

## 42 CFR 483.25

This section is current through the March 20, 2014 issue of the Federal Register

**Code of Federal Regulations > TITLE 42-- PUBLIC HEALTH > CHAPTER IV-- CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES > SUBCHAPTER G-- STANDARDS AND CERTIFICATION > PART 483-- REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES > SUBPART B-- REQUIREMENTS FOR LONG TERM CARE FACILITIES**

**§ 483.25 Quality of care.**

Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.

- (a) Activities of daily living. Based on the comprehensive assessment of a resident, the facility must ensure that --
  - (1) A resident's abilities in activities of daily living do not diminish unless circumstances of the individual's clinical condition demonstrate that diminution was unavoidable. This includes the resident's ability to --
    - (i) Bathe, dress, and groom;
    - (ii) Transfer and ambulate;
    - (iii) Toilet;
    - (iv) Eat; and
    - (v) Use speech, language, or other functional communication systems.
  - (2) A resident is given the appropriate treatment and services to maintain or improve his or her abilities specified in paragraph (a)(1) of this section; and
  - (3) A resident who is unable to carry out activities of daily living receives the necessary services to maintain good nutrition, grooming, and personal and oral hygiene.
- (b) Vision and hearing. To ensure that residents receive proper treatment and assistive devices to maintain vision and hearing abilities, the facility must, if necessary, assist the resident --
  - (1) In making appointments, and
  - (2) By arranging for transportation to and from the office of a practitioner specializing in the treatment of vision or hearing impairment or the office of a professional specializing in the provision of vision or hearing assistive devices.
- (c) Pressure sores. Based on the comprehensive assessment of a resident, the facility must ensure that --
  - (1) A resident who enters the facility without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrates that they were unavoidable; and
  - (2) A resident having pressure sores receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing.
- (d) Urinary Incontinence. Based on the resident's comprehensive assessment, the facility

must ensure that --

- (1) A resident who enters the facility without an indwelling catheter is not catheterized unless the resident's clinical condition demonstrates that catheterization was necessary; and
  - (2) A resident who is incontinent of bladder receives appropriate treatment and services to prevent urinary tract infections and to restore as much normal bladder function as possible.
- (e) Range of motion. Based on the comprehensive assessment of a resident, the facility must ensure that --
  - (1) A resident who enters the facility without a limited range of motion does not experience reduction in range of motion unless the resident's clinical condition demonstrates that a reduction in range of motion is unavoidable; and
  - (2) A resident with a limited range of motion receives appropriate treatment and services to increase range of motion and/or to prevent further decrease in range of motion.
- (f) Mental and Psychosocial functioning. Based on the comprehensive assessment of a resident, the facility must ensure that --
  - (1) A resident who displays mental or psychosocial adjustment difficulty, receives appropriate treatment and services to correct the assessed problem, and
  - (2) A resident whose assessment did not reveal a mental or psychosocial adjustment difficulty does not display a pattern of decreased social interaction and/or increased withdrawn, angry, or depressive behaviors, unless the resident's clinical condition demonstrates that such a pattern was unavoidable.
- (g) Naso-gastric tubes. Based on the comprehensive assessment of a resident, the facility must ensure that --
  - (1) A resident who has been able to eat enough alone or with assistance is not fed by naso-gastric tube unless the resident's clinical condition demonstrates that use of a naso-gastric tube was unavoidable; and
  - (2) A resident who is fed by a naso-gastric or gastrostomy tube receives the appropriate treatment and services to prevent aspiration pneumonia, diarrhea, vomiting, dehydration, metabolic abnormalities, and nasal-pharyngeal ulcers and to restore, if possible, normal eating skills.
- (h) Accidents. The facility must ensure that --
  - (1) The resident environment remains as free of accident hazards as is possible; and
  - (2) Each resident receives adequate supervision and assistance devices to prevent accidents.
- (i) Nutrition. Based on a resident's comprehensive assessment, the facility must ensure that a resident --
  - (1) Maintains acceptable parameters of nutritional status, such as body weight and protein levels, unless the resident's clinical condition demonstrates that this is not possible; and

- (2) Receives a therapeutic diet when there is a nutritional problem.
- (j) Hydration. The facility must provide each resident with sufficient fluid intake to maintain proper hydration and health.
- (k) Special needs. The facility must ensure that residents receive proper treatment and care for the following special services:
  - (1) Injections;
  - (2) Parenteral and enteral fluids;
  - (3) Colostomy, ureterostomy, or ileostomy care;
  - (4) Tracheostomy care;
  - (5) Tracheal suctioning;
  - (6) Respiratory care;
  - (7) Foot care; and
  - (8) Prostheses.
- (l) Unnecessary drugs -- (1) General. Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used:
  - (i) In excessive dose (including duplicate drug therapy); or
  - (ii) For excessive duration; or
  - (iii) Without adequate monitoring; or
  - (iv) Without adequate indications for its use; or
  - (v) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or
  - (vi) Any combinations of the reasons above.
  - (2) Antipsychotic Drugs. Based on a comprehensive assessment of a resident, the facility must ensure that --
    - (i) Residents who have not used antipsychotic drugs are not given these drugs unless antipsychotic drug therapy is necessary to treat a specific condition as diagnosed and documented in the clinical record; and
    - (ii) Residents who use antipsychotic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.
- (m) Medication Errors. The facility must ensure that --
  - (1) It is free of medication error rates of five percent or greater; and
  - (2) Residents are free of any significant medication errors.
- (n) Influenza and pneumococcal immunizations -- (1) Influenza. The facility must develop policies and procedures that ensure that --
  - (i) Before offering the influenza immunization, each resident or the resident's legal representative receives education regarding the benefits and potential side effects

of the immunization;

- (ii) Each resident is offered an influenza immunization October 1 through March 31 annually, unless the immunization is medically contraindicated or the resident has already been immunized during this time period;
  - (iii) The resident or the resident's legal representative has the opportunity to refuse immunization; and
  - (iv) The resident's medical record includes documentation that indicates, at a minimum, the following:
    - (A) That the resident or resident's legal representative was provided education regarding the benefits and potential side effects of influenza immunization; and
    - (B) That the resident either received the influenza immunization or did not receive the influenza immunization due to medical contraindications or refusal.
- (2) Pneumococcal disease. The facility must develop policies and procedures that ensure that --
- (i) Before offering the pneumococcal immunization, each resident or the resident's legal representative receives education regarding the benefits and potential side effects of the immunization;
  - (ii) Each resident is offered an pneumococcal immunization, unless the immunization is medically contraindicated or the resident has already been immunized;
  - (iii) The resident or the resident's legal representative has the opportunity to refuse immunization; and
  - (iv) The resident's medical record includes documentation that indicates, at a minimum, the following:
    - (A) That the resident or resident's legal representative was provided education regarding the benefits and potential side effects of pneumococcal immunization; and
    - (B) That the resident either received the pneumococcal immunization or did not receive the pneumococcal immunization due to medical contraindication or refusal.
  - (v) Exception. As an alternative, based on an assessment and practitioner recommendation, a second pneumococcal immunization may be given after 5 years following the first pneumococcal immunization, unless medically contraindicated or the resident or the resident's legal representative refuses the second immunization.

<b>Statutory Authority</b>
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**AUTHORITY NOTE APPLICABLE TO ENTIRE PART:**

Secs. 1102, 1128I and 1871 of the Social Security Act ([42 U.S.C. 1302](#), 1320a-7j, and 1395hh).

<b>History</b>
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[56 FR 48873, Sept. 26, 1991, as amended at [57 FR 43925](#), Sept. 23, 1992; [70 FR 58834, 58851](#), Oct. 7, 2005]

## Annotations

Notes
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### [EFFECTIVE DATE NOTE:

[70 FR 58834, 58851](#), Oct. 7, 2005, added paragraph (n), effective Oct. 7, 2005.]

Case Notes
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### NOTES TO DECISIONS: COURT AND ADMINISTRATIVE DECISIONS SIGNIFICANTLY DISCUSSING SECTION --

[Crestview Parke Care Ctr. v Thompson \(2004, CA6\) 373 F3d 743, 2004 FED App 196P](#)

[Woodstock Care Ctr. v Thompson \(2003, CA6\) 363 F3d 583, 80 Fed Appx 962](#), reh den, reh, en banc, den (2004, CA6) [2004 US App LEXIS 7792](#)

[Frantz v HCR Manor Care, Inc. \(2003, Co Ct\) 64 Pa D & C4th 457](#)

[Goda v White Cliff Leasing P'ship \(2003, Co Ct\) 62 Pa D & C4th 476](#)

### LexisNexis® Notes

Case Notes Applicable to Entire Part

Administrative Law : Judicial Review : Standards of Review : General Overview

Administrative Law : Separation of Powers : Jurisdiction

Civil Procedure : Jurisdiction : Subject Matter Jurisdiction : Federal Questions : General Overview

Governments : Legislation : Statutory Remedies & Rights

Healthcare Law : Actions Against Facilities : Facility Liability : Nursing Facilities

Healthcare Law : Actions Against Facilities : Standards of Care : General Overview

Healthcare Law : Actions Against Facilities : Standards of Care : Nursing Facilities

Healthcare Law : Business Administration & Organization : Judicial Review : Substantial Evidence

Healthcare Law : Business Administration & Organization : Licenses : General Overview

Healthcare Law : Business Administration & Organization : Patient Confidentiality : General Overview

Healthcare Law : Insurance : Reimbursement : Fiscal Intermediaries

Public Health & Welfare Law : Healthcare : Services for Disabled & Elderly Persons : General Overview

Public Health & Welfare Law : Healthcare : Services for Disabled & Elderly Persons : Care Facilities :

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Public Health & Welfare Law : Social Security : Medicaid : Coverage : General Overview

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Public Health &amp; Welfare Law : Social Security : Medicaid : Providers : Types : Nursing Facilities

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Public Health &amp; Welfare Law : Social Security : Medicare : Providers : Types : Nursing Facilities

Public Health &amp; Welfare Law : Social Services : Disabled &amp; Elderly Persons : Agency Actions &amp; Procedures :

Public Health &amp; Welfare Law : Social Services : Disabled &amp; Elderly Persons : Agency Actions &amp; Procedures :

Real Property Law : Zoning &amp; Land Use : Comprehensive Plans

Torts : Negligence : Standards of Care : Special Care : Highly Skilled Professionals

**Case Notes Applicable to Entire Part**[Part Note](#)**Administrative Law : Judicial Review : Standards of Review : General Overview**[Lakeridge Villa Health Care Ctr. v. Leavitt, 2006 U.S. App. LEXIS 27338](#) (6th Cir Nov. 3, 2006) (Unpublished).

**Overview:** *A civil monetary penalty against a nursing care facility for violations of requirements as described in the Social Security Act, [42 U.S.C.S. § 1395i-3\(a\)-\(d\)](#), was upheld per [42 U.S.C.S. § 1320a-7a](#) as supported by substantial evidence as, inter alia, the facility did not prevent accidents and improperly used restraints, and the fine was reasonable.*

- Neither [42 C.F.R. § 483.25\(h\)\(2\)](#) nor the U.S. Court of Appeals for the Sixth Circuit requires that actual harm occur for an immediate jeopardy finding against a nursing facility to be valid. This holding does not impose strict liability but rather requires a nursing facility to take reasonable care to avoid accidents. The question of whether a facility's precautions are reasonable is highly fact-bound and can only be answered on the basis of expertise in nursing home management. As such, it is a question the resolution of which the Sixth Circuit defers to the expert administrative agency, the U.S. Department of Health and Human Services. [Go To Headnote](#)

**Administrative Law : Separation of Powers : Jurisdiction**[Talbot v. Lucy Corr, 1996 U.S. Dist. LEXIS 8886](#) (ED Va Mar. 19, 1996).

**Overview:** *A patient could not pursue a claim under [42 U.S.C.S. § 1983](#) against a nursing home for alleged failure to comply with [42 U.S.C.S. 1395i\(3\)\(c\)](#) because she first was required to exhaust the administrative remedies established by Virginia, pursuant to [42 C.F.R. § 488 et seq.](#)*

- The Secretary of the Department of Health and Human Services has promulgated rules and regulations implementing the Nursing Home Reform Law. These regulations address, among other things: residents rights ([42 C.F.R § 483.10](#)); admission, transfer, and discharge rights ([42 C.F.R § 483.12](#)); resident behavior and facility practices ([42 C.F.R. § 483.13](#)); quality of life ([42 C.F.R. § 483.15](#)); and quality of care ([42 C.F.R. § 483.25](#)). To aid in implementing these requirements and procedures, the administrative scheme includes a state appeals process for transfers and discharges of patients. [42 C.F.R. § 431.205](#). The regulations provide that the state agency responsible for maintaining an appeals system must

provide information regarding hearing procedures, notice to the beneficiary of the action that the skilled nursing facility intends to take, the reasons for the intended action, and the specific regulations that require that action. Moreover, a hearing is required for any resident who believes that a skilled nursing facility has transferred or discharged her in error. [42 C.F.R. § 431.220](#). [Go To Headnote](#)

### **Civil Procedure : Jurisdiction : Subject Matter Jurisdiction : Federal Questions : General Overview**

[Schneller v. Crozer Chester Med. Ctr., 2010 U.S. App. LEXIS 14966](#) (3rd Cir July 20, 2010), writ of certiorari denied by [131 S. Ct. 1684, 179 L. Ed. 2d 617, 2011 U.S. LEXIS 2222, 79 U.S.L.W. 3538 \(U.S. 2011\)](#).

*Overview:* A district court's dismissal of an individual's case was affirmed since the district court lacked diversity jurisdiction and federal question jurisdiction; *inter alia*, the individual's § 1983 claim failed, he did not have a private right of action under the Assisted Suicide Funding Restriction Act of 1997 or the federal controlled substances laws.

- [42 C.F.R. §§ 483.10, 483.13, 483.15](#), and [483.25](#) do not provide a basis for jurisdiction pursuant to [28 U.S.C.S. § 1331](#) because they merely set forth the requirements that a facility must meet in order to qualify to participate in Medicare and Medicaid; they do not confer a private cause of action. [Go To Headnote](#)

### **Governments : Legislation : Statutory Remedies & Rights**

[Schneller v. Crozer Chester Med. Ctr., 2010 U.S. App. LEXIS 14966](#) (3rd Cir July 20, 2010), writ of certiorari denied by [131 S. Ct. 1684, 179 L. Ed. 2d 617, 2011 U.S. LEXIS 2222, 79 U.S.L.W. 3538 \(U.S. 2011\)](#).

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- [42 C.F.R. §§ 483.10, 483.13, 483.15](#), and [483.25](#) do not provide a basis for jurisdiction pursuant to [28 U.S.C.S. § 1331](#) because they merely set forth the requirements that a facility must meet in order to qualify to participate in Medicare and Medicaid; they do not confer a private cause of action. [Go To Headnote](#)

### **Healthcare Law : Actions Against Facilities : Facility Liability : Nursing Facilities**

[Fal-Meridian, Inc. v. United States HHS, 604 F.3d 445, 2010 U.S. App. LEXIS 9266](#) (7th Cir May 6, 2010).

*Overview:* Civil penalty was properly imposed on nursing home for violation of [42 C.F.R. § 483.25\(h\)](#) under Medicare and Medicaid provisions, [42 U.S.C.S. §§ 1302, 1395hh](#); placing resident who had feeding tube and strict "nothing by mouth" order with a roommate who did not eat in room would have significantly reduced danger of choking death at reasonable cost.

- The Social Security Act provides that a skilled nursing facility must provide services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, in accordance with a written plan of care. [42 U.S.C.S. § 1395i-3\(b\)\(2\)](#). The "as is possible" language of [42 C.F.R. § 483.25\(h\)](#) is more or less consistent with "highest

practicable." The U.S. Supreme Court has distinguished "feasibility analysis" from "cost-benefit analysis" in other regulatory settings, and the "as is possible" regulation is suggestive of the former. In "feasibility," or its equivalent "achievability," analysis, the regulatory agency is required to consider costs of compliance; but only if they are in some sense prohibitive do they provide a defense. *Go To Headnote*

[Sunbridge Care & Rehab. for Pembroke v. Leavitt, 2009 U.S. App. LEXIS 16287](#) (4th Cir July 22, 2009).

**Overview:** *Substantial evidence under [42 U.S.C.S. § 1320a-7\(e\)](#) supported the imposition of civil monetary penalties on a skilled nursing facility for failing to comply with federal health and safety regulations because there were two incidents wherein facility residents were injured by falling out of wheelchairs while being transported in the facility's van.*

- Although the Social Security Act and [42 C.F.R. § 483.25](#) do not specifically mention motor vehicles, the U.S. Department of Health and Human Services has reasonably interpreted § 483.25(h)(1) to authorize the issuance of citations to skilled nursing facilities for violations arising from the use of motor vehicles. This regulation should be interpreted as broadly as is necessary to protect residents in all locations under a facility's control, including facility vehicles, and it would be incongruous to hold that residents travel at their own risk when the facility to which they have entrusted their care transports them off-site. *Go To Headnote*
- [42 C.F.R. § 483.25\(h\)\(1\)](#) requires a facility to ensure that the resident environment remains as free of accident hazards as is possible. *Go To Headnote*
- The regulation regarding accidents applies only to those risks of harm that are foreseeable. To determine whether a facility has complied with [42 C.F.R. § 483.25\(h\)\(1\)](#), a court may evaluate whether the facility has addressed foreseeable risks by identifying and removing hazards, where possible, or, where the hazard is unavoidable because of other resident needs, managing the hazard by reducing the risk of accident to the extent possible. *Go To Headnote*

[Lakeridge Villa Health Care Ctr. v. Leavitt, 2006 U.S. App. LEXIS 27338](#) (6th Cir Nov. 3, 2006) (Unpublished).

**Overview:** *A civil monetary penalty against a nursing care facility for violations of requirements as described in the Social Security Act, [42 U.S.C.S. § 1395i-3\(a\)-\(d\)](#), was upheld per [42 U.S.C.S. § 1320a-7a](#) as supported by substantial evidence as, inter alia, the facility did not prevent accidents and improperly used restraints, and the fine was reasonable.*

- Neither [42 C.F.R. § 483.25\(h\)\(2\)](#) nor the U.S. Court of Appeals for the Sixth Circuit requires that actual harm occur for an immediate jeopardy finding against a nursing facility to be valid. This holding does not impose strict liability but rather requires a nursing facility to take reasonable care to avoid accidents. The question of whether a facility's precautions are reasonable is highly fact-bound and can only be answered on the basis of expertise in nursing home management. As such, it is a question the resolution of which the Sixth Circuit defers to the expert administrative agency, the U.S. Department of Health and Human Services. *Go To Headnote*

[Harmony Court v. Leavitt, 2006 U.S. App. LEXIS 20283](#) (6th Cir Aug. 1, 2006) (Unpublished).

**Overview:** *Substantial evidence supported civil monetary penalties against a skilled nursing facility, which violated several federal regulations in caring for its residents.*

- [42 C.F.R. § 483.25](#) requires a facility to provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychological well-being in accordance with the comprehensive assessment and plan of care. *Go To Headnote*
- [42 C.F.R. § 483.25\(c\)](#) says that a facility must ensure that: (1) a resident who enters the facility without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrates that they were unavoidable; and (2) a resident having pressure sores receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing. *Go To Headnote*
- [42 C.F.R. § 483.25\(d\)\(2\)](#) requires a resident who is incontinent of bladder to receive appropriate treatment and services to prevent urinary tract infections and to restore as much normal bladder function as possible. *Go To Headnote*
- [42 C.F.R. § 483.25\(e\)\(1\)](#) requires a facility to ensure that a resident who enters the facility without a limited range of motion does not experience reduction in range of motion unless the resident's clinical condition demonstrates that a reduction in range of motion is unavoidable. Section 428.25(e)(1) does not contain a difficult-to-work-with exemption. *Go To Headnote*
- [42 C.F.R. § 483.25\(h\)\(1\)](#) requires a facility to ensure that a resident environment remains as free of accident hazards as is possible. Actual harm is not required to impose a penalty; a threat of more-than-minimal harm suffices. *Go To Headnote*
- [42 C.F.R. § 483.25\(h\)\(2\)](#) requires a facility to ensure that each resident receives adequate supervision and assistance devices to prevent accidents. *Go To Headnote*

[Clermont Nursing & Convalescent Ctr. v. Leavitt, 2005 U.S. App. LEXIS 16318](#) (6th Cir Aug. 4, 2005) (Unpublished).

**Overview:** *A civil penalty was properly imposed on a nursing home because substantial evidence existed under [42 U.S.C.S. § 1320a-7a\(e\)](#) to show that pressure sores were not properly treated and prevented under [42 C.F.R. § 483.25\(c\)](#); moreover, accident prevention under § 483.25(h) was inadequate as well.*

- The key requirement under [42 C.F.R. § 483.25\(h\)\(2\)](#) is that the facility must eliminate or reduce the risk of accident to the greatest degree practicable. As a risk-oriented analysis, this does not require that either an accident or resident injury actually occur for a violation to exist. This eliminates the need to establish accident causation in determining whether there was a lack of substantial compliance with this requirement. *Go To Headnote*

[Livingston Care Ctr. v. Dep't of HHS, 388 F.3d 168, 2004 U.S. App. LEXIS 18186](#) (6th Cir Aug. 24, 2004).

**Overview:** *A skilled nursing facility was properly found to be in violation of Medicare participation requirements by failing to prevent residents' pressure sores and failing to provide the pressure-relieving devices indicated in the residents' plans of care.*

- Medicare regulations clearly state that evidence of actual harm is not a prerequisite for a finding of substantial noncompliance. [42 C.F.R. § 488.408](#) provides that every skilled nursing facility is subject to a monetary penalty if there are widespread deficiencies that constitute no actual harm with a potential for more than minimal harm but not immediate jeopardy; or one or more deficiencies that constitute actual harm that is not immediate jeopardy. Since a failure to provide pressure relieving devices represents a potential harm

for its residents, it may be properly sanctioned. Furthermore, the applicable participation requirement mandates that 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. [42 C.F.R. § 483.25](#). This preventive focus of the regulation directs facilities to provide a certain standard of care to prevent the risk of pressure sores for its residents, even if no pressure sores actually develop. That standard of care is tailored for each individual resident in his or her plan of care. [Go To Headnote](#)

[United States Ex Rel. Swan v. Covenant Care, Inc., 279 F. Supp. 2d 1212, 2002 U.S. Dist. LEXIS 26867](#) (ED Cal Aug. 5, 2002).

**Overview:** *Where essential elements of nursing home reform advocate's qui tam claim were disclosed in a prior lawsuit, and the advocate was not an original source of those disclosures, the court lacked subject matter jurisdiction over her False Claims Act suit.*

- The operation of skilled nursing facilities is governed by a comprehensive set of highly detailed and specific Medicare regulations. For example, skilled nursing facilities must formulate a written plan of care for each Medicare resident to ensure that the resident's activities of daily living are maintained and that a resident who is unable to carry out activities of daily living receives the necessary services to maintain good nutrition, grooming, and personal and oral hygiene. [42 C.F.R. § 483.25\(a\)\(2\) \(2001\)](#). In addition, the skilled nursing facility must have sufficient nursing staff to provide nursing and related services to attain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by the resident's individual plan of care and maintain accurate and complete medical records for each resident in accordance with accepted professional standards and practices. [42 C.F.R. §§ 483.30, 483.75\(1\) \(2001\)](#). [Go To Headnote](#)

### **Healthcare Law : Actions Against Facilities : Standards of Care : General Overview**

[Sanctuary at Whispering Meadows v. Thompson, 2005 U.S. App. LEXIS 21820](#) (6th Cir Oct. 7, 2005) (Unpublished).

**Overview:** *Substantial evidence supported ALJ's decision to credit determination of nurse surveyor over facility doctor's conclusions that pressure sores found on patient were unavoidable because doctor expressed the opinion that pressure sores were unavoidable only after it was apparent that the condition would have a serious negative impact on the facility.*

- [42 C.F.R. § 483.25\(c\)\(1\)](#) requires participating facilities to ensure that a resident who enters the facility without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrates that they were unavoidable. [Go To Headnote](#)

[Meadowwood Nursing Home v. United States HHS, 2004 U.S. App. LEXIS 4185](#) (6th Cir Mar. 2, 2004).

**Overview:** *Secretary of Health and Human Services' decision to impose civil monetary penalty on nursing home for failure to maintain nursing home as free of accident hazards as possible was affirmed where there was substantial evidence to support the decision.*

- [42 C.F.R. § 483.25\(h\)\(1\)](#) requires that a facility must ensure that a resident environment remains as free of accident hazards as is possible. [Go To Headnote](#)

[Meadowwood Nursing Home v. United States HHS, 364 F.3d 786, 2004 U.S. App. LEXIS 7260](#) (6th Cir Mar. 2, 2004).

**Overview:** *Decision finding long-term-care facility in non-compliance and imposing monetary penalties was affirmed where there was substantial evidence that it was on notice that condition of beds posed a risk of injury and could have taken steps to avoid harm.*

- [42 C.F.R. § 483.25\(h\)\(1\)](#) requires that a facility must ensure that the resident environment remains as free of accident hazards as is possible. [Go To Headnote](#)

### **Healthcare Law : Actions Against Facilities : Standards of Care : Nursing Facilities**

[Life Care Ctr. Tullahoma v. Sec'y of the United States HHS, 2011 U.S. App. LEXIS 25030](#) (6th Cir Dec. 16, 2011) (Unpublished).

**Overview:** *Based on the notes of the nurse practitioners, the Departmental Appeals Board justifiably concluded that the nursing home breached [42 C.F.R. § 483.10\(b\)\(11\)](#) when its nurses failed to immediately consult a doctor about three residents' cardiovascular and diabetic episodes.*

- [42 C.F.R. § 483.25](#) requires facilities to provide the necessary care and services to attain or maintain residents' highest practicable state of well-being. [Go To Headnote](#)
- [42 C.F.R. § 483.25](#) does not require the Secretary of Health and Human Services to show that the nursing home caused "actual harm" to residents' well-being. Instead, the regulation required the Secretary to show only that the nursing home failed to provide the necessary care and services. [Go To Headnote](#)
- In the context of [42 C.F.R. § 483.25\(m\)\(2\)](#), an error is significant if it has the "potential" to cause harm, and even a single medication error can be significant. The Departmental Appeals Board measures significance according to whether an error involving the drug could result in serious consequences, whether the resident could have easily recovered from the error, and whether there is evidence the error occurred more than once. [Go To Headnote](#)

[Cedar Lake Nursing Home v. United States HHS, 619 F.3d 453, 2010 U.S. App. LEXIS 19068](#) (5th Cir Sept. 13, 2010).

**Overview:** *A nursing home's petition for review of the imposition of a monetary penalty for violating [42 C.F.R. § 483.25\(h\)](#) regarding a resident wandering from its facility was dismissed as it was supported by the evidence in that its actions toward the resident were not reasonable in that it did not take all reasonable steps to prevent her from wandering.*

- [42 C.F.R. § 483.25\(h\)\(1\)-\(2\)](#) require a nursing facility to ensure that the resident environment remains as free of accident hazards as is possible and that each resident receives adequate supervision and assistance devices to prevent accidents. The standard of care imposed by those as is possible and adequate supervision regulations has been consistently interpreted by the United States Department of Health and Human Services and federal courts as a reasonableness standard. [Go To Headnote](#)

[Sunbridge Care & Rehab. for Pembroke v. Leavitt, 2009 U.S. App. LEXIS 16287](#) (4th Cir July 22, 2009).

**Overview:** *Substantial evidence under [42 U.S.C.S. § 1320a-7\(e\)](#) supported the imposition of civil monetary penalties on a skilled nursing facility for failing to comply with federal health and safety regulations because there were two incidents wherein facility residents were injured by falling out of wheelchairs while being transported in the facility's van.*

- [42 C.F.R. § 483.25\(h\)\(1\)](#) requires a facility to ensure that the resident environment remains as free of accident hazards as is possible. [Go To Headnote](#)

- The regulation regarding accidents applies only to those risks of harm that are foreseeable. To determine whether a facility has complied with [42 C.F.R. § 483.25\(h\)\(1\)](#), a court may evaluate whether the facility has addressed foreseeable risks by identifying and removing hazards, where possible, or, where the hazard is unavoidable because of other resident needs, managing the hazard by reducing the risk of accident to the extent possible. *Go To Headnote*

[Liberty Commons Nursing & Rehab Ctr. v. Leavitt, 2008 U.S. App. LEXIS 15459](#) (4th Cir July 18, 2008).

**Overview:** Under [42 U.S.C.S. § 1320a-7a\(e\)](#), DHHS's finding that nursing facility failed to adequately supervise resident and prevent accidents was supported by substantial evidence because resident was able to elope several times after facility had notice that resident was eloping by flipping bypass switch and resident was at high risk for experiencing falls.

- [42 C.F.R. § 483.25\(h\)\(2\)](#) states that a facility must ensure that each resident receives adequate supervision and assistance devices to prevent accidents. An accident is defined in the State Operations Manual issued by the Health Care Financing Administration as an unexpected, unintended event that can cause a resident bodily injury. In order for a facility to be in substantial compliance with this regulation, a provider must have no deficiencies that pose a risk to resident health or safety greater than the potential for causing minimum harm. [42 C.F.R. § 488.301](#). *Go To Headnote*

[Century Care of the Crystal Coast v. Leavitt, 2008 U.S. App. LEXIS 12538](#) (4th Cir June 11, 2008).

**Overview:** Skilled nursing facility was not in compliance with [42 C.F.R. §§ 483.25\(h\)\(2\)](#) and [483.75 \(2007\)](#) because facility did not adequately investigate smoking policy violations or supervise problem smokers and it was foreseeable that mentally impaired resident who was on oxygen and had history of unsafe smoking behaviors might have fire-related accident.

- [42 C.F.R. § 483.25\(h\)\(2\) \(2007\)](#) requires a facility to take reasonable steps to ensure that a resident receives supervision and assistance devices designed to meet his or her assessed needs and to mitigate foreseeable risks of harm from accidents. *Go To Headnote*

[Lakeridge Villa Health Care Ctr. v. Leavitt, 2006 U.S. App. LEXIS 27338](#) (6th Cir Nov. 3, 2006) (Unpublished).

**Overview:** A civil monetary penalty against a nursing care facility for violations of requirements as described in the Social Security Act, [42 U.S.C.S. § 1395i-3\(a\)-\(d\)](#), was upheld per [42 U.S.C.S. § 1320a-7a](#) as supported by substantial evidence as, *inter alia*, the facility did not prevent accidents and improperly used restraints, and the fine was reasonable.

- [42 C.F.R. § 483.25\(h\)\(2\)](#) requires nursing facilities to provide adequate supervision and assistance devices to prevent accidents. *Go To Headnote*
- Neither [42 C.F.R. § 483.25\(h\)\(2\)](#) nor the U.S. Court of Appeals for the Sixth Circuit requires that actual harm occur for an immediate jeopardy finding against a nursing facility to be valid. This holding does not impose strict liability but rather requires a nursing facility to take reasonable care to avoid accidents. The question of whether a facility's precautions are reasonable is highly fact-bound and can only be answered on the basis of expertise in nursing home management. As such, it is a question the resolution of which the Sixth Circuit defers to the expert administrative agency, the U.S. Department of Health and Human Services. *Go To Headnote*

## Healthcare Law : Business Administration & Organization : Judicial Review : Substantial Evidence

[Lakeridge Villa Health Care Ctr. v. Leavitt, 2006 U.S. App. LEXIS 27338](#) (6th Cir Nov. 3, 2006) (Unpublished).

**Overview:** *A civil monetary penalty against a nursing care facility for violations of requirements as described in the Social Security Act, [42 U.S.C.S. § 1395i-3\(a\)-\(d\)](#), was upheld per [42 U.S.C.S. § 1320a-7a](#) as supported by substantial evidence as, inter alia, the facility did not prevent accidents and improperly used restraints, and the fine was reasonable.*

- Neither [42 C.F.R. § 483.25\(h\)\(2\)](#) nor the U.S. Court of Appeals for the Sixth Circuit requires that actual harm occur for an immediate jeopardy finding against a nursing facility to be valid. This holding does not impose strict liability but rather requires a nursing facility to take reasonable care to avoid accidents. The question of whether a facility's precautions are reasonable is highly fact-bound and can only be answered on the basis of expertise in nursing home management. As such, it is a question the resolution of which the Sixth Circuit defers to the expert administrative agency, the U.S. Department of Health and Human Services. *Go To Headnote*

## Healthcare Law : Business Administration & Organization : Licenses : General Overview

[Clermont Nursing & Convalescent Ctr. v. Leavitt, 2005 U.S. App. LEXIS 16318](#) (6th Cir Aug. 4, 2005) (Unpublished).

**Overview:** *A civil penalty was properly imposed on a nursing home because substantial evidence existed under [42 U.S.C.S. § 1320a-7a\(e\)](#) to show that pressure sores were not properly treated and prevented under [42 C.F.R. § 483.25\(c\)](#); moreover, accident prevention under [§ 483.25\(h\)](#) was inadequate as well.*

- [42 C.F.R. § 483.25\(c\)](#) mandates that a facility ensure that a resident who enters the facility without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrates that they were unavoidable. The regulation further requires that a facility ensure that a resident having pressure sores receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing. A pressure sore is defined as damage to the skin or underlying structure as a result of tissue compression and inadequate perfusion. They typically occur in patients who are bed or chair bound. *Go To Headnote*
- [42 C.F.R. § 483.25\(h\)\(2\)](#) requires that a facility ensure that each resident receives adequate supervision and assistance devices to prevent accidents. *Go To Headnote*
- The key requirement under [42 C.F.R. § 483.25\(h\)\(2\)](#) is that the facility must eliminate or reduce the risk of accident to the greatest degree practicable. As a risk-oriented analysis, this does not require that either an accident or resident injury actually occur for a violation to exist. This eliminates the need to establish accident causation in determining whether there was a lack of substantial compliance with this requirement. *Go To Headnote*

[Crestview Parke Care Ctr. v. Thompson, 373 F.3d 743, 2004 U.S. App. LEXIS 13230](#) (6th Cir June 28, 2004).

**Overview:** *Although an ALJ had the power to grant summary judgment upholding a penalty against a skilled nursing facility for violation of federal regulations, summary judgment was improper on disputed questions of the preventability of patients' bedsores.*

- The lack of strict liability in [42 C.F.R. § 483.25\(h\)](#) does not automatically mean that a violation of the general language of § 483.25 is not a strict-liability infraction, but the use of the word "practicable" in § 483.25 suggests that a party can offer reasons for the failure to adhere to a comprehensive plan of care. The regulation employs the phrase "highest practicable physical, mental, and psychosocial well-being," [42 C.F.R. § 483.25](#), which suggests that a reasonableness standard inheres in the regulation. Similar to the word "adequate" in § 483.25(h)(2), "practicable" intimates that it is possible for a petitioner to show that there was a justifiable reason for the violation of § 483.25. Therefore, [42 C.F.R. § 483.25](#) is not a strict-liability regulation. *Go To Headnote*

### **Healthcare Law : Business Administration & Organization : Patient Confidentiality : General Overview**

[Sanctuary at Whispering Meadows v. Thompson, 2005 U.S. App. LEXIS 21820](#) (6th Cir Oct. 7, 2005) (Unpublished).

*Overview:* Substantial evidence supported ALJ's decision to credit determination of nurse surveyor over facility doctor's conclusions that pressure sores found on patient were unavoidable because doctor expressed the opinion that pressure sores were unavoidable only after it was apparent that the condition would have a serious negative impact on the facility.

- [42 C.F.R. § 483.25\(c\)\(1\)](#) requires participating facilities to ensure that a resident who enters the facility without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrates that they were unavoidable. *Go To Headnote*

### **Healthcare Law : Insurance : Reimbursement : Fiscal Intermediaries**

[Windsor Health Ctr. v. Leavitt, 2005 U.S. App. LEXIS 6465](#) (6th Cir Apr. 13, 2005) (Unpublished).

*Overview:* ALJ and Departmental Appeals Board of U.S. Department of Health and Human Services correctly evaluated summary judgment motion of Centers for Medicare and Medicaid Services in finding that skilled nursing facility was noncompliant with [42 C.F.R. § 483.25\(h\)\(2\)](#), which required adequate supervision and assistance devices to prevent accidents.

- [42 C.F.R. § 483.25](#) is not a strict liability regulation. *Go To Headnote*

### **Public Health & Welfare Law : Healthcare : Services for Disabled & Elderly Persons : General Overview**

[Sanctuary at Whispering Meadows v. Thompson, 2005 U.S. App. LEXIS 21820](#) (6th Cir Oct. 7, 2005) (Unpublished).

*Overview:* Substantial evidence supported ALJ's decision to credit determination of nurse surveyor over facility doctor's conclusions that pressure sores found on patient were unavoidable because doctor expressed the opinion that pressure sores were unavoidable only after it was apparent that the condition would have a serious negative impact on the facility.

- [42 C.F.R. § 483.25\(c\)\(1\)](#) requires participating facilities to ensure that a resident who enters the facility without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrates that they were unavoidable. *Go To Headnote*

[Crestview Parke Care Ctr. v. Thompson, 373 F.3d 743, 2004 U.S. App. LEXIS 13230](#) (6th Cir June 28, 2004).

*Overview:* Although an ALJ had the power to grant summary judgment upholding a penalty

*against a skilled nursing facility for violation of federal regulations, summary judgment was improper on disputed questions of the preventability of patients' bedsores.*

- The lack of strict liability in [42 C.F.R. § 483.25\(h\)](#) does not automatically mean that a violation of the general language of § 483.25 is not a strict-liability infraction, but the use of the word "practicable" in § 483.25 suggests that a party can offer reasons for the failure to adhere to a comprehensive plan of care. The regulation employs the phrase "highest practicable physical, mental, and psychosocial well-being," [42 C.F.R. § 483.25](#), which suggests that a reasonableness standard inheres in the regulation. Similar to the word "adequate" in § 483.25(h)(2), "practicable" intimates that it is possible for a petitioner to show that there was a justifiable reason for the violation of § 483.25. Therefore, [42 C.F.R. § 483.25](#) is not a strict-liability regulation. *Go To Headnote*

### **Public Health & Welfare Law : Healthcare : Services for Disabled & Elderly Persons : Care Facilities :**

[Talbot v. Lucy Corr, 1996 U.S. Dist. LEXIS 8886](#) (ED Va Mar. 19, 1996).

**Overview:** *A patient could not pursue a claim under [42 U.S.C.S. § 1983](#) against a nursing home for alleged failure to comply with [42 U.S.C.S. 1395i\(3\)\(c\)](#) because she first was required to exhaust the administrative remedies established by Virginia, pursuant to [42 C.F.R. § 488 et seq.](#)*

- The Secretary of the Department of Health and Human Services has promulgated rules and regulations implementing the Nursing Home Reform Law. These regulations address, among other things: residents rights ([42 C.F.R § 483.10](#)); admission, transfer, and discharge rights ([42 C.F.R § 483.12](#)); resident behavior and facility practices ([42 C.F.R. § 483.13](#)); quality of life ([42 C.F.R. § 483.15](#)); and quality of care ([42 C.F.R. § 483.25](#)). To aid in implementing these requirements and procedures, the administrative scheme includes a state appeals process for transfers and discharges of patients. [42 C.F.R. § 431.205](#). The regulations provide that the state agency responsible for maintaining an appeals system must provide information regarding hearing procedures, notice to the beneficiary of the action that the skilled nursing facility intends to take, the reasons for the intended action, and the specific regulations that require that action. Moreover, a hearing is required for any resident who believes that a skilled nursing facility has transferred or discharged her in error. [42 C.F.R. § 431.220](#). *Go To Headnote*

### **Public Health & Welfare Law : Healthcare : Services for Disabled & Elderly Persons : Care Facilities :**

[Greenbrier Nursing & Rehab. Ctr. v. United States HHS, 686 F.3d 521, 2012 U.S. App. LEXIS 14583](#) (8th Cir July 17, 2012).

**Overview:** *Resident's care plan called for monthly testing, per physician, and physician told state surveyor that patient taking stable dose of drug at issue should have had monitoring once a month. It was reasonable for DHHS to conclude standard of care did not allow staff to send fax to doctor and wait indefinitely for response that might never come.*

- [42 C.F.R. § 483.25](#) requires facilities to provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychological well-being of their residents. The Department of Health and Human Services interprets this regulation to require facilities to meet professional standards of care. Section 483.25(j) requires the facility to provide each resident with sufficient fluid intake to maintain proper hydration and

health. And [42 C.F.R. § § 483.60\(c\)](#) requires that each resident's drug regimen be reviewed at least once a month by a licensed pharmacist and that the pharmacist report any irregularities to the attending physician. *Go To Headnote*

[Windsor Place v. United States HHS, 649 F.3d 293, 2011 U.S. App. LEXIS 12391](#) (5th Cir June 17, 2011).

**Overview:** *Substantial evidence supported a finding that a nursing facility was not in compliance with [42 C.F.R. §§ 483.20\(b\)\(2\)\(ii\)](#) and [483.25\(c\)](#) based on a resident's development of pressure sores; there was a sufficient showing that the sores had an impact on more than one area of the resident's health and that the development of sores was not unavoidable.*

- [42 C.F.R. § 483.25\(c\)](#) requires that a resident who enters a nursing facility without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrates that they were unavoidable. *Go To Headnote*
- [42 C.F.R. § 483.25\(a\)\(3\)](#) requires a nursing facility to ensure that a resident who is unable to carry out activities of daily living receives the necessary services to maintain good nutrition, grooming, and personal and oral hygiene. *Go To Headnote*
- [42 C.F.R. § 483.25\(c\)](#) requires that a nursing facility ensure that a resident who enters the facility without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrates that they were unavoidable. A pressure sore can be considered unavoidable only if routine preventive care is provided. *Go To Headnote*
- [42 C.F.R. § 483.25\(a\)\(3\)](#) requires that a nursing facility ensure that a resident who is unable to carry out activities of daily living receives the necessary services to maintain good nutrition, grooming, and personal and oral hygiene. *Go To Headnote*
- A negative outcome need not occur for the Centers for Medicare & Medicaid Services to find that the service offered by a nursing facility was insufficient. Nothing in the text of [42 C.F.R. § 483.25\(a\)\(3\)](#) indicates that in order for a service to be necessary, a resident first show previous harm from its absence. *Go To Headnote*

[Senior Rehab. & Skilled Nursing Ctr. v. HHS, 2010 U.S. App. LEXIS 25885](#) (5th Cir Dec. 20, 2010).

**Overview:** *Where an ALJ determined that a nursing home was not in substantial compliance with the physician consultation requirement in [42 C.F.R. § 483.10\(b\)\(11\)](#), a statement from the treating physician that the home kept him reasonably and timely informed was the doctor's individual opinion, not evidence of material facts under the governing regulation.*

- The requirement regarding pressure sores is part of the quality of care standards in [42 C.F.R. § 483.25](#), which compels a facility to 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. The subsection on pressure sores states, in part, based on the comprehensive assessment of a resident, the facility must ensure that a resident having pressure sores receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing. [42 C.F.R. § 483.25\(c\)\(2\)](#). *Go To Headnote*

[Fal-Meridian, Inc. v. United States HHS, 604 F.3d 445, 2010 U.S. App. LEXIS 9266](#) (7th Cir May 6, 2010).

**Overview:** *Civil penalty was properly imposed on nursing home for violation of [42 C.F.R. §](#)*

[483.25\(h\)](#) under Medicare and Medicaid provisions, [42 U.S.C.S. §§ 1302, 1395hh](#); placing resident who had feeding tube and strict "nothing by mouth" order with a roommate who did not eat in room would have significantly reduced danger of choking death at reasonable cost.

- The Social Security Act provides that a skilled nursing facility must provide services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, in accordance with a written plan of care. [42 U.S.C.S. § 1395i-3\(b\)\(2\)](#). The "as is possible" language of [42 C.F.R. § 483.25\(h\)](#) is more or less consistent with "highest practicable." The U.S. Supreme Court has distinguished "feasibility analysis" from "cost-benefit analysis" in other regulatory settings, and the "as is possible" regulation is suggestive of the former. In "feasibility," or its equivalent "achievability," analysis, the regulatory agency is required to consider costs of compliance; but only if they are in some sense prohibitive do they provide a defense. *Go To Headnote*

[Universal Healthcare/king v. United States HHS, 2010 U.S. App. LEXIS 2043](#) (4th Cir Jan. 29, 2010).

**Overview:** Findings of the DHHS that a skilled nursing facility was not in compliance with 42 C.F.R. §§ 483, § 483.13(c), 483.60(a), and 483.25, relating to residents' well-being and safety, were supported by substantial evidence, a finding of immediate jeopardy was not clearly erroneous, and the civil monetary penalties that were imposed were reasonable.

- [42 C.F.R. § 483.25](#) requires skilled nursing facilities to provide each patient with high quality care in accordance with the patient's comprehensive assessment. *Go To Headnote*

[Hayward v. Jack's Pharm., Inc., 141 Idaho 622, 115 P.3d 713, 2005 Ida. LEXIS 94](#) (Idaho June 15, 2005).

**Overview:** Medical director was not sometimes a medical director and sometimes a physician; instead, he was at all times some of each, so under Idaho Code § 6-1012, his standard of care included the minimum standards set by applicable state and federal law, not local standards. Decedent's medical malpractice case against him and local pharmacy could proceed.

- Nursing homes are required to follow federal and state guidelines relating to patient care, including the prescription of pharmaceuticals, and that they are responsible when those standards are not met. [42 U.S.C.S. § 1396r; 42 C.F.R. §§ 483.25, 483.60](#); Idaho Admin. Code § 16.03.02.154.01.c. Therefore, it follows that the standard of care for a physician treating a patient in a nursing home would be governed by those standards. *Go To Headnote*

[Livingston Care Ctr. v. Dep't of HHS, 388 F.3d 168, 2004 U.S. App. LEXIS 18186](#) (6th Cir Aug. 24, 2004).

**Overview:** A skilled nursing facility was properly found to be in violation of Medicare participation requirements by failing to prevent residents' pressure sores and failing to provide the pressure-relieving devices indicated in the residents' plans of care.

- Medicare regulations clearly state that evidence of actual harm is not a prerequisite for a finding of substantial noncompliance. [42 C.F.R. § 488.408](#) provides that every skilled nursing facility is subject to a monetary penalty if there are widespread deficiencies that constitute no actual harm with a potential for more than minimal harm but not immediate jeopardy; or one or more deficiencies that constitute actual harm that is not immediate jeopardy. Since a failure to provide pressure relieving devices represents a potential harm for its residents, it may be properly sanctioned. Furthermore, the applicable participation requirement mandates that 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. [42 C.F.R. § 483.25](#). This preventive focus of the regulation directs facilities to provide a certain standard of care to prevent the risk of pressure sores for its residents, even if no pressure sores actually develop. That standard of care is tailored for each individual resident in his or her plan of care. [Go To Headnote](#)

[United States Ex Rel. Swan v. Covenant Care, Inc., 279 F. Supp. 2d 1212, 2002 U.S. Dist. LEXIS 26867 \(ED Cal Aug. 5, 2002\)](#).

**Overview:** *Where essential elements of nursing home reform advocate's qui tam claim were disclosed in a prior lawsuit, and the advocate was not an original source of those disclosures, the court lacked subject matter jurisdiction over her False Claims Act suit.*

- The operation of skilled nursing facilities is governed by a comprehensive set of highly detailed and specific Medicare regulations. For example, skilled nursing facilities must formulate a written plan of care for each Medicare resident to ensure that the resident's activities of daily living are maintained and that a resident who is unable to carry out activities of daily living receives the necessary services to maintain good nutrition, grooming, and personal and oral hygiene. [42 C.F.R. § 483.25\(a\)\(2\) \(2001\)](#). In addition, the skilled nursing facility must have sufficient nursing staff to provide nursing and related services to attain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by the resident's individual plan of care and maintain accurate and complete medical records for each resident in accordance with accepted professional standards and practices. [42 C.F.R. §§ 483.30, 483.75\(1\) \(2001\)](#). [Go To Headnote](#)

## Public Health & Welfare Law : Social Security : General Overview

[Clermont Nursing & Convalescent Ctr. v. Leavitt, 2005 U.S. App. LEXIS 16318 \(6th Cir Aug. 4, 2005\)](#) (Unpublished).

**Overview:** *A civil penalty was properly imposed on a nursing home because substantial evidence existed under [42 U.S.C.S. § 1320a-7a\(e\)](#) to show that pressure sores were not properly treated and prevented under [42 C.F.R. § 483.25\(c\)](#); moreover, accident prevention under [§ 483.25\(h\)](#) was inadequate as well.*

- [42 C.F.R. § 483.25\(c\)](#) mandates that a facility ensure that a resident who enters the facility without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrates that they were unavoidable. The regulation further requires that a facility ensure that a resident having pressure sores receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing. A pressure sore is defined as damage to the skin or underlying structure as a result of tissue compression and inadequate perfusion. They typically occur in patients who are bed or chair bound. [Go To Headnote](#)
- [42 C.F.R. § 483.25\(h\)\(2\)](#) requires that a facility ensure that each resident receives adequate supervision and assistance devices to prevent accidents. [Go To Headnote](#)
- The key requirement under [42 C.F.R. § 483.25\(h\)\(2\)](#) is that the facility must eliminate or reduce the risk of accident to the greatest degree practicable. As a risk-oriented analysis, this does not require that either an accident or resident injury actually occur for a violation to exist. This eliminates the need to establish accident causation in determining whether

there was a lack of substantial compliance with this requirement. *Go To Headnote*

## **Public Health & Welfare Law : Social Security : Medicaid : General Overview**

*Schneller v. Crozer Chester Med. Ctr.*, 2010 U.S. App. LEXIS 14966 (3rd Cir July 20, 2010), writ of certiorari denied by *131 S. Ct. 1684, 179 L. Ed. 2d 617, 2011 U.S. LEXIS 2222, 79 U.S.L.W. 3538 (U.S. 2011)*.

**Overview:** *A district court's dismissal of an individual's case was affirmed since the district court lacked diversity jurisdiction and federal question jurisdiction; inter alia, the individual's § 1983 claim failed, he did not have a private right of action under the Assisted Suicide Funding Restriction Act of 1997 or the federal controlled substances laws.*

- [42 C.F.R. §§ 483.10, 483.13, 483.15](#), and [483.25](#) do not provide a basis for jurisdiction pursuant to [28 U.S.C.S. § 1331](#) because they merely set forth the requirements that a facility must meet in order to qualify to participate in Medicare and Medicaid; they do not confer a private cause of action. *Go To Headnote*

*Meadowwood Nursing Home v. United States HHS*, 2004 U.S. App. LEXIS 4185 (6th Cir Mar. 2, 2004).

**Overview:** *Secretary of Health and Human Services' decision to impose civil monetary penalty on nursing home for failure to maintain nursing home as free of accident hazards as possible was affirmed where there was substantial evidence to support the decision.*

- [42 C.F.R. § 483.25\(h\)\(1\)](#) requires that a facility must ensure that a resident environment remains as free of accident hazards as is possible. *Go To Headnote*

*Woodstock Care Ctr. v. Thompson*, 363 F.3d 583, 2003 U.S. App. LEXIS 23561 (6th Cir Nov. 17, 2003).

**Overview:** *The imposition of a civil monetary fine by the Department of Health and Human Services against a skilled nursing facility was affirmed given the number of elopements that happened in a short period of time and the vulnerable state of the residents.*

- The United States Department of Health and Human Services (HHS) is authorized under [42 U.S.C.S. § 1395i-3\(h\)\(2\)\(B\)\(ii\)](#) to impose a civil monetary penalty on a skilled nursing facility that is out of compliance with [42 C.F.R. § 483.25](#). *Go To Headnote*

*Pa. Prot. & Advocacy, Inc. v. Dep't of Pub. Welfare*, 243 F. Supp. 2d 184, 2003 U.S. Dist. LEXIS 754 (MD Pa Jan. 15, 2003).

**Overview:** *An advocacy group failed to sufficiently establish that a state agency and state officials violated Title XIX of the Social Security Act, the ADA, or the Rehabilitation Act, to survive their motion for summary judgment.*

- [42 C.F.R. § 483.25\(1\)](#) prohibits the unnecessary use of drugs, defined as an excessive dose, use for an excessive duration, or without adequate monitoring, or without adequate indications for its use, or in the presence of adverse effects indicating that the drug should be discontinued or reduced in dosage. [42 C.F.R. § 483.25\(1\)](#). [42 C.F.R. § 483.25\(2\)](#) provides that no antipsychotic drug be given unless necessary and that residents on antipsychotic drugs have their dosage reduced and be given behavioral interventions unless not clinically indicated. [42 C.F.R. § 483.25\(2\)](#). *Go To Headnote*

## Public Health & Welfare Law : Social Security : Medicaid : Coverage : General Overview

[Concourse Rehab. & Nursing Ctr. Inc. v. Whalen, 249 F.3d 136, 2001 U.S. App. LEXIS 8153](#) (2d Cir May 4, 2001).

**Overview:** *New York State Department of Health's use of an actual improvement standard to estimate the number of Medicaid patients who ought to receive restorative therapy was not arbitrary and capricious.*

- Health Care Financing Administration regulations provide that if specialized rehabilitative services are required in a resident's comprehensive plan of care, the facility must either provide those services or obtain those services from an outside source. [42 C.F.R. § 483.45\(a\) \(2000\)](#); [42 C.F.R. 483.25 \(2000\)](#); [42 U.S.C.S. § 1395i-3\(h\)](#). It is the cost of such rehabilitative services that the former Boren Amendment required States to "take into account." [42 U.S.C.S. § 1396a\(a\)\(13\)\(A\)\(repealed\)](#). [Go To Headnote](#)

## Public Health & Welfare Law : Social Security : Medicaid : Coverage : Pharmaceutical Services

[Hayward v. Jack's Pharm., Inc., 141 Idaho 622, 115 P.3d 713, 2005 Ida. LEXIS 94](#) (Idaho June 15, 2005).

**Overview:** *Medical director was not sometimes a medical director and sometimes a physician; instead, he was at all times some of each, so under Idaho Code § 6-1012, his standard of care included the minimum standards set by applicable state and federal law, not local standards. Decedent's medical malpractice case against him and local pharmacy could proceed.*

- Nursing homes are required to follow federal and state guidelines relating to patient care, including the prescription of pharmaceuticals, and that they are responsible when those standards are not met. [42 U.S.C.S. § 1396r](#); [42 C.F.R. §§ 483.25, 483.60](#); Idaho Admin. Code § 16.03.02.154.01.c. Therefore, it follows that the standard of care for a physician treating a patient in a nursing home would be governed by those standards. [Go To Headnote](#)

## Public Health & Welfare Law : Social Security : Medicaid : Negative Actions

[Barbourville Nursing Home v. United States HHS, 2006 U.S. App. LEXIS 8710](#) (6th Cir Apr. 6, 2006) (Unpublished).

**Overview:** *Imposition of civil monetary penalties under [42 U.S.C.S. § 1395i-3\(h\)\(2\)\(B\)\(ii\)](#) by the DHHS against a nursing facility, a Medicare participant, was affirmed because substantial evidence supported the finding that the facility's noncompliance with standards of care was so severe that it warranted the immediate jeopardy level of severity.*

- Federal regulations impose significant requirements on skilled nursing facilities that choose to participate in Medicare and Medicaid. 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. [42 C.F.R. § 483.25](#). Substandard quality of care means one or more deficiencies related to participation requirements under [42 C.F.R. § 483.25](#), which constitute either immediate jeopardy to resident health or safety; a pattern of or widespread actual harm that is not immediate jeopardy; or a widespread potential for more than minimal harm, but less than immediate jeopardy, with no actual harm. [42 C.F.R. § 488.301](#). [Go To Headnote](#)

- The Department of Health and Human Services is authorized to impose a civil monetary penalty on a facility that chooses to participate in Medicare and Medicaid that is out of compliance with [42 C.F.R. § 483.25](#). The Secretary may impose a civil money penalty in an amount not to exceed \$ 10,000 for each day of noncompliance. [42 U.S.C.S. § 1395i-3\(h\)\(2\)\(B\)\(ii\)](#). Penalties in the range of \$ 3,050 -- \$ 10,000 per day are imposed for deficiencies constituting immediate jeopardy. [42 C.F.R. § 488.438\(a\)\(1\)\(I\)](#). *Go To Headnote*
- The standard of care for pressure sores requires facilities that choose to participate in Medicare and Medicaid programs to ensure that (1) a resident who enters the facility without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrates that they were unavoidable; and, (2) a resident having pressure sores receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing. [42 C.F.R. § 483.25\(c\)](#). This preventive focus of the regulation directs facilities to provide a certain standard of care to prevent the risk of pressure sores for its residents, even if no pressure sores actually develop. As the regulations state with respect to infection control: The facility must establish an infection control program under which it: (1) Investigates, controls, and prevents infections in the facility; (2) Decides what procedures, such as isolation, should be applied to an individual resident; and (3) Maintains a record of incidents and corrective actions related to infections. [42 C.F.R. § 483.65\(a\)\(1\)-\(3\)](#). *Go To Headnote*

#### **Public Health & Welfare Law : Social Security : Medicaid : Providers : Payments & Reimbursements :**

[Concourse Rehab. & Nursing Ctr. Inc. v. Whalen, 249 F.3d 136, 2001 U.S. App. LEXIS 8153](#) (2d Cir May 4, 2001).

*Overview:* *New York State Department of Health's use of an actual improvement standard to estimate the number of Medicaid patients who ought to receive restorative therapy was not arbitrary and capricious.*

- Health Care Financing Administration regulations provide that if specialized rehabilitative services are required in a resident's comprehensive plan of care, the facility must either provide those services or obtain those services from an outside source. [42 C.F.R. § 483.45\(a\) \(2000\)](#); [42 C.F.R. 483.25 \(2000\)](#); [42 U.S.C.S. § 1395i-3\(h\)](#). It is the cost of such rehabilitative services that the former Boren Amendment required States to "take into account." [42 U.S.C.S. § 1396a\(a\)\(13\)\(A\)\(repealed\)](#). *Go To Headnote*

#### **Public Health & Welfare Law : Social Security : Medicaid : Providers : Types : Nursing Facilities**

[Life Care Ctr. of Bardstown v. Sec'y of United States HHS, 2013 U.S. App. LEXIS 18657](#) (6th Cir Sept. 6, 2013) (Unpublished).

*Overview:* *A mere finding a skilled nursing facility's policy was in compliance with the Medicare and Medicaid facility administration requirement in [42 C.F.R. § 483.75](#) was not a finding that all of the facility's staff were properly trained to administer that policy.*

- The quality of care standard requires facilities to carry out every applicable physician order and ensure the sufficiency of resident care plans so that each resident receives all of the necessary care and services to attain or maintain the highest practicable physical, mental,

and psychosocial well-being. [42 C.F.R. § 483.25](#). *Go To Headnote*

[Claiborne-Hughes Health Ctr. v. Sebelius](#), 609 F.3d 839, 2010 U.S. App. LEXIS 13126 (6th Cir June 25, 2010).

**Overview:** *Substantial evidence supported the imposition of sanctions against a nursing facility where it, inter alia, failed to notify a resident's family and doctor when there was a significant change in the resident's condition, and where its noncompliance with [42 C.F.R. § 483.10\(b\)\(11\)](#) put other residents in immediate jeopardy.*

- Under federal law, a facility must provide each resident with sufficient fluid intake to maintain proper hydration and health. [42 C.F.R. § 483.25\(j\)](#). *Go To Headnote*

[Fal-Meridian, Inc. v. United States HHS](#), 604 F.3d 445, 2010 U.S. App. LEXIS 9266 (7th Cir May 6, 2010).

**Overview:** *Civil penalty was properly imposed on nursing home for violation of [42 C.F.R. § 483.25\(h\)](#) under Medicare and Medicaid provisions, [42 U.S.C.S. §§ 1302, 1395hh](#); placing resident who had feeding tube and strict "nothing by mouth" order with a roommate who did not eat in room would have significantly reduced danger of choking death at reasonable cost.*

- The Social Security Act provides that a skilled nursing facility must provide services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, in accordance with a written plan of care. [42 U.S.C.S. § 1395i-3\(b\)\(2\)](#). The "as is possible" language of [42 C.F.R. § 483.25\(h\)](#) is more or less consistent with "highest practicable." The U.S. Supreme Court has distinguished "feasibility analysis" from "cost-benefit analysis" in other regulatory settings, and the "as is possible" regulation is suggestive of the former. In "feasibility," or its equivalent "achievability," analysis, the regulatory agency is required to consider costs of compliance; but only if they are in some sense prohibitive do they provide a defense. *Go To Headnote*

[Liberty Commons Nursing & Rehab Ctr. v. Leavitt](#), 2008 U.S. App. LEXIS 15459 (4th Cir July 18, 2008).

**Overview:** *Under [42 U.S.C.S. § 1320a-7a\(e\)](#), DHHS's finding that nursing facility failed to adequately supervise resident and prevent accidents was supported by substantial evidence because resident was able to elope several times after facility had notice that resident was eloping by flipping bypass switch and resident was at high risk for experiencing falls.*

- [42 C.F.R. § 483.25\(h\)\(2\)](#) states that a facility must ensure that each resident receives adequate supervision and assistance devices to prevent accidents. An accident is defined in the State Operations Manual issued by the Health Care Financing Administration as an unexpected, unintended event that can cause a resident bodily injury. In order for a facility to be in substantial compliance with this regulation, a provider must have no deficiencies that pose a risk to resident health or safety greater than the potential for causing minimum harm. [42 C.F.R. § 488.301](#). *Go To Headnote*
- A participant in Medicare and Medicaid funding is obligated to ensure that each resident receives adequate supervision and assistance devices to prevent accidents. [42 C.F.R. § 483.25\(h\)\(2\)](#). The regulation directs a facility to take all reasonable precautions to prevent situations that have the potential for causing harm to a resident. *Go To Headnote*
- The purpose of [42 C.F.R. § 483.25\(h\)\(2\)](#) is to prevent not only actual harm, but also likely harm to a resident. Therefore, a facility is to take all reasonable precautions to prevent

unintended events that can cause a resident bodily injury. The question whether a facility took all reasonable precautions is highly fact-bound and can only be answered on the basis of expertise in nursing home management. As such, it is a question the resolution of which the court of appeals defers to the expert administrative agency. *Go To Headnote*

### **Public Health & Welfare Law : Social Security : Medicare : General Overview**

[Schneller v. Crozer Chester Med. Ctr., 2010 U.S. App. LEXIS 14966](#) (3rd Cir July 20, 2010), writ of certiorari denied by *131 S. Ct. 1684, 179 L. Ed. 2d 617, 2011 U.S. LEXIS 2222, 79 U.S.L.W. 3538 (U.S. 2011)*.

**Overview:** *A district court's dismissal of an individual's case was affirmed since the district court lacked diversity jurisdiction and federal question jurisdiction; inter alia, the individual's § 1983 claim failed, he did not have a private right of action under the Assisted Suicide Funding Restriction Act of 1997 or the federal controlled substances laws.*

- [42 C.F.R. §§ 483.10, 483.13, 483.15, and 483.25](#) do not provide a basis for jurisdiction pursuant to *28 U.S.C.S. § 1331* because they merely set forth the requirements that a facility must meet in order to qualify to participate in Medicare and Medicaid; they do not confer a private cause of action. *Go To Headnote*

[Windsor Health Ctr. v. Leavitt, 2005 U.S. App. LEXIS 6465](#) (6th Cir Apr. 13, 2005) (Unpublished).

**Overview:** *ALJ and Departmental Appeals Board of U.S. Department of Health and Human Services correctly evaluated summary judgment motion of Centers for Medicare and Medicaid Services in finding that skilled nursing facility was noncompliant with [42 C.F.R. § 483.25\(h\)\(2\)](#), which required adequate supervision and assistance devices to prevent accidents.*

- [42 C.F.R. § 483.25](#) is not a strict liability regulation. *Go To Headnote*

[Livingston Care Ctr. v. Dep't of HHS, 388 F.3d 168, 2004 U.S. App. LEXIS 18186](#) (6th Cir Aug. 24, 2004).

**Overview:** *A skilled nursing facility was properly found to be in violation of Medicare participation requirements by failing to prevent residents' pressure sores and failing to provide the pressure-relieving devices indicated in the residents' plans of care.*

- Under [42 C.F.R. § 483.25\(c\)](#), a facility will not be penalized if a pressure sore is identified as medically unavoidable, unless the facility fails to provide services that are necessary for the prevention and healing of the pressure sore. *Go To Headnote*

[Meadowwood Nursing Home v. United States HHS, 2004 U.S. App. LEXIS 4185](#) (6th Cir Mar. 2, 2004).

**Overview:** *Secretary of Health and Human Services' decision to impose civil monetary penalty on nursing home for failure to maintain nursing home as free of accident hazards as possible was affirmed where there was substantial evidence to support the decision.*

- [42 C.F.R. § 483.25\(h\)\(1\)](#) requires that a facility must ensure that a resident environment remains as free of accident hazards as is possible. *Go To Headnote*

### **Public Health & Welfare Law : Social Security : Medicare : Coverage : General Overview**

[Asbury Ctr. v. United States HHS, 2003 U.S. App. LEXIS 20335](#) (6th Cir Oct. 2, 2003) (Unpublished).

**Overview:** *Government's imposition of civil penalties against a Medicare-certified residential nursing facility was affirmed where the facility's lack of compliance with federal regulations contributed to the death of an unmonitored resident.*

- Medicare's quality of care requirement demands that each resident receive, and that all facilities provide, the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the resident's comprehensive assessment and plan of care. [42 C.F.R. § 483.25](#). Specifically, a facility must provide an environment as free from accident hazards as possible and in which residents receive adequate supervision and assistance to prevent accidents. [42 C.F.R. § 483.25\(h\)](#). [Go To Headnote](#)

## **Public Health & Welfare Law : Social Security : Medicare : Providers : Types : Nursing Facilities**

[Villa v. Sebelius, 2013 U.S. App. LEXIS 23796](#) (9th Cir Nov. 26, 2013).

**Overview:** *In case where patient committed suicide, Centers for Medicare and Medicaid Services state surveyors did not err in citing nursing facility for failure to adequately supervise patient under [42 C.F.R. § 483.25\(h\)\(2\)](#) as staff allowed patient to go outside for smoke unsupervised when it was reasonably foreseeable that some accident could have occurred.*

- [42 C.F.R. 483.25\(h\)\(2\)](#) provides that a Medicare-participating nursing facility must ensure that each resident receives adequate supervision and assistance devices to prevent accidents. [Go To Headnote](#)

[Life Care Ctr. of Bardstown v. Sec'y of United States HHS, 2013 U.S. App. LEXIS 18657](#) (6th Cir Sept. 6, 2013) (Unpublished).

**Overview:** *A mere finding a skilled nursing facility's policy was in compliance with the Medicare and Medicaid facility administration requirement in [42 C.F.R. § 483.75](#) was not a finding that all of the facility's staff were properly trained to administer that policy.*

- The quality of care standard requires facilities to carry out every applicable physician order and ensure the sufficiency of resident care plans so that each resident receives all of the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being. [42 C.F.R. § 483.25](#). [Go To Headnote](#)

[Miss. Care Ctr. of Greenville v. United States HHS, 2013 U.S. App. LEXIS 2668](#) (5th Cir Feb. 7, 2013).

**Overview:** *Civil monetary penalties were properly imposed on nursing home because substantial evidence supported (1) determination that the home violated [42 C.F.R. §§ 483.13\(c\)](#) and [483.25\(h\)](#), and (2) designation of immediate jeopardy because the home's failure to prevent or address resident's elopements had potential to result in serious harm to the resident.*

- [42 C.F.R. § 483.25\(h\)](#) requires a facility to ensure that the resident environment remains as free of accident hazards as is possible; and each resident receives adequate supervision and assistance devices to prevent accidents. [Go To Headnote](#)
- [42 C.F.R. 483.25\(h\)](#) requires a skilled nursing facility to ensure that (1) The resident environment remains as free of accident hazards as is possible; and (2) Each resident receives adequate supervision and assistance devices to prevent accidents. The U.S. Department of Health and Human Services and federal courts have interpreted the standard of care

imposed by these "as is possible" and "adequate supervision" regulations as a reasonableness standard. *Go To Headnote*

[Greenbrier Nursing & Rehab. Ctr. v. United States HHS, 686 F.3d 521, 2012 U.S. App. LEXIS 14583](#) (8th Cir July 17, 2012).

**Overview:** *Resident's care plan called for monthly testing, per physician, and physician told state surveyor that patient taking stable dose of drug at issue should have had monitoring once a month. It was reasonable for DHHS to conclude standard of care did not allow staff to send fax to doctor and wait indefinitely for response that might never come.*

- [42 C.F.R. § 483.25](#) requires facilities to provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychological well-being of their residents. The Department of Health and Human Services interprets this regulation to require facilities to meet professional standards of care. Section 483.25(j) requires the facility to provide each resident with sufficient fluid intake to maintain proper hydration and health. And [42 C.F.R. §§ 483.60\(c\)](#) requires that each resident's drug regimen be reviewed at least once a month by a licensed pharmacist and that the pharmacist report any irregularities to the attending physician. *Go To Headnote*

[Windsor Place v. United States HHS, 649 F.3d 293, 2011 U.S. App. LEXIS 12391](#) (5th Cir June 17, 2011).

**Overview:** *Substantial evidence supported a finding that a nursing facility was not in compliance with [42 C.F.R. §§ 483.20\(b\)\(2\)\(ii\)](#) and [483.25\(c\)](#) based on a resident's development of pressure sores; there was a sufficient showing that the sores had an impact on more than one area of the resident's health and that the development of sores was not unavoidable.*

- A negative outcome need not occur for the Centers for Medicare & Medicaid Services to find that the service offered by a nursing facility was insufficient. Nothing in the text of [42 C.F.R. § 483.25\(a\)\(3\)](#) indicates that in order for a service to be necessary, a resident first show previous harm from its absence. *Go To Headnote*

[Jewish Home v. Ctrs. for Medicare & Medicaid Servs., 2011 U.S. App. LEXIS 2681](#) (3rd Cir Feb. 11, 2011), substituted opinion at [693 F.3d 359, 2011 U.S. App. LEXIS 26441 \(3d Cir. 2011\)](#), writ of certiorari denied by [132 S. Ct. 837, 181 L. Ed. 2d 527, 2011 U.S. LEXIS 8695, 80 U.S.L.W. 3333 \(U.S. 2011\)](#), vacated by [2012 U.S. App. LEXIS 16933](#) (3d Cir. Aug. 14, 2012).

**Overview:** *Limits under [42 U.S.C.S. § 1396r\(b\)\(1\)\(B\)](#) on disclosure and use of the records of a nursing facility's quality assurance committee did not apply to contemporaneous incident reports that were not minutes, internal papers, or conclusions of the committee. Fines imposed against the facility did not violate the Equal Protection Clause.*

- [42 C.F.R. § 483.25\(h\)\(2\)](#) requires a facility to ensure that each resident receives adequate supervision and assistance with devices to prevent accidents. *Go To Headnote*

[Cedar Lake Nursing Home v. United States HHS, 619 F.3d 453, 2010 U.S. App. LEXIS 19068](#) (5th Cir Sept. 13, 2010).

**Overview:** *A nursing home's petition for review of the imposition of a monetary penalty for violating [42 C.F.R. § 483.25\(h\)](#) regarding a resident wandering from its facility was dismissed as it was supported by the evidence in that its actions toward the resident were not reasonable in that it did not take all reasonable steps to prevent her from wandering.*

- [42 C.F.R. § 483.25\(h\)](#) requires a nursing home to ensure that the resident environment

remains as free of accident hazards as is possible; and that each resident receives adequate supervision and assistance devices to prevent accidents. *Go To Headnote*

- [42 C.F.R. § 483.25\(h\)\(1\)](#)-(2) require a nursing facility to ensure that the resident environment remains as free of accident hazards as is possible and that each resident receives adequate supervision and assistance devices to prevent accidents. The standard of care imposed by those as is possible and adequate supervision regulations has been consistently interpreted by the United States Department of Health and Human Services and federal courts as a reasonableness standard. *Go To Headnote*

[Claiborne-Hughes Health Ctr. v. Sebelius](#), 609 F.3d 839, 2010 U.S. App. LEXIS 13126 (6th Cir June 25, 2010).

**Overview:** *Substantial evidence supported the imposition of sanctions against a nursing facility where it, inter alia, failed to notify a resident's family and doctor when there was a significant change in the resident's condition, and where its noncompliance with [42 C.F.R. § 483.10\(b\)\(11\)](#) put other residents in immediate jeopardy.*

- Under federal law, a facility must provide each resident with sufficient fluid intake to maintain proper hydration and health. [42 C.F.R. § 483.25\(j\)](#). *Go To Headnote*

[Fal-Meridian, Inc. v. United States HHS](#), 604 F.3d 445, 2010 U.S. App. LEXIS 9266 (7th Cir May 6, 2010).

**Overview:** *Civil penalty was properly imposed on nursing home for violation of [42 C.F.R. § 483.25\(h\)](#) under Medicare and Medicaid provisions, [42 U.S.C.S. §§ 1302](#), 1395hh; placing resident who had feeding tube and strict "nothing by mouth" order with a roommate who did not eat in room would have significantly reduced danger of choking death at reasonable cost.*

- The Social Security Act provides that a skilled nursing facility must provide services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, in accordance with a written plan of care. [42 U.S.C.S. § 1395i-3\(b\)\(2\)](#). The "as is possible" language of [42 C.F.R. § 483.25\(h\)](#) is more or less consistent with "highest practicable." The U.S. Supreme Court has distinguished "feasibility analysis" from "cost-benefit analysis" in other regulatory settings, and the "as is possible" regulation is suggestive of the former. In "feasibility," or its equivalent "achievability," analysis, the regulatory agency is required to consider costs of compliance; but only if they are in some sense prohibitive do they provide a defense. *Go To Headnote*

[Liberty Commons Nursing & Rehab Ctr. v. Leavitt](#), 2008 U.S. App. LEXIS 15459 (4th Cir July 18, 2008).

**Overview:** *Under [42 U.S.C.S. § 1320a-7a\(e\)](#), DHHS's finding that nursing facility failed to adequately supervise resident and prevent accidents was supported by substantial evidence because resident was able to elope several times after facility had notice that resident was eloping by flipping bypass switch and resident was at high risk for experiencing falls.*

- [42 C.F.R. § 483.25\(h\)\(2\)](#) states that a facility must ensure that each resident receives adequate supervision and assistance devices to prevent accidents. An accident is defined in the State Operations Manual issued by the Health Care Financing Administration as an unexpected, unintended event that can cause a resident bodily injury. In order for a facility to be in substantial compliance with this regulation, a provider must have no deficiencies that pose a risk to resident health or safety greater than the potential for causing minimum harm. [42 C.F.R. § 488.301](#). *Go To Headnote*

- A participant in Medicare and Medicaid funding is obligated to ensure that each resident receives adequate supervision and assistance devices to prevent accidents. [42 C.F.R. § 483.25\(h\)\(2\)](#). The regulation directs a facility to take all reasonable precautions to prevent situations that have the potential for causing harm to a resident. *Go To Headnote*
- The purpose of [42 C.F.R. § 483.25\(h\)\(2\)](#) is to prevent not only actual harm, but also likely harm to a resident. Therefore, a facility is to take all reasonable precautions to prevent unintended events that can cause a resident bodily injury. The question whether a facility took all reasonable precautions is highly fact-bound and can only be answered on the basis of expertise in nursing home management. As such, it is a question the resolution of which the court of appeals defers to the expert administrative agency. *Go To Headnote*

[Livingston Care Ctr. v. Dep't of HHS, 388 F.3d 168, 2004 U.S. App. LEXIS 18186](#) (6th Cir Aug. 24, 2004).

**Overview:** *A skilled nursing facility was properly found to be in violation of Medicare participation requirements by failing to prevent residents' pressure sores and failing to provide the pressure-relieving devices indicated in the residents' plans of care.*

- Medicare regulations clearly state that evidence of actual harm is not a prerequisite for a finding of substantial noncompliance. [42 C.F.R. § 488.408](#) provides that every skilled nursing facility is subject to a monetary penalty if there are widespread deficiencies that constitute no actual harm with a potential for more than minimal harm but not immediate jeopardy; or one or more deficiencies that constitute actual harm that is not immediate jeopardy. Since a failure to provide pressure relieving devices represents a potential harm for its residents, it may be properly sanctioned. Furthermore, the applicable participation requirement mandates that 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. [42 C.F.R. § 483.25](#). This preventive focus of the regulation directs facilities to provide a certain standard of care to prevent the risk of pressure sores for its residents, even if no pressure sores actually develop. That standard of care is tailored for each individual resident in his or her plan of care. *Go To Headnote*

[Woodstock Care Ctr. v. Thompson, 363 F.3d 583, 2003 U.S. App. LEXIS 23561](#) (6th Cir Nov. 17, 2003).

**Overview:** *The imposition of a civil monetary fine by the Department of Health and Human Services against a skilled nursing facility was affirmed given the number of elopements that happened in a short period of time and the vulnerable state of the residents.*

- The United States Department of Health and Human Services (HHS) is authorized under [42 U.S.C.S. § 1395i-3\(h\)\(2\)\(B\)\(ii\)](#) to impose a civil monetary penalty on a skilled nursing facility that is out of compliance with [42 C.F.R. § 483.25](#). *Go To Headnote*

[United States Ex Rel. Swan v. Covenant Care, Inc., 279 F. Supp. 2d 1212, 2002 U.S. Dist. LEXIS 26867](#) (ED Cal Aug. 5, 2002).

**Overview:** *Where essential elements of nursing home reform advocate's qui tam claim were disclosed in a prior lawsuit, and the advocate was not an original source of those disclosures, the court lacked subject matter jurisdiction over her False Claims Act suit.*

- The operation of skilled nursing facilities is governed by a comprehensive set of highly detailed and specific Medicare regulations. For example, skilled nursing facilities must

formulate a written plan of care for each Medicare resident to ensure that the resident's activities of daily living are maintained and that a resident who is unable to carry out activities of daily living receives the necessary services to maintain good nutrition, grooming, and personal and oral hygiene. [42 C.F.R. § 483.25\(a\)\(2\) \(2001\)](#). In addition, the skilled nursing facility must have sufficient nursing staff to provide nursing and related services to attain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by the resident's individual plan of care and maintain accurate and complete medical records for each resident in accordance with accepted professional standards and practices. [42 C.F.R. §§ 483.30, 483.75\(1\) \(2001\)](#). [Go To Headnote](#)

### **Public Health & Welfare Law : Social Services : Disabled & Elderly Persons : Agency Actions & Procedures :**

[Sunbridge Care & Rehab. for Pembroke v. Leavitt, 2009 U.S. App. LEXIS 16287](#) (4th Cir July 22, 2009). *Overview: Substantial evidence under [42 U.S.C.S. § 1320a-7\(e\)](#) supported the imposition of civil monetary penalties on a skilled nursing facility for failing to comply with federal health and safety regulations because there were two incidents wherein facility residents were injured by falling out of wheelchairs while being transported in the facility's van.*

- The regulation regarding accidents applies only to those risks of harm that are foreseeable. To determine whether a facility has complied with [42 C.F.R. § 483.25\(h\)\(1\)](#), a court may evaluate whether the facility has addressed foreseeable risks by identifying and removing hazards, where possible, or, where the hazard is unavoidable because of other resident needs, managing the hazard by reducing the risk of accident to the extent possible. [Go To Headnote](#)

### **Public Health & Welfare Law : Social Services : Disabled & Elderly Persons : Agency Actions & Procedures :**

[Cedar Lake Nursing Home v. United States HHS, 619 F.3d 453, 2010 U.S. App. LEXIS 19068](#) (5th Cir Sept. 13, 2010).

*Overview: A nursing home's petition for review of the imposition of a monetary penalty for violating [42 C.F.R. § 483.25\(h\)](#) regarding a resident wandering from its facility was dismissed as it was supported by the evidence in that its actions toward the resident were not reasonable in that it did not take all reasonable steps to prevent her from wandering.*

- [42 C.F.R. § 483.25\(h\)](#) requires a nursing home to ensure that the resident environment remains as free of accident hazards as is possible; and that each resident receives adequate supervision and assistance devices to prevent accidents. [Go To Headnote](#)
- [42 C.F.R. § 483.25\(h\)\(1\)-\(2\)](#) require a nursing facility to ensure that the resident environment remains as free of accident hazards as is possible and that each resident receives adequate supervision and assistance devices to prevent accidents. The standard of care imposed by those as is possible and adequate supervision regulations has been consistently interpreted by the United States Department of Health and Human Services and federal courts as a reasonableness standard. [Go To Headnote](#)

## Real Property Law : Zoning & Land Use : Comprehensive Plans

[Crestview Parke Care Ctr. v. Thompson, 373 F.3d 743, 2004 U.S. App. LEXIS 13230](#) (6th Cir June 28, 2004).

**Overview:** *Although an ALJ had the power to grant summary judgment upholding a penalty against a skilled nursing facility for violation of federal regulations, summary judgment was improper on disputed questions of the preventability of patients' bedsores.*

- The lack of strict liability in [42 C.F.R. § 483.25\(h\)](#) does not automatically mean that a violation of the general language of § 483.25 is not a strict-liability infraction, but the use of the word "practicable" in § 483.25 suggests that a party can offer reasons for the failure to adhere to a comprehensive plan of care. The regulation employs the phrase "highest practicable physical, mental, and psychosocial well-being," [42 C.F.R. § 483.25](#), which suggests that a reasonableness standard inheres in the regulation. Similar to the word "adequate" in § 483.25(h)(2), "practicable" intimates that it is possible for a petitioner to show that there was a justifiable reason for the violation of § 483.25. Therefore, [42 C.F.R. § 483.25](#) is not a strict-liability regulation. *Go To Headnote*

[Concourse Rehab. & Nursing Ctr. Inc. v. Whalen, 249 F.3d 136, 2001 U.S. App. LEXIS 8153](#) (2d Cir May 4, 2001).

**Overview:** *New York State Department of Health's use of an actual improvement standard to estimate the number of Medicaid patients who ought to receive restorative therapy was not arbitrary and capricious.*

- Health Care Financing Administration regulations provide that if specialized rehabilitative services are required in a resident's comprehensive plan of care, the facility must either provide those services or obtain those services from an outside source. [42 C.F.R. § 483.45\(a\) \(2000\)](#); [42 C.F.R. 483.25 \(2000\)](#); [42 U.S.C.S. § 1395i-3\(h\)](#). It is the cost of such rehabilitative services that the former Boren Amendment required States to "take into account." [42 U.S.C.S. § 1396a\(a\)\(13\)\(A\)\(repealed\)](#). *Go To Headnote*

## Torts : Negligence : Standards of Care : Special Care : Highly Skilled Professionals

[Hayward v. Jack's Pharm., Inc., 141 Idaho 622, 115 P.3d 713, 2005 Ida. LEXIS 94](#) (Idaho June 15, 2005).

**Overview:** *Medical director was not sometimes a medical director and sometimes a physician; instead, he was at all times some of each, so under Idaho Code § 6-1012, his standard of care included the minimum standards set by applicable state and federal law, not local standards. Decedent's medical malpractice case against him and local pharmacy could proceed.*

- Nursing homes are required to follow federal and state guidelines relating to patient care, including the prescription of pharmaceuticals, and that they are responsible when those standards are not met. [42 U.S.C.S. § 1396r](#); [42 C.F.R. §§ 483.25, 483.60](#); Idaho Admin. Code § 16.03.02.154.01.c. Therefore, it follows that the standard of care for a physician treating a patient in a nursing home would be governed by those standards. *Go To Headnote*

**NOTES APPLICABLE TO ENTIRE CHAPTER:**

[PUBLISHER'S NOTE: Nomenclature changes affecting Chapter IV appear at 45 FR 53806, Aug. 13, 1980; 50 FR 12741, Mar. 29, 1985; [50 FR 33034](#), Aug. 16, 1985; 51 FR 41338, Nov. 14, 1986; 53 FR 6634, Mar. 2, 1988; 53 FR 47201, Nov. 22, 1988; 56 FR 8852, Mar. 1, 1991; [66 FR 39450, 39452](#), July 31, 2001; [67 FR 36539, 36540](#), May 24, 2002; [77 FR 29002, 29028](#), May 16, 2012.]

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