 C.F.R. § 483.25 (1999) (using slightly different language -- "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.").

[267]*See* HCFA GUIDANCE, *supra* note 10, at PP-46.

[268]42 U.S.C. §§ 1395i-3(b)(3)(C)(i) [Medicare] & 1396r(b)(3)(C)(i) [Medicaid]; 42 C.F.R. § 483.20(d)(2) (1999). *See also* Valdivia v. California Dep't of Health Servs., No. S-90-1226EJG EM, 1991 WL 80896, at *4 (E.D. Cal. Feb. 25, 1991) (detailing the basic criteria for comprehensive resident assessments).

bathe, see, hear, communicate, understand, and remember.[269] It also details significant impairments in functional capacity.[270] A decision to use physical restraints and/or siderails should be made after clinical evaluation and interdisciplinary care planning determines the purpose for the intervention.[271]

After a comprehensive resident assessment has been completed, the nursing home must develop a written care plan for each resident.[272] A written care plan describes the resident's medical, nursing, and psychosocial needs and how to meet those needs.[273] The facility must engage in a systematic and gradual process toward restraint and siderail reduction for those residents whose care plans indicate their need.[274] For example, gradually increasing the amount of time the resident walks each day and receives muscle strengthening activities[275] or reducing the use of two full-length siderails to one full-length siderail.[276]

The resident and/or the resident's legal representative have a right to participate in comprehensive care planning conferences.[277] The attorney representing the resident or the caregiver should alert the

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[269] *See generally* John M. Morris et al., *A Commitment to Change: Revision of HCFA's RAI*, 45 J. AM. GERIATRICS SOC'Y 1011 (1997); Charles D. Phillips et al., *Association of the Resident Assessment Instrument (RAI) with Changes in Function, Cognition, and Psychosocial Status*, 45 J. AM. GERIATRICS SOC'Y 986 (1997); Brant E. Fries et al., *Effect of the National Resident Assessment Instrument on Selected Health Conditions and Problems*, 45 J. AM. GERIATRICS SOC'Y 994 (1997); Theresamarie Mantese, *Nursing Homes and the Care of the Elderly*, 51 J. MO. B. 155 (May/June 1995) (describing resident assessment instruments).

[270] *See* 42 U.S.C. §§ 1395i-3(b)(3)(A) (Supp. III 1997) [Medicare] & 1396r(b)(3)(A) (1994 & Supp. III 1997) [Medicaid]; 42 C.F.R. § 483.20(b)(i)-(xiii) (1999).

[271] *See* SIDERAILS INTERIM POL'Y, *supra* note 19.

[272] *See* 42 U.S.C. §§ 1395i-3(b)(2) & (4)(A)(i) [Medicare]; 42 U.S.C. §§ 1396r(b)(2) & (4)(A)(i) [Medicaid]; 42 C.F.R. § 483.25 (1999) (featuring slightly different language -- "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.").

[273] *See* 42 U.S.C. §§ 1395i-3(b)(2)(A) [Medicare] & 1396r(b)(2)(A) [Medicaid]; 42 C.F.R. § 483.20(d). State regulation also addresses resident care plans. *See, e.g.*, N.Y. COMP. CODES R. & REGS. tit. 10 § 415.4(a)(2)(ii) (noting that the resident's comprehensive care plan must specify the type of restraint, release schedules, type of exercise, necessary skin care, and ambulation to be provided).

[274] *See* HCFA GUIDANCE, *supra* note 10, at PP- 44.

[275] *See id.*

[276] *Id.* at PP-46.

[277] *See* 42 C.F.R. § 483.20(d) (1999).

facility of the client's interest in attending such conferences.[278] The attorney who wants to attend should secure written authorization from the resident or caregiver allowing attorney participation.[279] Care plan conferences may be used to raise concerns about physical restraint and/or siderail use.[280]

The care plan is significant from a legal point of view because it defines the standard of care to which the nursing home can be held accountable.[281] Nursing homes have a duty to provide care that meets the needs of the resident's known physical and mental condition.[282]

Physician Order

According to federal law, restraint use requires a physician's written order[283]specifying circumstances and duration of use.[284] Clearly, the decision to restrain falls within the physician's professional ethic and judgment rather than administrative routine.[285]

In *Saunders v. Beverly Enterprises*, a 56-year-old terminal cancer patient, a known smoker, was admitted to the defendant's nursing home with orders for bed rest and restraint as needed.[286] Instead of following physician orders for treatment and restraint, a computerized nursing

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[278]H. Kennard Bennett, *Nursing Home: The Care Plan is the Contract* 1, 17-18 *presented at* Fundamental & Emerging Issues for the Elder Law Practitioner (Nat'l Academy of Elder Law Attorneys, May 14-17, 1997 (Las Vegas, NV)) (copy on file with authors).

[279]*Id.* at 18.

[280]*Id.* at 19 (advising the attorney to make a list identifying issues and concerns to raise at the care planning conference).

[281]42 C.F.R. § 483.20(k)(3) (1999) ("The service provided or arranged by the facility must (i) Meet professional standards of quality; and, (ii) Be provided by qualified persons in accordance with each resident's written plan of care.").

[282]42 U.S.C. §§ 1395i-3(b)(2)(a) (Supp. IV 1998), 1396r(b)(2)(a) (Supp. IV 1998); 42 C.F.R. § 483.20(d)(1)(i) (1999).

[283]*See* Joseph G. Ouslander & Dan Osterweil, *Physician Evaluation and Management of Nursing Home Residents*, 121 ANNALS INTERN. MED. 584, 586 (1994).

[284]42 U.S.C. §§1395i-3(c)(1)(A)(ii)(II) (Supp. IV 1998) [Medicare] & 1396r(c)(1)(A)(ii)(II) (Supp. IV 1998) [Medicaid].

[285]*See* Johnson, *supra* note 2, at 268 ("What may occur over time . . . is a shift toward physician liability for malpractice in the use of restraints. One impact of such a shift could be a change in the assumptions on the use of restraints, including a clear identification of restraints as falling within the professional judgment rather than administrative routine.").

[286]Saunders v. Beverly Enters., No. 89C-10930 (Marion Cty. Ct. Or. filed Mar. 18, 1991).

order form required that the resident be restrained 24 hours a day.[287] Thirty-six hours after facility admission, the resident began "to act out from the combination of his unchanged, extremely soiled clothes and constant restraints."[288] The resident, tied to a wheelchair, went into resident rooms, rummaging through their possessions.[289] Then, "he requested a knife to cut himself free of the restraints."[290] The staff responded to this behavior by placing the resident in his room with the door closed.[291] The resident obtained a lighter and tried to "burn himself free from the restraints, setting himself on fire."[292] Two weeks later, the hospitalized man died from second and third degree burns to his torso and neck.[293] An Oregon jury awarded $22,500 in special damages, $250,000 in non-economic damages, and one million in punitive damages.[294]

In *Wilks v. Avenue Care Center, Inc.*, an 87-year-old nursing home resident at high risk for falls "got out of bed and fell."[295] As a result of the fall, the resident suffered a subdural hematoma and subsequently died.[296] An Illinois jury returned a $216,771 verdict (plus attorneys' fees) finding that the defendant facility ignored a physician's orders to place the resident in a vest restraint.[297] The defendant unsuccessfully argued that it "had discretion as to whether to follow the [physician's] order."[298]

In *Matteo v. Geisinger Wyoming Valley Medical Center and Geisinger Clinic*, a 91-year-old woman who fell during her hospital stay died of complications from surgery following a severely fractured

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[287] *See Punitive Damages Assessed against Nursing Home for Substandard Care*, 12 No. 2 VERDICTS, SETTLEMENTS & TACTICS 43, 43 (Feb. 1992) (discussing Saunders v. Beverly Enters.) [hereinafter *Punitive Damages*].

[288] *Id.*

[289] *Id.* at 43-44.

[290] *Id.* at 44.

[291] *Id.*

[292] *See Punitive Damages*, *supra* note 287, at 44.

[293] *Id.*

[294] *Id.*

[295] Wilks v. Avenue Care Ctr., Inc., No. 95 L 5369 (Cook Cty. Cir. Ct. Chicago, Ill. filed Feb. 23, 1999).

[296] *Id.*

[297] *Nursing Home Found Liable for Failure to Place Patient in Restraints*, 19 No. 7 VERDICTS, SETTLEMENTS & TACTICS 302 (July 1999) (discussing Wilks v. Avenue Care Ctr.).

[298] *Id.*

right hip sustained as a result of the fall.[299] The four months prior to the fall at the hospital the woman "had resided in a nursing home and was under an order for soft belt restraint, both in and out of bed, for her safety."[300] Her family physician had determined that she needed the restraint because "she was a fall risk" and "the restraint was the least restrictive means of ensuring her safety."[301] The jury agreed and awarded $943,974.41 in the wrongful death and survival action.[302]

A Houston jury returned a verdict for $39.4 million in the case of an 84-year-old resident who had been restrained in her bed with a vest-type restraint and was found hanging from the side of her bed strangled.[303] One report of this case suggests that the resident was restrained without physician order for three days.[304]

In *Smith v. Gravois Rest Haven*, the Missouri Court of Appeals affirmed a verdict against a nursing home where a resident restrained by physician order fell out of bed and fractured her hip.[305]

Informed Consent

Nursing home residents, the potential plaintiffs, must be involved in the process of informed, voluntary consent to, or refusal of, physical restraint use.[306] In order for the consent to be legally binding, the resident must be fully informed of the risks and benefits associated with restraints and their alternatives, thereby allowing the resident to make

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[299] Matteo v. Geisinger Wyoming Valley Med. Ctr. & Geisinger Clinic, No 7248-C (Luzerne Cty. Ct. of Common Pleas, Pa. filed Oct. 1, 1998).

[300] *Hospital Found Liable for Failure to Restrain Nursing Home Patient Who Fell During Hospital Stay*, 18 No. 12 VERDICTS, SETTLEMENTS & TACTICS 545 (Dec. 1998) (discussing Matteo v. Geisinger).

[301] *Id.*

[302] *Id.*

[303] Wayne E. Green & Ellen Joan Pollack, *Nursing Home is Liable in Restraint Case*, WALL ST. J., Mar. 26, 1990, at B5.

[304] *See* Johnson, *supra* note 2, at 267 *citing* Woolsey & Bradford, *Two Separate Texas Juries Award $40 Million for Wrongful Deaths*, BUS. INS., Apr. 9, 1990, at ECFC3

[305] Smith v. Gravois Rest Haven, 662 S.W.2d 880, 882 (Mo. Ct. App. 1983)

[306] On informed consent generally, *see, e.g.*, RUTH R. FADEN & TOM L. BEAUCHAMP, A HISTORY AND THEORY OF INFORMED CONSENT (1986); PAUL S. APPELBAUM, CHARLES W. LIDZ, & ALAN MEISEL, INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE (1987); PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RES., MAKING HEALTH CARE DECISIONS: THE ETHICAL AND LEGAL IMPLICATIONS OF INFORMED CONSENT IN THE PATIENT-PRACTITIONER RELATIONSHIP (1982).

an informed choice.[307] Furthermore, all of this must be documented in the resident's nursing home record and/or consent form.[308]

In *Lynch v. Huntington Memorial Hospital*, an 84-year-old hospital patient was placed in a vest restraint at night because he "was confused, combative at times and could not walk without assistance."[309] One night he slept without the restraint "because he no longer wanted to wear" the vest.[310] He got out of bed, fell and broke his hip.[311] Arguments that "he was confused and disoriented and was unable to competently refuse" the vest restraint failed.[312] The jury found that the defendant institution had honored the plaintiff's request not to be restrained.[313]

If a resident is incapable of making an informed choice, the legally authorized surrogate decision maker may exercise the right based on the same information that would have been provided to the resident.[314]

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[307]HCFA GUIDANCE, *supra* note 10, at PP-44 (highlighting facility responsibility to explain the negative outcomes of restraint use to the resident).

[308]A sample consent form for the use/non-use of restraints may close with the following language above the signature lines for the resident; facility representative; authorized surrogate decision maker, if applicable; and a witness.

> I have been informed of, and understand, the information described in this consent form. The risks and benefits regarding the application of restraints have been explained and I acknowledge understanding the implications of consenting to or refusing such measures. I hereby agree to the intervention described despite the possibility that his/her/my health and safety may be negatively affected by this decision.

Informed Consent for Use or Non-Use of Physical Restraints, CONTINUING CARE RISK MANAGEMENT, PATIENT/RESIDENT CARE 15 (ECRI (Plymouth Meeting, PA) 1995) reprinting with permission of Polyclinic Med. Center (Harrisburg, PA). Obtain more information about ECRI risk management products by writing ECRI, 5200 Butler Pike, Plymouth Meeting, PA 19462-1298; by telephone: (610) 825-6000; by facsimile (610) 834-1275, or by e-mail ccrm@ecri.org.

[309]Lynch v. Huntington Mem'l Hosp., No. GC015100, 1996 WL 526082 at *1 (Los Angeles Cty. Sup. Ct. CA, June 25, 1996).

[310]*Id.* at *1

[311]*Id.*

[312]*Id.*

[313]*Id.* at *2.

[314]*See* HCFA GUIDANCE, *supra* note 10, at PP-44, 45; 42 C.F.R. §§ 483.10(a)(3) (1999) (providing that "in the case of a resident adjudged incompetent under the laws of a State by a court of competent jurisdiction, the rights of the resident are exercised by the person appointed under State law to act on the resident's behalf.") & (4) (1999) ("In the case of a resident who has not been adjudged incompetent by the State court, any legal-surrogate designated in accordance with state law may exercise the resident's right to the extent provided by State law.").

However, the representative cannot give permission to restrain for discipline, convenience, or when not necessary to treat medical symptoms.[315]

The fact that a resident or surrogate consents does not excuse liability for an improper decision to apply a restraint, improper application of a restraint, improper monitoring of a restrained resident, or a failure to revise a resident's treatment plan.[316]

Arguably, restraining an individual without their prior consent constitutes battery (an intentional, unconsented-to, offensive invasion of the resident's bodily integrity).[317] Legally, when someone places their hands on an individual or restricts the individual's ability to move freely without the individual's prior consent, the person initiating the physical contact may be held liable for battery.[318]

Alternatively, consider the resident's ability to claim false imprisonment. For example, in *Big Town Nursing Home v. Newman*, the nursing home resident successfully claimed the facility confined him against his will.[319]

Emergency Care

Emergencies are a legally recognized exception to informed consent requirements.[320] Restraints may be used for brief periods to allow emergency medical care to proceed unless the nursing home has notice of a previously made valid refusal of the treatment in question.[321]

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[315] *See* HCFA GUIDANCE, *supra* note 10, at PP-45.

[316] *Id.*

[317] *See* Kapp, *Legal Issues*, *supra* note 248, at 581; Kapp, *Governing Board's Role*, *supra* note 39, at 23.

[318] *See* Kapp, *Legal Issues*, *supra* note 248, at 581.

[319] Big Town Nursing Home v. Newman, 461 S.W.2d 195, 196 (Tex. Civ. App. 1970) (claiming false imprisonment based on restraint use).

[320] *See* W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS 117 (5th ed. 1984) (summarizing the basic requirements for emergency treatment without consent).

[321] *See* HCFA GUIDANCE, *supra* note 10, at PP-46; 42 U.S.C. §§ 1395i-3(c)(1)(A)(i) (stating that a resident has right "to be fully informed in advance about care and treatment, to be fully informed in advance of any changes in care or treatment and to participate in planning care and treatment or changes in care and treatment") [Medicare] & 1396r(c)(1)(A)(i) (reciting the same language as Medicare) [Medicaid]. State regulation also provides for restraint use in an emergency. *See, e.g.*, N.Y. COMP. CODES R. & REGS. tit. 10 §§ 415.4(a)(6)(i) (allowing a physical restraint to be applied in an emergency if approved by the medical director, attending physician, or nursing director, or, in their absence, by a registered professional nurse) *and* 415.4(a)(6)(ii) (restricting restraint use to a limited period of time and requiring physician consultation about such use within 24 hours of the emergency). *See generally* George J. Annas,

HCFA INTERPRETIVE GUIDELINES

HCFA Interpretive Guidelines serve as the primary federal guide to nursing home surveyors when evaluating nursing home compliance with federal requirements.[322] Incentives for nursing home compliance with these requirements, in terms of legal and economic survival, are tremendous.[323] Surveyors examine, among other things, the appropriateness of physical restraint and siderail use.[324] The federal

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The Last Resort – The Use of Physical Restraints in Medical Emergencies, 341 NEW ENG. J. MED. 1408-12 (1999).

[322]*See, e.g.*, U.S. GEN. ACCT. OFFICE, Testimony Before the Special Committee on Aging, U.S. Senate, *Nursing Homes: Enhanced HCFA Oversight of State Programs Would Better Ensure Quality Care*, (GAO/T-HEHS-00-27, Nov. 4, 1999) (recounting testimony regarding the oversight of state agencies that perform surveys of nursing homes to ensure that homes meet federal care standards protecting residents); U.S. GEN. ACCT. OFFICE, Report to the Special Committee on Aging, U.S. Senate, *Nursing Homes: Enhanced HCFA Oversight of State Programs Would Better Ensure Quality Care*, (GAO/HEHS-00-6, Nov. 4, 1999) (reviewing survey process); U.S. GEN. ACCT. OFFICE, [Letter Report] *Nursing Home Oversight: Industry Examples Do Not Demonstrate That Regulatory Actions Were Unreasonable* (GAO/HEHS-99-154R, Aug. 13, 1999) (responding to survey findings); U.S. GEN. ACCT. OFFICE, Report to the Special Committee on Aging, U.S. Senate, *California Nursing Homes: Care Problems Persist Despite Federal and State Oversight* (GAO/HEHS-98-202, July 1998) (considering the survey process in California).

[323]U.S. GEN. ACCT. OFFICE, Report to the Special Committee on Aging, U.S. Senate, *California Nursing Homes: Care Problems Persist Despite Federal and State Oversight* (GAO/HEHS-98-202, July 1998) (noting the federal government, through the Medicare and Medicaid programs, paid more than 17,000 nursing homes nearly $28 billion in 1997); Administration on Aging and the Older Americans Act, *available at* http://www.aoa.dhhs.gov/aoa/pages/aoafact.html (visited Sept. 10, 2000) (estimating persons age 60 and older will more than double to 85 million by the year 2030, and those 85 and older will triple to 8 million, thus requiring more nursing home beds); *Nursing Homes: When a Loved One Needs Care*, CONSUMER REP., Aug. 1995, at 519 (reporting that Beverly Enterprises runs more than 700 nursing homes with annual revenues of nearly $3 billion); Kapp, *Restraints & Legal Liability*, *supra* note 39, at 17 (discussing legal and economic incentives for nursing home compliance with federal requirements).

[324]*See, e.g.*, Beverly California Corp. d/b/a Applegate East Nursing Home v. Shalala, 78 F.3d 403 (8th Cir. 1996). Regulatory violations observed by a survey team at a 105-bed Illinois facility include:

> *restraints left on residents without release for periods exceeding two hours; vest restraints applied improperly creating a risk of strangulation*; frail residents lifted and ambulated in a manner that posed a substantial threat of injury; failure to observe basic hygiene conventions creating a serious risk of infection; dirty and unlabeled personal items and equipment scattered throughout the facility; physical therapy administered by an unqualified employee; inadequate physical therapy regiments; and discontinuation or delay of physical therapy without physician consultation.

government has indicated publicly that it will encourage surveyors to take an aggressive stance in enforcing the statutory and regulatory requirements concerning restraint use.[325] Anyone has the right to obtain survey results from the facility[326] and from the state's certification and/or licensure agency.[327]

Survey Process

The states conduct annual, random, unannounced standard surveys of Medicare and Medicaid certified nursing homes.[328] These surveys are periodic, resident-centered inspections that gather information about the quality of service furnished in a nursing home to determine facility compliance with statutory requirements.[329] Recent survey scheduling criteria changes are intended to make the timing of surveys less predictable.[330] The survey is based upon federally approved protocol.[331] Surveyors use detailed federal standards, methods, forms, and procedures.[332] State surveyors certify facility compliance or cite

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Id. at 405-406 (emphasis added).

[325] *See generally*, U.S. GEN. ACCT. OFFICE, *Nursing Homes: Additional Steps Needed to Strengthen Enforcement of Federal Quality Standards* 1 (GAO/HEHS-99-46, Mar. 18, 1999) (reviewing, among other things, criteria for applying sanctions); *Poor Care in CA Nursing Homes Mirrors National Problem, GAO Tells Congress*, 6 No. 2 ANDREWS HEALTH L. LITIG. REP. 17 (Sept. 1998) ("In a hearing before the Senate Committee on Aging, William Scanlon, a GAO director, called for tougher enforcement of existing regulations and new compliance guidelines"); *Special Report: OBRA*, 3 BROWN U. LONG-TERM CARE LETTER 1 (Sept. 1, 1991).

[326] *See* 42 C.F.R. § 483.10(g)(1) (1999).

[327] *See* 42 C.F.R. § 483.10(b)(7)(iii) (1999) (noting the facility must furnish written description of resident's legal rights and post names, addresses, and telephone numbers of all pertinent state client advocacy groups such as the state survey and certification agency, state licensure office, state ombudsman program, the protection and advocacy network, and the Medicaid fraud control unit).

[328] *See* 42 U.S.C. §§ 1395i-3(g)(2) (1994 & Supp. III 1997) [Medicare] & 1396r(g)(2) (1994 & Supp. III 1997) [Medicaid].

[329] DEP'T HEALTH & HUM. SERVS., HEALTH CARE FIN. ADMIN., STATE OPERATIONS MANUAL – PROVIDER CERTIFICATION (Transmittal 273, June 1995) 7-8 [hereinafter SOM].

[330] *See* 42 C.F.R. §488.307 (1999).

[331] *See* 42 U.S.C. §§ 1395i-3(g)(2)(C) (Supp. III 1997) [Medicare] & 1396r(g)(2)(C) (Supp. 1997), [Medicaid].

[332] *See* 42 C.F.R. § 431.610(f)(1) (1999) (discussing federal requirements and the forms, methods and procedures used to determine eligibility and certification under Medicaid); 42 C.F.R. § 488, Subpart C (Survey Forms and Procedures) (1999). Survey (or deficiency) reports are found on Form HCFA-2567.

non-compliance with statutory requirements.[333] If the nursing home is not in compliance with one or more regulatory standards, then the surveyor issues a deficiency.[334] Possible violations include: restraining residents without release for periods exceeding two hours; improperly applying vest restraints creating a risk of strangulation; using restraints without physician order; failing to determine, through the use of a care plan, that restraints were necessary or that less-restrictive alternatives were not feasible; and applying a restraint for discipline or convenience, and not required to treat a medical symptom.[335] The scope and severity of the deficiencies is considered before imposing a penalty.[336] In addition, prior compliance history impacts the type of penalties that may be imposed for deficiencies cited in the future (for example, is it a repeated deficiency or an isolated violation?).[337]

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[333] *See* 42 U.S.C. §§ 1395i-3(g) (1994 & Supp. III 1997) (describing the Medicare survey and certification process) & 1396r(g) (1994 & Supp. III 1997) (describing the Medicaid survey and certification process).

[334] *See* U.S. GEN. ACCT. OFFICE, Report to the Special Committee on Aging, U.S. Senate, *California Nursing Homes: Care Problems Persist Despite Federal and State Oversight* 6 (GAO/HEHS-98-202, July 1998). HCFA has four categories of deficiencies: 1) No actual harm, with potential for minimal harm (minimal); 2) No actual harm, with potential for more than minimal harm (less serious); 3) Actual harm that does not put the resident in immediate jeopardy (serious); and 4) Immediate jeopardy to resident health or safety (most serious). *Id.* "HCFA also classifies deficiencies by their scope, or extent, as follows: (1) isolated, defined as affecting a limited number of residents; (2) pattern, defined as affecting more than a limited number of residents; and (3) widespread, defined as affecting all or almost all residents." *Id.* *See also* 42 C.F.R. § 488.404 (1999) (identifying factors considered when determining the seriousness of a deficiency).

[335] *See* HCFA GUIDANCE, *supra* note 10, at PP-44. A deficiency is given when a nursing home fails to comply with federal or state requirements related to quality of care, quality of life, and resident behavior and facility practices. U.S. GEN. ACCT. OFFICE, Report to the Special Committee on Aging, U.S. Senate, *California Nursing Homes: Care Problems Persist Despite Federal and State Oversight* 7 (GAO/HEHS-98-202, July 1998).

[336] 42 C.F.R. § 488.404(b)(2) (1999) (noting that scope of deficiency depends on whether noted deficiencies are isolated, constitute a pattern, or are widespread). To be classified as "widespread" deficiencies must be pervasive throughout an entire facility, and not just throughout a particular unit or wing. *See* Memorandum from Director of Office of Survey and Certification to Associate Regional Administrators and State Survey Agencies, *Clarification of Definition of "Widespread" Scope* (Sept. 12, 1995); Beverly California Corp. d/b/a Applegate East Nursing Home v. Shalala, 78 F.3d 403, 406 (8th Cir. 1996) (considering "severity and frequency of any deficiencies" before making a decertification decision); Lake City Extended Care Ctr. v. Health Care Fin. Admin., DAB 1658 (1998) [ALJ Decision] (addressing an administrative law judge's authority to review HCFA's determination of scope); Carlson, *supra* note 51, at § 2.26[3] (discussing HCFA's scope and severity standards).

[337] 42 C.F.R. § 488.404(c) (1999). *See, e.g.*, Beverly California Corp. d/b/a Applegate East Nursing Home v. Shalala, 78 F.3d 403, 407 (8th Cir. 1996) ("[U]nder current regulations,

A one million dollar settlement was reached in *Austin v. Cherry Street Manor* where a 31-year-old blind and mentally retarded nursing home resident was found strangled on a vest restraint tied to her bed.[338] About one year before her death, the Texas Department of Human Services cited the nursing home and its owners for improperly restraining and inadequately monitoring her.[339] The Texas Attorney General's Office is seeking civil penalties against the home and its owners stemming from this incident.[340]

Administrative or Regulatory Sanctions

Inappropriate and indiscriminate restraint use where alternatives are available exposes nursing homes to foreseeable and avoidable civil and regulatory liability and punishments.[341] Administrative or regulatory sanctions at the federal level include:[342]

- termination of the provider agreement;[343]

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the prior survey history of a nursing home facility impacts the types of penalties that may be imposed for cited deficiencies in the future."); Belmont Nursing & Rehabilitation Ctr. v. Health Care Fin. Admin., DAB CR507 (Nov. 25, 1997) [ALJ Decision] (considering a Wisconsin facility's history of noncompliance as well as the seriousness and scope of the deficiencies); Baltic Country Manor v. Health Care Fin. Admin., DAB C-96-281 (1996) [ALJ Decision] (viewing the nursing home's poor compliance history); Del Rosa Villa, Inc. v. Shalala, 1997 WL 269487, at *1 (C.D. Cal. 1997) (considering the issue of harm suffered as a result of prior decisions); Rafeal Convalescent Hosp. v. Health Care Fin. Admin., DAB CR444 (1996) [ALJ Decision] (considering the issue of harm suffered as a result of prior decisions).

[338] Austin v. Cherry Street Manor, No. 64774 (Lamar Cty. Jud. Dist. Ct. Tex. Jan. 7, 1998).

[339] *Settlement in Suit Alleging Improper Care*, 18 No. 2 VERDICTS, SETTLEMENTS & TACTICS 65 (Feb. 1998).

[340] *Id.*

[341] *See* Kapp, *Restraints & Legal Liability*, *supra* note 39, at 17 (discussing legal and economic incentives for nursing home compliance with federal requirements); Montgomery Health Care Facility, Inc. v. Ballard, 565 So.2d 221 (Ala. 1990) (ignoring deficiencies received from the Alabama Department of Public Health led to one resident's death and a lawsuit).

[342] *See* SOM, *supra* note 329, at 7-39; 42 U.S.C. § 1395i-3(h) (Supp. III 1997) (detailing enforcement process) [Medicare] & 1396r(h) (Supp. III 1997) [Medicaid]; *see also* Kapp, *Restraints & Legal Liability*, *supra* note 39, at 17.

[343] 42 C.F.R. § 488.406 (1999); International Long Term Care, Inc. v. Shalala, 947 F. Supp. 15 (D.D.C. 1996) (holding that termination from Medicaid is automatic upon termination from Medicare); *see, e.g.*, Beverly California Corp. d/b/a Applegate East Nursing Home v. Shalala, 78 F.3d 403 (8th Cir. 1996) (upholding termination decision); *see generally*, U.S. Gen. Accounting Office, Report to the Special Committee on Aging, U.S. Senate, *California Nursing Homes: Care Problems Persist Despite Federal and State Oversight* 1, 27 (GAO/HEHS-98-202, July 1998) ("Of the 16 homes terminated in the 1995 to 1998 time period, 14 have been reinstated. Eleven . . . reinstated under the same ownership they had

- temporary management;[344]
- decertification from participation in the Medicare/Medicaid programs;[345]
- restriction or moratorium on new Medicare/Medicaid admissions;[346]
- temporary denial of Medicare/Medicaid payments for some or all federally-funded residents;[347]
- civil monetary penalties, not to exceed $10,000 for each day of non-compliance;[348]

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before termination. Of the 14 reinstated homes, at least six have been cited since their reinstatement with new deficiencies that harmed residents."); John Wark, *Why AHCA Doesn't Work, Part 2*, TAMPA TRIB., Nov. 22, 1997 (noting that from 1992 to 1997 only one nursing home in Florida was terminated); Mediplex of Massachusetts, Inc. d/b/a SunRise Care and Rehabilitation Ctr. a/k/a Randolph Crossings Nursing Ctr. v. Shalala, No. 98-12363-DPW (D. Mass. filed Jan. 19, 1999) (granting a request for a preliminary injunction to enjoin the U.S. Department of Health and Human Services from terminating a nursing home's Medicare and Medicaid provider agreements given the substantial risk of "transfer trauma" to the residents); *HHS Ordered to Continue Medicare/Medicaid Funding to Nursing Home*, 6 No. 8 ANDREWS HEALTH L. LITIG. REP. 14 (Mar. 1999) (discussing Mediplex v. Shalala).

[344]42 C.F.R. § 488.406 (1999); U.S. v. Chester Care Ctr., No. 98-CV-139 (E.D. Pa. 1998 consent order and judgment approved Feb. 5, 1998) (requiring a temporary manager to oversee the nursing home to ensure compliance with all federal law and regulations).

[345]*See, e.g.*, Oak Lawn Pavilion, Inc. v. Health Care Fin. Admin., DAB C-95-155 (May 21, 1997) [ALJ Decision] (challenging termination of Illinois skilled nursing facility participation in the Medicare program); Robert Tomsho, *Old Problem: A Trail of Complaints Slows but Can't Stop Nursing-Home Mogul*, WALL ST. J., Sept. 3, 1997, at A1 (noting a Texas nursing home's Medicaid certification was terminated and fines imposed following the death of two residents and within seven months the facility's Medicaid certification was reinstated and its fines were reduced); Sensitive Care, Inc. v. Texas Dept. of Human Servs, 926 S.W.2d 823 (Tex. Ct. App. 1996) (appealing decertification).

[346]42 C.F.R. § 488.406 (1999); *see, e.g.*, *TRO Halts New Admissions to IN Nursing Home*, 3 No. 9 ANDREWS HEALTH CARE FRAUD LITIG. REP. 12 (June 1998) (imposing a 45-day ban on admissions at Indiana nursing home serving 70 residents); Belmont Nursing & Rehabilitation Ctr. v. Health Care Fin. Admin., DAB CR507 (Nov. 25, 1997) [ALJ Decision] (denying payment for new admissions to 100-plus-bed skilled nursing facility located in Wisconsin where one of the survey deficiencies involved physical restraints).

[347]*See, e.g.*, Somers Manor Nursing Home, Inc. v. Health Care Fin. Admin., DAB C-96-054 (June 4, 1996) [ALJ Decision] (suspending payments for new admissions to a New York nursing home).

[348]42 C.F.R. §§ 488.406, 488.408(d)(3)(ii) and 488.408(e) (1999); Health Care Fin. Admin., Fact Sheet: Assuring Quality Care for Nursing Home Residents (Mar. 16, 1999), *available at* http://www.hcfa.gov/facts/fs0316.99.htm (last visited Sept. 10, 2000) (noting that states can now assess fines up to $10,000 for individual health and safety violations); John Pray, Note, *State v. Serebin: Causation and the Criminal Liability of Nursing Home Administrators*, 1986 WIS. L. REV. 339, 360 (1986) (noting that even after a nursing home was cited with several deficiencies and entered into a settlement with the state attorney general for $104,000, the home failed to correct the conditions for which it was cited); U.S. v. City of Philadelphia, No. 2:98CV4253 (E.D. Pa, Aug. 13, 1998, settlement) (according to the terms of

- state monitoring;[349]
- transfer of residents;[350]
- transfer of residents coupled with facility closure;[351]
- a directed plan of correction to allow facility management to implement a detailed plan for eliminating deficiencies;[352]
- directed in-service training;[353] and

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a settlement agreement reached after suit was filed under the False Claims Act, the nursing home agreed to pay the federal government $50,000, and to create a $15,000 fund for a special project); U.S. v. Chester Care Ctr., No. 98-CV-139 (E.D. Pa. 1998 consent order and judgment approved Feb. 5, 1998) (according to the terms of a consent order reached after suit was filed under the False Claims Act, the nursing home agreed to pay the federal government $500,000, and to implement a comprehensive compliance program); *PA Nursing Homes Enter $500,000 Settlement Over Inadequate Care Claims*, 10 No. 27 ANDREWS GOV'T CONTRACT LITIG. REP. 7 (Mar. 4, 1998) (discussing U.S. v. Chester Care Ctr.); *PA Nursing Homes Enter $500,000 Settlement Over Inadequate Care Claims*, 10 No. 27 ANDREWS HEALTH CARE FRAUD LITIG. REP. 4 (Feb. 1998) (discussing U.S. v. Chester Care Ctr.); Belmont Nursing & Rehabilitation Ctr. v. Health Care Fin. Admin., DAB CR507 (Nov. 25, 1997) [ALJ Decision] (imposing a civil monetary penalty of $300 per day upon a Wisconsin nursing home); Cross Creek Health Care Ctr. v. Health Care Fin. Admin., DAB CR504 (July 14, 1998) [ALJ Decision] (challenging amount of civil monetary penalties assessed to Florida nursing home); AGENCY FOR HEALTH CARE ADMIN., *Federal Judge Upholds Record Fine Against Tampa Nursing Home*, *at* http://www.fdhc.state.fl.us/pio/press/Wellington.htm (last visited Sept. 7, 2000) (citing "the asphyxiation death of one resident who died after getting her head caught in a bed rail, insufficient staffing, failure to properly assess the needs of residents, and inappropriate use of restraints" as the basis for the fine).

[349] 42 C.F.R. § 488.406 (1999); U.S. v. GMS Management-Tucker, Inc., No. 96-1271 (E.D. Pa. 1996) (according to the terms of a consent order reached after suit was filed under the False Claims Act, the nursing home agreed to pay the federal government $25,000, to provide training to its staff, and to allow a third party to monitor the nursing home at any time); U.S. v. Chester Care Ctr., No. 98-CV-139 (E.D. Pa. 1998 consent order and judgment approved Feb. 5, 1998) (providing for a federal monitor to observe the facilities for at least two years); *TRO Halts New Admissions to IN Nursing Home*, 3 No. 9 ANDREWS HEALTH CARE FRAUD LITIG. REP. 12 (June 1998) (ordering a monitor to observe conditions at Indiana nursing home).

[350] 42 C.F.R. § 488.406 (1999); Mediplex of Massachusetts, Inc. d/b/a SunRise Care and Rehabilitation Ctr. a/k/a Randolph Crossings Nursing Ctr. v. Shalala, No. 98-12363-DPW (D. Mass. Jan. 19, 1999) (considering impact of resident transfer in a decision to enjoin termination of Medicare and Medicaid provider agreements for 168-bed skilled nursing facility in Massachusetts); *HHS Ordered to Continue Medicare/Medicaid Funding to Nursing Home*, 6 No. 8 ANDREWS HEALTH L. LITIG. REP. 14 (Mar. 1999) (discussing *Mediplex v. Shalala*).

[351] 42 C.F.R. § 488.406 (1999).

[352] 42 C.F.R. §§ 488.401, 488.402(d), 488.406 and 488.408(f)(1) (1999); *see, e.g.*, Fort Tryon v. Health Care Fin. Admin., DAB CR425 (1996) [ALJ Decision]; Arcadia Acres, Inc. v. Health Care Fin. Admin., DAB 1607 (1997) [ALJ Decision]; Golden State Manor and Rehabilitation Ctr. v. Health Care Fin. Admin., DAB CR412 (Sept. 16, 1996) [ALJ Decision] (appealing certification denial until plan of correction addresses all cited deficiencies).

[353] 42 C.F.R. § 488.406 (1999); *Integrated Health Services Pays $195,000 Penalty for Alleged Quality-of-Care Violations*, 4 No. 9 ANDREWS HEALTH CARE FRAUD LITIG. REP. 11 (June 1999) (discussing a $195,000 settlement agreement between the federal government and

- alternative or additional state remedies approved by HCFA.[354]

For example, a settlement reached in *United States v. City of Philadelphia* required the nursing home to pay a $50,000 fine and resolve to, among other things, "limit the use of physical restraints."[355]

In *United States v. Northern Health Facilities, Inc. d/b/a/ Greenbelt Nursing & Rehabilitation Center*, a preliminary injunctive order sought to remedy systemic care deficiencies.[356] The order requested the appointment of a temporary manager and monitor for the nursing home.[357] The order provided "standards for comprehensive assessment and care plans, wound treatment, the *use of restraints*, and nutrition."[358] Prior to the order, HCFA notified the facility that it was "no longer qualified to participate as a provider under the Medicare and Medicaid programs" because of the deficiencies identified in the state surveys.[359] In addition, HCFA advised that "its provider agreement would be terminated if the home did not come into substantial compliance" with federal requirements.[360] A fine of $700 per day was imposed.[361] Subsequently, the facility submitted a plan of correction and HCFA withdrew its termination action and discounted the fine.[362]

Integrated Health Services at Penn Inc., a nursing home chain, requiring, among other terms, staff training); U.S. v. GMS Management-Tucker, Inc., No. 96-1271 (E.D. Pa. 1996) (according to the terms of a consent order reached after suit was filed under the False Claims Act, the nursing home agreed to pay the federal government $25,000, to provide training to its staff, and to allow a third party to monitor the nursing home at any time).

[354] 42 C.F.R. § 488.406 (1999).

[355] U.S. v. City of Philadelphia et al., No. 2:98CV4253 (E.D. Pa, Aug. 13, 1998, settlement); *see also Govt. Settles Civil Rights Action Against Philadelphia Nursing Homes*, 6 No. 2 ANDREWS HEALTH L. LITIG. REP. 16 (Sept. 1998) (discussing U.S. v. City of Philadelphia).

[356] U.S. v. Northern Health Facilities, Inc. d/b/a/ Greenbelt Nursing & Rehabilitation Ctr. et al, No. AW-98-3113 (D. Md. Sept. 14, 1998).

[357] *US Seeks Order to Address Nursing Home Care Deficiencies*, 6 No. 4 ANDREWS HEALTH L. LITIG. REP. 6 (Nov. 1998) (discussing U.S. v. Northern Health Facilities, Inc. d/b/a/ Greenbelt Nursing & Rehabilitation Ctr).

[358] *Id.* (emphasis added)

[359] *Id.*

[360] *Id.*

[361] *Id.*

[362] *Id.*

FDA REGULATION

Nursing homes also must be aware of potential liability connected to federal Food and Drug Administration regulation of restraints as medical devices. The FDA designates physical restraints as medical devices[363]and, as such, they are subject to medical device reporting regulations.

FDA regulations define a physical restraint as

> a device, including but not limited to a wristlet, anklet, vest, mitt, straight jacket, body/limb holder, or other type of strap, that is intended for medical purposes and that limits the [resident's] movements to the extent necessary for treatment, examination, or protection of the [resident] or others.[364]

FDA regulation is not limited to these examples. Rather, "[t]he identification is based on the product's intended use."[365] Compare the FDA definition with the broader HCFA definition (discussed earlier) that defines restraint as any device that restricts voluntary movement.[366]

Some find the FDA identification of restraint "too narrow, leaving major gaps in the coverage of a growing list of potentially dangerous devices that are routinely used to restrain residents and that are "falsely marketed" as restraint alternatives."[367] The FDA disagrees and emphasizes that restraint identification is based upon the product's intended use:[368]

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[363]21 C.F.R. § 880.6760 (2000). *See also* 21 U.S.C. § 360(i)(b) (1994); 21 U.S.C. § 321(h) (1994); Medical Devices; Protective Restraints; Revocation of Exemptions From the 510(k) Premarket Notification Procedures and Current Good Manufacturing Practice Regulations, 61 Fed. Reg. 8,432, 8,433 (1996) (to be codified at 21 C.F.R. pts. 880 and 890 (advising that restraints are medical devices because they are intended for use in the cure, mitigation, treatment, or prevention of diseases).

[364]21 C.F.R. § 880.6760.

[365]61 Fed. Reg. 8,432, 8,435 (1996).

[366]Timothy M. Westmoreland & David W. Feigal, DEP'T OF HEALTH & HUM. SERVS., Health Care Fin. Admin., Letter to Cathy Morris (Aug. 1, 2000) (copy on file with authors) (clarifying the difference between the FDA and HCFA concerning what constitutes a physical restraint, especially as it relates to side rail use).

[367]*Id.*

[368]*Id.*

> [E]vidence of a device's intended use is not limited to labeling claims or to verbal representations. It may be shown by the circumstances that the device is offered and used for a purpose for which it is neither labeled nor advertised. FDA considers any actions that otherwise represent a device's intended use, as well as labeling, to determine a device's intended use. Therefore, even devices that are "falsely marketed" as alternatives to restraints will fall under the identification of protective restraint if their intended use is to function as a protective restraint. If a manufacturer intends a device to be used as a restraint or is aware that the device is used as a restraint, that manufacturer must comply with requirements for protective restraints.[369]

Pre-Market Notification and CGMP Exemptions Revoked

In 1980, the FDA exempted manufacturers of restraints and wheelchair accessories (such as armboard, lapboard, pusher cuff, crutch and cane holder, overhead suspension sling, head and trunk support, and blanket and leg rest strap)[370] intended for use as restraints from pre-market notification [501(k)] procedures[371] and certain current good manufacturing practice ("CGMP") requirements.[372] Requirements concerning records[373] and complaint files remain.[374] In 1996, however, the FDA published a final rule ending this exemption in response to "numerous reports of serious injuries and deaths that have been attributed to incorrect supervision, handling, or application of protective restraints."[375] Revoking the pre-marketing exemption allows the agency to monitor device marketing, and review and identify unclear labeling that may result in applying restraints incorrectly.[376] Ending the exemption from CGMP requirements helps "ensure that

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[369] *Id.*

[370] *See* 61 Fed. Reg. 8,439, 8,439 (1996) (identifying and classifying wheelchair accessory).

[371] *See* 21 C.F.R. § 807.81 (2000); 61 Fed. Reg. 8,440, 8,440 (1996) (announcing availability of FDA draft guidance document for preparation of pre-market notification (510(k)) submissions for restraints and wheelchair accessories intended for use as restraints).

[372] *See* 21 C.F.R. § 820.1 (2000).

[373] *See* 21 C.F.R. §§ 820.180 & 820.198(e) (2000).

[374] *See* 21 C.F.R. § 820.198 (2000). Reports complaints under 21 C.F.R. pt. 803 or pt. 806 (2000).

[375] 61 Fed. Reg. 8,432, 8,432 (1996).

[376] *Id.*

restraints are safe by conforming to appropriate specifications for design, materials, performance, and labeling."[377] In addition, the manufacturers are subject to good manufacturing practice inspections to ensure quality control.[378]

A draft guidance document assists in preparing pre-market notification submissions for restraints and wheelchair accessories intended for use as restraints.[379] Such guidance does not create or confer any rights for or on any person and does not bind the FDA or others; however, it does represent the agency's current thinking on the subject.[380] Characteristics that manufacturers should address in their 510(k) submissions include: specific intended use of the device; ease of release of the device in the event of emergencies; tear strength of the materials; potential for injury (for example, whether there are abrasive materials, such as metal fasteners, that would come in contact with the wearer's skin); ease of size identification; completeness, conspicuousness, and simplicity of directions and labeling; care and/or cleaning instructions; biocompatibility of material; safety testing data and, for certain circumstances, patient testing data.[381]

Medical Bulletins and Safety Alerts

FDA medical bulletins and safety alerts offer emerging evidence of safety problems associated with particular restraint devices.[382] On November 16, 1991, the FDA issued a medical bulletin entitled *Potential Hazards with Restraint Devices* which was reissued on July 15, 1992, as an FDA Safety Alert warning of the hazards associated with restraint use.[383] The alert outlines appropriate standards of care for restraint use, describes requirements for restraint manufacturers, and includes a consumer information page.[384] Another alert, *Entrapment Hazards with Hospital Bed Siderails*, addresses potential

[377] *Id.*

[378] *Id.*

[379] *See* 61 Fed. Reg. 8,432, 8,434 (1996); 61 Fed. Reg. 8,440 (1996)

[380] *See* 61 Fed. Reg. 8,440, 8,440 (1996).

[381] *See* 61 Fed. Reg. 8,432, 8,434 (1996); 61 Fed. Reg. 8,440 (1996).

[382] *See, e.g.*, *Potential Hazards with Restraint Devices*, FOOD & DRUG ADMIN. (July 15, 1992).

[383] *See id.*

[384] *Id.*

entrapment hazards associated with siderails and recommends precautions to reduce further incidents.[385]

Prescription Status

FDA regulations require that physical restraints bear a prescription-only label to ensure appropriate medical intervention in application and use.[386] Prescription medical devices may be used only if a physician, or other health care professional licensed to prescribe, specifically orders a restraint for an individual.[387] The FDA strongly encourages restraint application only by adequately trained personnel, according to state licensure and federal facility certification requirements.[388]

Labeling Requirements

Manufacturers must adhere to many labeling requirements in addition to labeling their restraints as prescription only.[389] Vests, jackets and other upper torso restraints, for example, must display a position label noting device orientation (such as top/bottom, front/back, and inside/outside).[390] Further, labels must display size (such as small, medium, large) plus body measurements and weight ranges; cleaning instructions; specific warnings relating to incorrect placement; cautionary information (such as flammability); and important application steps.[391]

Although product labeling alone cannot protect nursing home residents from injury or death, well-presented labeling written in a salient, informative, and concise manner motivates the user to read

[385] *See* FDA ENTRAPMENT ALERT, *supra* note 165.

[386] *See* 61 Fed. Reg. 8,432, 8,433 (1996).

[387] *Id.* at 8,433.

[388] *Id.*

[389] *See* GEN. HOSP. DEVICES BRANCH, DIV. OF DENTAL INFECTION CONTROL & GEN. HOSP. DEVICES, OFFICE OF DEVICE EVALUATION, GUIDANCE ON THE CONTENT OF PREMARKET NOTIFICATION [501(k)] SUBMISSIONS FOR PROTECTIVE RESTRAINTS (Dec. 1995); 61 Fed. Reg. 8,432, 8,434, 8,436, 8,347 (1996) *citing Labeling: Regulatory Requirements for Medical Devices*, DEP'T OF HEALTH & HUM. SERVS., FDA Pub. No. 89-4203 (Aug. 1989) (offering additional labeling guidance); *Device Labeling Guidance*, OFFICE OF DEVICE EVALUATION, FDA Pub. G91-1 (Mar. 8, 1991) (labeling guidance document) [hereinafter *Device Labeling Guidance*].

[390] *See Device Labeling Guidance*, *supra* note 402.

[391] *Id.*

instructions.[392] Studies, as early as 1960, illustrate that warnings and safety posters in the workplace affect behavior.[393] More recent studies demonstrate that user behavior is clearly influenced by the presence and location of warnings and adequate use instructions.[394]

The Safe Medical Devices Act

The *Safe Medical Devices Act of 1990*[395] and its implementing regulations obligate nursing homes to report any adverse event (death, serious illnesses, and injuries) directly to the FDA within 10 working days of becoming aware of the event.[396] Reports encompass many different restraint types regardless of manufacturer or design, various types of patient populations, regardless of clinical indications for use, and various types of healthcare facilities, including nursing homes.[397] Given the probability of underreporting restraint-related deaths and injuries, the absence of complaints for a particular manufacturer does not indicate that the device is problem free.[398] Failure to report in a timely manner may result in civil and/or criminal penalties.[399]

FDA Complaint Files

Importantly, the FDA maintains reports concerning specific restraints, including siderails.[400] This information is accessible to the public, including plaintiffs' attorneys, upon request under the federal Freedom of Information Act ("FOIA").[401] When assembling evidence of a safety problem with a particular siderail, provide the name of a specific manufacturer, product, or class of products (such as siderails) in the FOIA request. If problems involving specific restraints become public

[392] *See* 61 Fed. Reg. 8,432, 8,437 (Mar. 4, 1996) *citing* S. Laner & R.G. Sell, *An Experiment on the Effect of Specially Designed Safety Posters*, 34 OCCUPATIONAL PSYCHOLOGY 153, 153-69 (1960).

[393] *Id.*

[394] *See* 61 Fed. Reg. 8,432, 8,437 (Mar. 4, 1996) *citing* M.S. Wolgalter et al., *Effectiveness of Warnings*, 29 HUM. FACTORS 599, 612 (1987).

[395] 104 STAT. § 4511 (eff. Nov. 28, 1991).

[396] *See* 21 U.S.C. § 360i(b) (1994 & Supp. IV 1998).

[397] *See* Kapp, *Legal Issues*, *supra* note 248, at 581.

[398] *Id.*

[399] *Id.*

[400] *See* 21 C.F.R. § 820.198 (Supp. 1997). Report complaints under 21 C.F.R. pts. 803 or 804.

[401] *See* 5 U.S.C. § 552 (1994 & Supp. IV. 1998); 21 C.F.R. pt. 20 (conveying FDA's FOIA implementation regulations).

record, and a facility persists in their use and injury occurs for which compensation is sought, it becomes difficult for the nursing home to persuade the trier of fact that restraint use was appropriate given that the facility had or should have possessed information about the hazards associated with the device.[402]

FDA Enforcement

Any manufacturer distributing a restraint not meeting FDA provisions risks enforcement action including seizure, injunction, civil penalties, and criminal prosecution.[403] A 518(e) recall occurs only after finding that the device would cause serious adverse health consequences or death.[404] The FDA will not recall a specific restraint (for example, criss-crossed vests) if, in the "best interest of public health," the benefits outweigh the risks.[405]

STATE LAW AND REGULATION

Extensive regulation of nursing homes also occurs on the state level.[406] In general, the regulations define the term restraint and detail

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[402]*See* Kapp, *Restraints & Legal Liability, supra* note 39, at 22; MARSHALL B. KAPP, GERIATRICS AND THE LAW: PATIENT AND PROFESSIONAL RESPONSIBILITIES 163 (2d ed. 1992) [hereinafter GERIATRICS AND THE LAW].

[403]*Id.* at 22.

[404]21 C.F.R. § 810.10(a) (2000).

[405]*Id.*

[406]*See* Kapp, *Restraints & Legal Liability, supra* note 39, at 21-22 n. 113. Kapp generously included citations to relevant state law excerpted and updated by the authors for reader convenience.

> **ALA:** RULES OF ALA. ST. BD. OF HEALTH, DIV. OF LICENSURE & CERTIFICATION §§ 420-5-4-.01, 420-5-10.07(1)(a) (1996); **ALASKA:** ALASKA STAT. § 47.30.825(d) (Michie 1996); **ARIZ:** ARIZ. ADMIN. CODE § R9-10-917(C)(3)(a) (1995); **ARK:** ARK. STAT. ANN. § 20-10-1204(a)(14)(A) (1998); **CAL:** CAL. CODE OF REG. tit. 22, § 73080 (2000); **COLO:** COLO. REV. STAT. § 25-1-120(1)(j) (1999); **CONN:** CONN. GEN. STAT. § 19A-550(b)(8) (1999); **DEL:** *Patient's Bill of Rights* pursuant to 16 DEL. CODE § 1121(7) (1999); **FLA:** FLA. STAT. § 400.022(1)(o); § 400.402(7), (18) (1999); **GA:** GA. DEP'T OF HUM. RESOURCES R. & REGS. § 290-5-39-.09(a) & 290-5-8.10(9) (1999); **HAW:** HAW. CODE § 11-99-79(8) (1989); **IDAHO:** IDAHO DEP'T OF HEALTH & WELF. REGS. § 16.03.02.100.03(c)(vii)(1999); **ILL:** 210 ILL. COMP. STAT. ANN. 45/1-101, *et seq.* (Nursing Home Care Act) (West 2000); **IND:** IND. ADMIN. CODE tit. 410, r.16.2-3.1-3(1999); **IOWA:** IOWA CODE ANN. § 135 C.14(8) (West 1993); IOWA ADMIN.

requirements governing their use.[407] For example, Arkansas law protects nursing home residents by prohibiting physical restraint unless

CODE ch. 481, § 58.43 (1990); **KAN:** KAN. DEP'T OF HEALTH & ENVIRONMENT REGS. § 28-39-144(rr) & 28-39-150(a) (1999); **KY:** KEN. REV. STAT. ANN. § 216.515 (Michie 1998); KEN. HEALTH FACILITIES & HEALTH SERVS. CERTIFICATE OF NEED & LICENSURE BD. REGS. § 3(c), 4(5)5.a. & b. (1989); **LA:** *Resident's Bill of Rights*, LA. REV. STAT. ANN. §§ 40:2010.7 through 40:2010.8 (West 1999); **ME:** ME. REV. STAT. ANN. tit. 5, § 19503 (West 1998); **MD:** MD. ANN. CODE art. 19, § 343(5) (1997); **MASS:** MASS. GEN. LAWS ANN. ch. 111, §§ 70E, 72F (1996); **MICH:** MICH. COMP. LAWS ANN. § 333.20201 (1997); **MINN:** MINN. STAT. § 114.651(4) (1999); **MO:** MO. REV. STAT. § 198.088.1(6)(g) (1994 & Supp. 1998); MO. CODE OF REGS., R. OF DEP'T OF SOCIAL SERVS. tit. 13, § 15-18.010(19) & (20) (1999); **MONT:** MONT. CODE ANN. § 50-5-1104(1) (1990); **NEB:** NEB. REV. STAT. §§ 71-460, 71-461 (2000); **NEV:** NEV. REV. STAT. § 449 *et seq.* (2000); **NH:** N.H. REV. STAT. ANN. § 151:21(vii) (1999); **NJ:** N.J. ADMIN. CODE tit. 8, § 8:43-14.2(a)(6) (1999); **NY:** N.Y. COMP. CODES R. & REGS. tit. 10 § 86-2.30(18)(M) (2000); **NC:** N.C. GEN. STAT. § 131E-117(6) (1999); N.C. ADMIN. CODE tit. 10, § 3H.2305(c) (1999); **ND:** N.D. CENT. CODE § 50-10.2-02(k) (1999); **OHIO:** OHIO REV. CODE ANN. § 37321.13(a)(13) (1999); **OKLA:** OKLA. STAT. tit. 63, § 1-1918(9) (1990); **OR:** OR. REV. STAT. § 441.605(7) (1990); OR. ADMIN. R. § 411-85-310(7) (1990); **PA:** PENN. STAT. ANN. tit. 18, §§ 921(a) (1990), 2713(A)(2)(1999); PENN. DEP'T OF HEALTH REGS. § 211.8 (1987); **RI:** R.I. GEN. LAWS § 23-17.5-9(a) (1999); **SC:** S.C. CODE ANN. § 44-81-40(F) (1989); **SD:** S.D. CODIFIED LAWS § 34-12-1 *et seq.* (2000); **TENN:** TENN. CODE ANN. § 68-11-910(7) (1990); **TEX:** TEXAS HEALTH & SAFETY CODE ANN. § 102.003(c) (1989); **UTAH:** UTAH ADMIN. CODE § 432-150-5.216, 5.217 (1989); **VT:** VT. STAT. ANN. tit. 18, § 2107(7) (1991); **VA:** VA. CODE ANN. § 32.1-138(7) (Michie 2000); **WASH:** WASH ADMIN. CODE § 248-14-260(3) (1995); **W.VA.:** W. VA. CODE § 16-5C-5 (1989); **WIS:** WIS. STAT. § 50.09(3)(k) (1990).

[407] *See, e.g.*, N.Y. COMP. CODES R. & REGS. tit. 10 §§ 415.4(a)(2) (1990) (defining physical restraint to include, among others, posey jackets, bed rails, and gerichairs); 415.4(a)(7) (noting that each facility must have a written restraint policy that describes the kinds of restraints used in the facility and the purpose for which they may be used); 415.4(a)(2)(iv) (prohibiting restraint use for staff convenience, for purposes of discipline, or to substitute for direct care, activities, or other services); 415.4(a)(2)(iii) (stating that restraints may be used only in unusual circumstances and only after all less restrictive alternatives have been considered and attempted, unless to do so clearly jeopardizes the resident's safety); 415.4(a)(2)(vi) (demanding informed consent before restraint use, except in an emergency); 415.4(a)(2)(i) (requiring restraint use only to protect the resident's health and safety and to assist the resident to attain and maintain optimum levels of physical and emotional functioning); and 415.4(a)(2)(ii) (relating that resident's comprehensive care plan must specify type of restraint, release schedules, type of exercise, necessary skin care, and ambulation to be provided).

Vermont law defines abuse as:

authorized by a physician for a specific time period or needed for an emergency.[408] Residents injured by a facility's violation of this law may sue to recover actual and punitive damages, but the court cannot award attorneys' fees.[409]

Colorado law limits using physical restraints[410] and seclusion[411] to instances in which there is an emergency and no less restrictive alternatives are available or appropriate.[412] According to state law, emergency means a serious, probable imminent threat of bodily harm to self or others.[413] State agencies that use physical restraints must ensure that they do not place excess pressure on the chest or back or inhibit breathing.[414] Staff must release physically restrained persons within statutorily specified time periods, except when precluded for safety reasons.[415]

> (A) Any treatment of an elderly or disabled adult which places life, health or welfare in jeopardy or which is likely to result in impairment of health;
> (B) Any conduct committed with an intent or reckless disregard that such conduct is likely to cause unnecessary harm, unnecessary pain or unnecessary suffering to an elderly or disabled adult;
> (C) *Unnecessary confinement or unnecessary restraint of an elderly or disabled adult*;
> (D) Any sexual activity with an elderly or disabled adult by a caregiver, either, while providing a service for which he or she receives financial compensation, or at a caregiving facility or program;
> (E) Any pattern of malicious behavior which results in impaired emotional well being of an elderly or disabled adult.

VT. STAT. ANN. tit. 33, § 6902(1)(A)-(E) (Butterworth Supp. 1994) (emphasis added).

408 *State Actions*, 23 MENTAL & PHYSICAL DISABILITY L. REP. 437, 437 (May/June 1999) (discussing Arkansas S.B.226 (1999)) [hereinafter *State Actions*].

409 *Id.*

410 COLO. REV. STAT. ANN. art. 20 § 26-20-102 (6) (1992) (defining physical restraint).

411 *Id.* at § 26-20-115 (7) (defining seclusion).

412 *Id.* at §§ 26-20-103 (eff. Apr. 22, 1999) (describing the basis for restraint use and seclusion) and 26-20-104 (eff. Apr. 22, 1999) (detailing the duties related to restraint use and seclusion).

413 *State Actions*, *supra* note 421, at 437 (mentioning Colorado H.B. 99-1090 (1999)).

414 COLO. REV. STAT. ANN. art. 20 § 26-20-104(1)(b) ("No physical or mechanical restraint of an individual shall place excess pressure on the chest and back of that individual or inhibit or impede the individual's ability to breathe[.]").

415 *Id.* at §§ 26-20-104(2) (outlining relief periods from physical restraint), (3) (delineating relief periods from seclusion) and (4) (governing release from restraint).

> For individuals in mechanical restraints, agency staff shall provide relief periods, except when the individual is sleeping, of at least ten minutes as often as every two hours, so long as relief from the mechanical restraint is determined to be safe. During such relief periods, the staff shall ensure proper positioning of the individual and provide movement of the limbs,

Connecticut law requires that residents must be free from physical restraints imposed for discipline or convenience and when not required to treat medical symptoms.[416] Restraints may be imposed only to ensure the safety of the resident or other residents, and then only (except in emergencies) upon a physician's written order that specifies the type of restraint and the duration and circumstances under which restraints can be used.[417]

In *Gray v. Jefferson Geriatric and Rehabilitation Center*, an Ohio trial court considered liability surrounding a resident's fall from a chair and granted summary judgment in favor of a nursing home, ruling that the law prohibited the facility from using restraints.[418] The appellate court reversed on the grounds that the nursing home could have used effective "nonintrusive methods" that would not have violated the state law governing restraints.[419]

The Minnesota legislature passed and Governor Jesse Ventura signed into law House File 40, *Requesting the Use of a Physical Restraint*.[420] The new law establishes the right of a competent resident or the family, guardian, conservator, or healthcare agent of an incompetent person to request the use of physical restraints.[421] The Minnesota Department of Public Health is in the unenviable position of defying federal law as they enforce new state law.[422]

> as necessary. In addition, during such relief periods, staff shall provide assistance for use of appropriate toiletting methods, as necessary. The individual's dignity and safety shall be maintained during relief periods. Staff shall note in the record of the individual being restrained the relief periods granted.

Id. at § 26-20-104(2).

[416] CONN. GEN. STAT. § 19a-550 (1991).

[417] *Id.*

[418] Gray v. Jefferson Geriatric and Rehabilitation Ctr., 602 N.E.2d 396, 398-99 (Ohio Ct. App. 1991).

[419] *Id.*

[420] Minn. House File 40 (1999) (making changes to state law governing restraint use).

[421] MINN. STAT. ANN. ch. 144 § 144.651 subdiv. 33(a) (Apr. 23, 1999) ("Competent nursing home residents, family members of residents who are not competent, and legally appointed conservators, guardians, and health care agents [as statutorily defined], have the right to request and consent to the use of physical restraint in order to treat the medical symptoms of a resident.").

[422] MINN. STAT. ANN. ch. 144A § 144A.10 subdiv. 11(2) (1999) (recommending "to the federal government that fines not be imposed on the [nursing home] facilities referred to in this subdivision or that any fines imposed on these [nursing home] facilities for violations of regulations governing use of physical restraints be rescinded.").

Private Right of Action

State law may provide a statutory private right of action to nursing home residents or their representatives for violations of residents' rights provisions.[423] In some states, the misuse of restraints is classified as a form of elder abuse.[424] In addition to civil sanctions, state elder abuse laws may include criminal sanctions for restraint misuse or for failing to report such misuse.[425] In some states, nursing home supervisors and/or corporate or individual facility owners who are not directly involved in or even aware of the willful misuse of restraints in their

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[423] *See generally*, H. Kennard Bennett, *Nursing Homes: Rights are all in writing*, 4 A.B.A J. 56, 56 (Apr. 1997) (noting that about a dozen states have adopted elder protection laws creating a private cause of action for breach); David F. Bragg, *Dealing with Nursing Home Neglect: The Need for Private Litigation*, 39 S. TEX. L. REV. 1, 2 (1997); Margaret M. Flint, *Nursing Homes*, 239 PRACTISING L. INST. (1995) (covering New York law); *see, e.g.*, 210 ILL. COMP. STAT. ANN. 45/3-602 (West 1993 & Supp. 1998) (providing nursing home residents with a private cause of action); Harris v. Manor Healthcare Corp., 489 N.E.2d 1374, 1384 (Ill. 1986) (holding the Illinois Nursing Home Reform Act's private right of action constitutional and a legitimate exercise of legislative power); Berlak v. Villa Scalabrini Home for the Aged, Inc., 671 N.E.2d 768, 772 (Ill. App. Ct. 1996) (commenting that the purpose of the private right of action "was to make nursing home residents 'private attorney general[s].' "); MO. REV. STAT. § 198.093 (1994 & Supp. 1998) (providing for a private right of action for nursing home residents whose rights are violated); Stiffelman v. Abrams, 655 S.W.2d 522, 530 (Mo. 1983) (finding that the purpose of the private right of action was to "bring about compliance with the provisions of the [state Omnibus Nursing Home] Act" by adopting the "private attorney general concept."); CAL. WELF. & INST. CODE §§ 15600-15675 (West 1991 & Supp. 1999) (enacting a private cause of action in an effort to promote compliance with state nursing home regulations); OR. REV. STAT. §§ 124.005-40 (1997) (providing a private cause of action against a person who commits elder abuse); LA. REV. STAT. ANN. § 40:2010.9 (West 1995 & Supp. 1999) (providing a private cause of action which allows nursing home residents to collect damages for any violation of the state Residents' Bill of Rights); Petre v. Living Ctrs.-East, Inc. d/b/a/ Chateau Living Ctr., 935 F. Supp. 808, 813 (E.D. La. 1996) ("Louisiana has created a private cause of action against nursing homes for any alleged" violation of statutory duties owed by the home); MASS. GEN. LAWS. ANN. ch. 111 § 70E (1993 & Supp. 1998) (creating a private cause of action that allows nursing home residents to sue based on a violation of the residents' rights as listed in the Massachusetts Residents' Bill of Rights); N.Y. PUB. HEALTH LAW § 2801-(d)(1)-(10) (McKinney 1985 & Supp. 1999) (adopting a private cause of action whereby a nursing home resident is entitled to a certain amount of compensatory damages for each day that the resident is injured due to the fact that the resident's rights or benefits were denied); WIS. STAT. § 50.10 (1992 & Supp. 1998) (offering a limited private right of action for nursing home residents, only allowing a resident to bring an action for mandamus against Wisconsin's enforcement agency or injunctive relief against the agency or nursing home).

[424] *See, e.g.*, CAL. WELF. & INST. CODE § 15610.63(f)(1)-(3) (West 1999) (classifying misuse of physical restraint as a form of physical abuse in state elder abuse and dependent adult civil protection act).

[425] *Id.*

facilities may not be insulated from vicarious criminal liability, an exception to the well-known principles of agency law.[426]

PENDING FEDERAL LEGISLATION

The 106th Congress is considering two Senate bills -- *Freedom from Restraint Act of 1999*[427] and the *Compassionate Care Act of 1999*[428]-- as well as one House bill, *Patient Freedom from Restraint Act.*[429] The *Freedom from Restraint Act of 1999* states that service providers eligible to be paid under the Medicare and Medicaid programs must "protect and promote the right of each such individual to be free from physical or mental abuse, corporal punishment, involuntary seclusion, and any physical or chemical restraints imposed for purposes of discipline or convenience."[430] This languages mirrors that of the NHRA.[431] Further, the measure requires restraint use "only to ensure the physical safety of the individual or other individuals in the [provider's] care" and "only upon the written order of a physician that specifies the duration and circumstances under which the restraints are to be used (except in emergency circumstances)."[432] Again, the language parallels that contained in the NHRA.[433]

Likewise, language analogous to the NHRA appears in the *Compassionate Care Act of 1999* which seeks to protect resident rights by requiring freedom from physical restraints used for punishment or convenience and allowing restraint use only to ensure the physical safety of the resident, or others, and only upon a physician's specific written order.[434]

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[426] *Id.*

[427] *See* S. 736, 106th Cong., 1st Sess. (1999), *available at* http://thomas.loc.gov (search by bill number S. 736 or use key words in title – Freedom from Restraint Act of 1999)

[428] *See* S. 750, 106th Cong., 1st Sess. (1999), *available at* http://thomas.loc.gov (search by bill number S. 750 or use key words in title – Compassionate Care Act of 1999)

[429] *See* H.B. 1313, 106th Cong., 1st Sess. (1999), *available at* http://thomas.loc.gov (search by bill number H.B. 1313 or use key words in title – Patient Freedom from Restraint Act of 1999).

[430] S. 736, 106th Cong., 1st Sess. (1999).

[431] *See supra* notes 249-321 and accompanying text.

[432] *See supra* note 427.

[433] *See supra* notes 249-321 and accompanying text.

[434] S. 750, 106th Cong., 1st Sess. (1999).

Similarly, the *Patient Freedom from Restraint Act of 1999* limits the use of restraints and seclusion in certain Medicare and Medicaid funded facilities using language resembling the NHRA.[435] Consider bill language protecting the right of each resident to be free from any physical restraint "imposed for purposes of discipline or convenience."[436] In addition, the measure imposes restraints and seclusion "to ensure the immediate physical safety of the resident" and "only upon the written order of a physician that specifies the duration (not to exceed 2 consecutive hours) and circumstances under which the restraints and seclusion are to be used" with an emergency exception.[437]

PROFESSIONAL STANDARDS OF PRACTICE

"[T]he legal standard of care in professional liability cases is determined in large part by the prevailing customary practice of the industry at the time the alleged negligence took place."[438] In the last decade, the permissible contexts for physical restraints and siderails have narrowed, making it difficult to demonstrate that restraint use is routine and constitutes accepted good practice in the nursing home setting.

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[435] H.B. 1313, 106th Cong., 1st Sess. (1999).

[436] *Id.*

[437] *Id.*

[438] *Governing Board's Role*, *supra* note 39, at 23; American College of Health Care Administrators, *Standards of Practice for Long-Term Care Administrators*, 15 J. LONG-TERM CARE ADMIN. 11 (1987) (promulgating standards relevant to the conduct of professionals working within the nursing home context); *Challenges of Implementing OBRA: Industry Leaders Discuss Hopes, Concerns*, 16 PROVIDER 16, 27 (Oct. 1990) (quoting American Health Care Association (principal national trade association for nursing facilities) president as stating that Nursing Home Reform Law "reflects what should be common practice throughout this industry").

MAJOR ORGANIZATIONAL POSITIONS ON RESTRAINTS

In addition to an increasing tendency for the courts to examine relevant government statutes and regulations, the courts also look to major organizational policy statements regarding restraint use as evidence of the appropriate standard of care under the circumstances. The American Geriatrics Society ("AGS"), for example, approved a Clinical Practice Statement on the use of restraints.[439] In May 1991, AGS took the position that it "strongly advocates the elimination of all types of mechanical restraints and strongly encourages restraint-free environments in all health care settings."[440] Moreover, a 1999 American Medical Association report recognizes that "bed rails used as restraints add risk to the resident by increasing the possibility of more significant injury caused by a fall from bed with bed rails as opposed to a fall from a bed without rails."[441]

VOLUNTARY ACCREDITATION STANDARDS

Physical restraint and siderail use is closely scrutinized by accrediting bodies in healthcare.[442] The Joint Commission on Accreditation of Healthcare Organizations is an independent organization of health care professionals that promulgates national standards for health care facilities.[443] A team of physicians, nurses, and administrators conducts an on-site survey of the nursing home.[444] Accreditation means that the nursing home meets JCAHO's minimal standards as evaluated by the surveying team.[445] Although adherence to JCAHO guidelines is voluntary, JCAHO standards often are allowed into evidence on the acceptable tort standard of care.[446]

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[439] *See AGS Position Statement: Guidelines for Restraint Use* (1991), *available at* http://www.americangeriatrics.org/products/positionpapers/restrain.shtml (visited Aug 17, 2000).

[440] *Id.*

[441] Guttman, *supra* note 48, at 101-05.

[442] *See, e.g.*, JOINT COMM'N ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS, LONG-TERM CARE STANDARDS MANUAL (1996), Standard RI.2.6 (defining restraint), Standard TX.8 (emphasizing a restraint-free environment), Standard TX.8.1 (requiring restraint alternatives and safe, appropriate restraint use when alternatives prove ineffective). [hereinafter JCAHO MANUAL]

[443] *See generally*, U.S. GEN. ACCT. OFFICE, [Letter Report] *Medicare: HCFA's Approval and Oversight of Private Accreditation Organizations* 1, 10-17 (GAO/HEHS-99-197R, Sept.

The 1996 *JCAHO Comprehensive Accreditation Manual for Long-Term Care* defines a physical restraint as "[a]ny method of physically restricting a person's freedom of movement, physical activity, or normal access to his or her body."[447] In general, the JCAHO standards address physicians' orders, time limitations and observations of restraint use with the goal of achieving a restraint-free environment.[448] The standards emphasize safe, appropriate restraint use when alternatives prove ineffective.[449]

RISK MANAGEMENT STRATEGIES

In nursing homes, risk management strategies seek to minimize lawsuits filed by or on behalf of residents, their families, staff, employees, and visitors.[450] Studies examining restraint use in nursing homes highlight the non-efficacy and unacceptable risk of using restraints to prevent falls and fall-related injuries.[451] Thus, routine restraint use does not constitute good legal risk management.

30, 1999) (discussing accreditation by a recognized private organization such as JCAHO); *Report to Congress: Study of Private Accreditation (Deeming) of Nursing Homes, Regulatory Incentives and Non-Regulatory Initiatives, and Effectiveness of the Survey and Certification System* (July 1998) (examining the three issues identified in the title); 42 C.F.R. Part 488 (addressing application and reapplication procedures that apply to private accreditation organizations requesting deeming authority to nursing homes); *Facts About The Joint Commission on Accreditation of Healthcare Organizations, available at* http://www.jcaho.org/about_jc/jcinfo.htm (last visited Sept. 10, 2000) (providing JCAHO mission statement, describing accreditation process generally, and relating organization history); 55 Fed. Reg. 51,434 (1990) (proposing JCAHO nursing home accreditation).

[444] *Long Term Care, available at* http://www.jcaho.org/acr_info/ltc.htm (last visited Sept. 8, 2000) (supplying a sample three-day initial long-term care survey agenda).

[445] *See generally*, JCAHO MANUAL, *supra* note 455.

[446] *See* Kapp, GERIATRICS AND THE LAW, *supra* note 415, at 144 ("[JCAHO] guidelines are frequently relied on by courts as legally enforceable standards.").

[447] *See* JCAHO MANUAL, *supra* note 455, at Standard RI.2.6.

[448] *See generally*, JCAHO MANUAL, *supra* note 455.

[449] *Id.*

[450] *See generally*, ANDREW D. WEINBERG, RISK MANAGEMENT IN LONG-TERM CARE (1998).

[451] *See supra* notes 79-139 and accompanying text.

An effective risk management program relies on several components, including, but not limited to, those discussed below. Unfortunately, even the best risk management program cannot immunize a nursing home from claim exposure.[452] For this reason, the facility should consider placing alternate dispute resolution procedures in resident service agreements and employment relationships.[453]

Institutional Philosophy

The facility should consider drafting an institutional philosophy on restraint and siderail use.[454] Reducing or eliminating physical restraint and siderail use takes an organized, planned effort. "If the administrator and the director of nursing become committed to restraint-free care, it will happen. In fact, this may be the single most important factor in achieving restraint-free care."[455]

Facility Policy and Procedure

All nursing homes should have policy and procedures regarding physical restraints and siderails consistent with federal and state regulations. A written institutional policy should include specific, well-defined indications for restraint use (for example, restrain a resident if

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[452]Barry D. Halpern & Thea F. Silverstein, *Ethical Considerations in Elder Care*, 44 U. KAN. L. REV. 783, 786 (July 1996).

[453]*Id.* at 786.

[454]An institutional philosophy on restraint use developed by a Baltimore nursing home for distribution to all new residents and families at the time of admission states:

> We believe that residents have the right to a care-giving environment that maximizes their mobility and personal autonomy. We have a responsibility to provide that environment, balancing safety and freedom of movement for all residents. The use of restraints and the immobility they cause may lead to physical and emotional problems. We are committed to providing individualized programs using creative alternatives to enable residents to attain their maximal levels of physical, mental, and psychosocial functioning. In this way, restraint use can be minimized. The involvement of the resident, family and friends is vital in establishing programs that will keep residents mobile, involved, and safe. Ongoing staff education about methods for promoting mobility and independence in elderly residents, including those who are confused, wandering, or disruptive, is essential. We believe that an involved and informed staff provides the optimal care-giving environment in which restraint use is minimized.

Kramer, *supra* note 101, at 160.

[455]Carter Catlett Williams & Caleb E. Finch, *Physical Restraint: Not Fit for Woman, Man, or Beast*, 45 J. AM. GERIATRICS SOC'Y 773, 774 (1997).

he or she poses an immediate threat to self or others) with clear parameters regarding administrative functions (informing a supervisor and/or director of nursing of the decision to restrain within an hour of receiving a physician's order or requiring multidisciplinary team/committee approval of restraint use) and time (such as limiting orders for restraints to 24 hours of use). Evidence that written institutional policies and procedures have not been enforced is essential for establishing that the standard of care has not been met.

Physician Responsible for Resident Care

Physicians responsible for resident care must be familiar with restraints and their alternatives. They should understand and subscribe to nursing home philosophy and expectations regarding their use. Medical staff bylaws should detail facility expectations regarding informed consent and other aspects of restraint and siderail use. Policy and procedure should promote careful assessment, application, and documentation of restraint use. The nursing home's quality assurance system should examine restraint ordering behavior, informed consent and other processes (such as assessments) involving restraints.[456] The deference courts show professional judgment involved in decisions not to use restraints or siderails should supply nursing home administrators with the confidence to develop and implement policies rejecting routine restraint use.[457]

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[456]*See* Kapp, *Restraints & Legal Liability*, *supra* note 39, at 29-30.

[457]*See, e.g.*, Judge v. Covina Valley Community Hosp., No. KC026950, 1998 WL 1017021 (Los Angeles Cty. Super. Ct. Dec. 28, 1998) (finding for the defendant hospital, the court agreed that the decision not to restrain the patient who fell and broke his hip while unrestrained was a judgment call on the part of the nurses); St. Fernandez v. John's Pleasant Valley Hosp., No. CIV 169167, 1997 WL 875018 (Ventura Cty. Super. Ct. Cal., Dec. 3, 1997) (deferring to professional judgment, a California jury returned a defense verdict in a case arising from a patient's fall from an exam table reasoning that the nursing standard of care did not require the use of side rails and a call light with a patient whose vital signs were normal, stable, and who had received a routine antibiotic injection); *Defense Verdict in Suit Arising from Patients Fall from Exam Table*, 18 No. 1 VERDICTS, SETTLEMENTS & TACTICS 9 (Jan. 1998) (discussing Fernandez v. John's Pleasant Valley Hosp.). Even when finding nursing homes liable, the courts consistently emphasize that the facilities could fulfill their responsibilities by monitoring and supervising residents instead of imposing restraints. *See, e.g.*, Robinson v. U.S., No. K85-349 CA (W.D. Mich. 1987) (finding that the Veterans Administration medical staff should have monitored and supervised the resident and noting no standard of care violation in deciding not to restrain the resident 24 hours a day); Krestview Nursing Home, Inc. v. Synowiec, 317 So.2d 94 (Fla. Dist. Ct. App. 1975), *cert. denied*, 333 So.2d 463 (Fla. 1976); McGillivray v. Rapides Iberia Management Enters., 493 So.2d 819, 823

Staff Education and Training

Another component of good risk management involves extensive education at all levels within the nursing home -- from the governing body to the nurses and nurses' aides who provide hands-on care to residents.[458] Education influences attitudes, beliefs, and knowledge regarding restraint and siderail use.[459] Facilities should mandate comprehensive, up-to-date staff development regarding restraints and fall prevention interventions for all administrative and resident care staff.[460] Introduction to this topic should be an essential part of a new employee's orientation.[461] A facility should establish regular staff training programs that:

- Describe research findings concerning restraint and siderail use and their application to clinical practice;
- Explain the ineffectiveness of restraints, including siderails, as a fall prevention strategy;
- Provide role playing or experiential activities emphasizing the resident's perspective on wearing a restraint;
- Emphasize resident quality of life and related rights;
- Reinforce facility philosophy regarding restraint use;
- Review institutional policy and procedure regarding restraints and stress the importance of institutional compliance with its own protocols;[462]
- Invite staff from nursing homes with successful restraint and siderail reduction or elimination programs to share their experiences;

(La. Ct. App. 1986) (stating that the findings "refer not to the failure of nurses to place Mr. Fox in the harness that night, but to their failure to guard against his leaving the premises.")

[458] *See* Patterson, *supra* note 129, at 231-35; Kapp, *Restraints & Legal Liability*, *supra*, note 39, at 29. Some state-approved nurse aide training programs must include identification and prevention of improper use of physical restraints in their curriculum pertaining to residents' rights. *See, e.g.*, PA. STAT. ANN. tit 63, § 673(4) (West 1999).

[459] *See* Patterson, *supra* note 129, at 231-35.

[460] *Id.*

[461] *See* Kapp, *Restraints & Legal Liability*, *supra* note 39, at 29-30.

[462] *See, e.g.*, Lajana Ledford & Janet Mentes, RES.-BASED PROTOCOL: RESTRAINTS (Marita G. Titler ed., 1997) (detailing a research-based practice protocol designed by the Univ. of Iowa College of Nursing with funding provided by Grant #P30 NRO3979 from the Nat'l Inst. of Nursing Research). Obtain copies of the protocol from Marita G. Titler, Director, Gerontological Nursing Interventions Research Ctr., Research and Dissemination Core, 4118 Westlawn, The Univ. of Iowa, Iowa City, IA 52242; telephone (319) 384-4429, facsimile (319) 353-5843. Alternatively, *at* http://www.nursing.uiowa.edu/gnic for protocol ordering information.

- Offer staff visits to restraint-free nursing homes;
- Incorporate educational videos on restraint and siderail issues;
- Describe categories of at-risk residents (for example, those with a fall history);
- Describe individualized interventions to address the at-risk resident's unique needs;
- Illustrate behavioral approaches in the management of behavioral symptoms such as wandering and agitation; and
- Highlight legal liability associated with restraints and siderails.

Documentation

The resident or their legal representative is guaranteed full access to the resident's medical record.[463] From a risk management perspective, documentation is imperative before employing or refraining from restraint or siderail use. The facility should systematically review documentation for all restrained residents to validate compliance with minimum standards of care as well as federal, state, and local laws regarding restraint use.[464]

"[C]are alternatives used to replace physical restraints may be as many as the reasons for using them and as varied as the specific needs of each nursing home resident."[465] Fortunately, products, educational manuals, and videos describing how to reduce restraint and siderail use as well as how to prevent falls are readily available.[466] An important

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[463] *See* 42 C.F.R. § 483.10(b)(2) (1999) ("The resident or [ ] legal representative has the right [u]pon an oral or written request, to access all records pertaining to [resident] including current clinical records within 24 hours[.]"); HCFA GUIDANCE, *supra* note 10, at PP-45.

[464] *See* Steven Lipson, *The Restraint-Free Approach to Behavior Problems in the Nursing Home*, 43 MD. MED. J. 155, 157 (1994) (outlining "restraint proper" approach to treating behavior problems: assess the problem, establish a presumptive diagnosis, consider the risks and benefits of treatment alternatives, select the best treatment for the individual patient, evaluate treatment effectiveness and side effects, change treatment as necessary, discontinue treatments when no longer needed, and provide documentation).

[465] Werner, *Individualized Care Alternatives for Restraint Removal, supra* note 129, at 321.

[466] *See* NEVILLE E. STRUMPF ET AL., RESTRAINT-FREE CARE: INDIVIDUALIZED APPROACHES FOR FRAIL ELDERS (1998). This manual helps clinicians, administrators, and families attain the goal of restraint-free care of frail elderly persons. Practical alternatives to restraint models of support, developed by nursing home and hospital caregivers, are presented as individualized care models. The manual is organized in outline form to highlight critical material and to ensure quick access to solutions. It highlights the objectives of restraint-free care including not only comfort and safety, but also the best possible quality of life. This philosophy of care requires that caregivers make sense of resident behaviors, rather than to simply control their responses. Contents include: rethinking restraint use; implementing a

component of risk management involves documenting the decision-making process involved in determining a plan of care to address fall risk and specific use of fall prevention interventions. This includes documentation of:

- The assessment of the resident for fall-related risk factors upon admission and after any fall;
- A process of professional judgment demonstrated by a multidisciplinary assessment and care plan;
- Alternative interventions implemented; and
- Resident's response to these interventions.

When restraint is employed, there must be considerable documentation regarding rationale for usage and the strategies used to reduce or eliminate restraint use. The heath care record must demonstrate:

- Why restraints are being considered;
- That the underlying conditions that contributed to fall risk have been adequately addressed;
- The resident's response to less restrictive alternatives implemented prior to restraint or siderail use;

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process of change; making sense of behavior; responding to behavioral phenomena; assessment and prevention of falls and injurious falls; caring for the person who interferes with treatment; and maintaining a process of change. Direct inquiries in writing to Springer Publishing Company, 536 Broadway, New York, NY 10012, by telephone to (212) 431-4370, or by facsimile to (212) 941-7842. *See also* Videotape: *Individualized Wheelchair Seating for Older Adults: An Important Link to Restraint-Free Care* (Benedictine Inst. for Long-Term Care (Mt. Angel, OR) 1998). This set of videotapes and manuals is designed to help professional and non-professional caregivers learn about the importance of proper seating for older adults. Many persons are restrained because they are sitting in the wrong wheelchair. Direct inquiries in writing to Benedictine Institute for Long Term Care, 980 S. Main St., Mt. Angel, OR 97362; by telephone to (503) 845-9495. *See also* Joanne Rader et al., *Individualized Wheelchair Seating: Reducing Restraints and Improving Comfort and Functions*, 15 TOPICS IN GERIATRIC REHABILITATION 34-47 (1999); Joanne Rader & Elizabeth M. Tornquist, INDIVIDUALIZED DEMENTIA CARE (Springer Publ'g Co. (New York, NY) (1995); Karen A. Talerico et al., Videotape, RESTRAINT FREE CARE (Healthcare Multimedia Group, Inc. 1995); Nancy Bochino et al., Videotape, RESTRAINT REDUCTION AND FALL PREVENTION (Envision, Inc. 1999); Joan M. Dunbar et al., *Retrain Don't Restrain: The Educational Intervention of the National Nursing Home Restraint Removal Project*, 36 GERONTOLOGIST 539, 539-42 (1996) (educating and encouraging direct-care interventions with the goal of restraint-free facilities).

- Physician's written order for restraint use, including type and size of restraint, when to be used, length of order, and rationale for usage;
- Time frame for restraint use;
- Evaluation of the continuing need for restraints or siderails because the resident's health/functional status can change;
- Specific restraint reduction efforts (for example, use of belt restraint in wheelchair removed two hours each day during group activities and family visits);
- How often the facility staff observe and monitor the restrained resident because restrained residents need extra monitoring, not less (for example, restrained residents should be observed frequently and the physical restraints should be removed at least every two hours (more often if necessary) for re-positioning in order to allow for normal body functioning and activities of daily living);
- Resident's clinical condition including circulation and skin integrity of limbs and dependent body part at least every two hours (for example, buttocks and posterior thighs if restrained in a wheelchair);
- Specific interventions to increase wearer's comfort;
- How staff have met the resident's hydration, feeding, and toilet needs; and
- Resident's verbal and behavioral response to restraint or siderails.

The nursing home record should document the resident's informed consent for restraint application or removal. For example, a woman with cerebral palsy who is unable to hold herself in an upright sitting position may choose to restrict freedom of movement so that she may engage in activities which she would otherwise be unable to do. This information would appear in her chart or care plan.[467] Staff may describe resident gestures evidencing restraint refusal in the nursing home record.[468] For example, a confused woman unable to speak, read, or write who angrily shakes her fist and stomps her feet at anyone attempting to apply a restraint is clearly communicating a desire to be free from restraints.[469]

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[467] *See* Dodds, *supra* note 231, at 160.

[468] *See* U.S. DEP'T OF HEALTH & HUM. SERVS., OFFICE OF INSPECTOR GEN., *Minimizing Restraints in Nursing Homes: A Guide to Action* 1, 6 (1992).

[469] *Id.*

Consultation Services & Industries Offering Restraint Alternatives

Consultation services have responded to the growing number of requests for information on restraint and siderail use and their relationship to falls and fall-related injuries. For example, the Gerontologic Nursing Consultation Service ("GNCS"), founded by several faculty members from the University of Pennsylvania School of Nursing in the late 1980s, provides consulting services on a variety of topics, including restraint use and its relationship to falls and fall-related injuries.[470] The GNCS client base includes: nursing homes; hospitals; area agencies on aging; law firms; individuals and their families; managed care; retirement communities and other long-term care systems; as well as engineering, architectural and other businesses involved in new product development and design.[471]

In addition, businesses have emerged to respond to the need for restraint alternatives. For example, RN+ Patient Monitoring System provides bed alarms that signal only when a resident is attempting to leave their bed or wheelchair unassisted.[472] A portable signal unit mounts on the resident's bed or chair with Velcro strips.[473] Thin, flexible weight-sensitive strips are placed under the bed linens or under most foam or sheepskin pads.[474] The sensor strips detect the absence of weight and sound an alarm.[475] The receiver operates independently of the nurse call system and may be kept at the nurse's station.[476] Clinical studies demonstrate a reduced fall rate with alarms that detect resident position changes[477] and associate a reduced fall rate with pressure-sensitive alarm use.[478] Alarm effectiveness, however, depends on the

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[470] Direct inquiries about GNCS to: Rebecca Snyder Phillips, Director, Gerontologic Nursing Consultation Service, Univ. of Pennsylvania, School of Nursing, Penn Nursing Network, 3615 Chestnut Street, RH #322, Philadelphia, PA 19104-2676 or telephone (215) 898-4998.

[471] *Id.*

[472] For more information, write RN+ Systems, Tactilitics, Inc., 5595 Arapahoe Road, Suite B, Boulder, Colorado 80303, or telephone (800) 727-868.

[473] RN+ Systems product brochures on file with authors.

[474] *Id.*

[475] *Id.*

[476] *Id.*

[477] *See, e.g.*, Else M. Innes, *Maintaining Fall Prevention*, 11 QUALITY REV. BULL. 217-21 (1985); Bette Widder, *A New Device to Decrease Falls*, 6 GERIATRIC NURSING 287-88 (1985).

[478] *See, e.g.*, Ann L. Hendrich, *An Effective Unit-Based Fall Prevention Plan*, 3 J. NURSING QUALITY ASSURANCE 28, 28-36 (1988); Ann L. Hendrich, *Unit-Based Fall Prevention*, 10 J. NURSING QUALITY ASSURANCE 15, 15-17 (1988).

ability of staff to reach the resident in a timely manner.[479] Non-restraint interventions described earlier have fostered the development of products by a variety of manufacturers to promote comfortable, individualized seating as well as facilitate safe mobility and transferring.

RISK MANAGEMENT STRATEGIES FOR RAILS

An effective risk management strategy to prevent entrapment deaths and injuries includes:[480]

- Inspecting all bed frames, bed siderails, and mattresses during a regular maintenance program seeking to identify possible entrapment areas.
- Assessing proper selection and fit. Mattress width, length, and/or depth, alignment of the bed frame, bed siderail, and mattress should leave no gap wide enough to entrap a resident's head or body between the rails and mattress. This is particularly important with confused or restless residents. Movement or compression of the mattress caused by a resident's weight, movement, or bed position may cause gaps.
- Confirming that the mattress matches and fits relative to rails width and height. Replacement mattresses and siderails may have dimensions that differ from the original equipment supplied or specified by the bed frame manufacturer. Not all siderails, mattresses, and bed frames are interchangeable. Variation in rail design and mattress thickness and/or density may affect the potential for entrapment. When siderails and mattresses are purchased separately from the bed frame, check with the manufacturer(s) to ensure compatibility of the siderails, mattresses, and bed frame.
- Installing siderails according to their manufacturer's instructions. This should make for a proper fit and avoid bowing, among other possible problems, by ensuring the proper distance from the head and footboard.
- Considering additional safety measures for residents identified as high-risk for entrapment (those with pre-existing conditions such as altered mental status (organic or medication related), confusion, restlessness, lack of muscle control, or a combination of these

[479] Capezuti & Lawson, *supra* note 16, at 215-16.
[480] *See* FDA ENTRAPMENT ALERT, *supra* note 165.

factors). Increased risk also occurs when the bed-bound resident's size and/or weight are inappropriate for the bed's dimension.

- Using siderail protective barriers to close off open spaces in which a person might accidentally become entrapped. Follow facility procedures and/or the manufacturer's recommendations for installing and maintaining siderail protective barriers for a particular bed frame and siderail.
- Following facility protocol and manufacturer instructions as well as federal, state, and local regulations regarding restraint use. Do not substitute siderails for other restraints, such as a vest or wrist/leg device.
- Giving careful (and creative) thought to develop other interventions to replace traditional siderail use. Switching from full to half rails or no rails does not automatically make the situation better. Nor does placing the bed on the floor. All devices must be individually and carefully assessed for how they affect the individual's safety, burden, comfort, and well being.

FALL PREVENTION ASSESSMENT SYSTEM

An interdisciplinary team can develop a fall prevention assessment system. The team should identify processes and protocols on resident falls; conduct a retrospective audit of incident reports related to falls per resident day; and audit resident charts for factors associated with falls. Supplement this internal benchmarking with external information about predicting and preventing falls (for example, a literature review).

In addition, require completion of a risk management occurrence report for every restraint- or siderail-related fall and injury to be forwarded to the risk management department within 24 hours. A fall resulting in a serious injury (such as, a fracture, head injury, laceration requiring suturing, or death) should be reported immediately to a physician. The licensed nurse and physician should document objective assessment and findings of the incident in the resident's medical record.

CONCLUSION

Despite growing empirical evidence that physical restraints and siderails do not prevent falls, administrators, nurses, and physicians are concerned with the legal implications of changing practice. This fear is

reinforced by a false perception that failure to use restraints and siderails puts facilities at risk for legal liability. The real basis of liability is a lack of care addressing fall risk. Federal regulations and professional standards of care support an individualized assessment of fall risk accompanied by appropriate intervention. Clearly, risk management strategies eliminating or reducing restraint use best serve the legal interests of nursing homes.