Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Britthaven of New Bern	)	
(CCN: 34-5211),	)	Date: September 2, 2008
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-08-70
	)	Decision No. CR1837
Centers for Medicare & Medicaid	)	
Services.	)	
	)	

DECISION

I sustain the determination of the Centers for Medicare & Medicaid Services (CMS) to impose remedies against Petitioner, Britthaven of New Bern, a skilled nursing facility which participates in the Medicare program and which does business in the State of North Carolina. All of these remedies address failures by Petitioner to comply substantially with Medicare participation requirements. The remedies I sustain are civil money penalties of:

- $250 per day for each day of a period beginning on July 14 and running through July 15, 2007;

- $4050 per day for each day of a period beginning on July 16 and running through July 18, 2007; and

- $200 per day for each day of a period beginning on July 19 and running through August 30, 2007.

I. Background

Petitioner's participation in Medicare as a skilled nursing facility is governed by sections 1819 and 1866 of the Social Security Act and by regulations at 42 C.F.R. Parts 483 and 488. Its right to a hearing in this case is governed by regulations at 42 C.F.R. Part 498.

Petitioner was surveyed for compliance with Medicare participation requirements in surveys that ended on July 25 (July survey) and on August 28 (August survey) 2007. The surveyors found noncompliance at each of these surveys. These noncompliance findings included two findings, made at the July survey, that Petitioner's noncompliance was so egregious as to pose immediate jeopardy for its residents. Regulations define "immediate jeopardy" as being noncompliance that causes or has the likelihood of causing serious injury, harm, impairment, or death to residents of a facility. 42 C.F.R. § 488.301. CMS accepted the surveyors' findings and determined to impose the remedies that I describe in this decision's opening paragraph.

Petitioner requested a hearing and the case was assigned to me for a hearing and a decision. The parties completed pre-hearing exchanges of proposed exhibits and briefs. I scheduled the case for an in-person hearing. CMS then moved for summary disposition and Petitioner opposed the motion. I conferred with the parties and they agreed that the case could be decided based on their written submissions. I therefore cancelled the in-person hearing and provided the parties with the opportunity to submit final briefs. Each party submitted a final brief. I then directed CMS to submit additional clarifying comments to address some ambiguities that I identified in its brief. CMS complied and Petitioner responded to that.[1]

CMS submitted proposed exhibits which it identified as CMS Ex. 1 - CMS Ex. 52. Petitioner submitted proposed exhibits which it identified as P. Ex. 1 - P. Ex. 23. I receive all of these exhibits into evidence.[2]

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[1] In its several briefs, CMS continues to advocate at times that I issue summary disposition in its favor. But, although some of the facts of this case are undisputed, summary disposition is not at issue here. Rather, the parties have agreed to have their cases tried based on their written submissions which include the written direct testimony of several witnesses.

[2] CMS submitted two amended exhibit lists and additional exhibits after it had completed its pre-hearing exchange. With its first amended exhibit list, CMS added four new exhibits, CMS Ex. 53 - CMS Ex. 56. With its second amended exhibit list, CMS added two additional new exhibits, CMS Ex. 57 and CMS Ex. 58. I am excluding CMS

II. Issues, findings of fact and conclusions of law

A. Issues

The issues in this case are whether:

1. Petitioner failed to comply substantially with Medicare participation requirements at the July and August surveys.

2. CMS's determination that Petitioner's noncompliance at the July survey constituted immediate jeopardy level noncompliance is clearly erroneous.

3. Petitioner's non-immediate jeopardy level compliance persisted through August 30, 2007.

4. CMS's remedy determinations are reasonable.

B. Findings of fact and conclusions of law

I make findings of fact and conclusions of law (Findings) to support my decision. I set forth each Finding below as a separate heading.

1. Petitioner was noncompliant with Medicare participation requirements as of the July survey.

Here I address the two immediate jeopardy level findings of noncompliance that were made at the July survey. There was a third finding of noncompliance, an alleged failure by Petitioner to comply with the requirements of 42 C.F.R. § 483.12(a)(7), about which neither party has provided argument, and which I do not address.

Ex. 53 - CMS Ex. 58 because CMS failed to file them timely, and failed to make a showing of good cause for not filing the exhibits timely. My initial pre-hearing order in this case made it plain to the parties that I expected that they would file *all* of their proposed exhibits with their initial exchanges and that I would allow a party to supplement its exchange only with a showing of good cause and an absence of prejudice to the opposing party. CMS has not made either showing here.

a. Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.13(a).

The regulation which is at issue here states that a resident of a skilled nursing facility has a right to be free from any physical or chemical restraints imposed by a facility for purposes of discipline or convenience and not required to treat the resident's medical symptoms. CMS alleges that Petitioner restrained four of its residents inappropriately. These residents are identified in the July survey report as Residents #s 1, 2, 3, and 4. CMS Ex. 16, at 6.

The undisputed facts establish that Petitioner imposed involuntary restraints on all of these residents as a measure to prevent them from falling. Each of these residents had medical and or psychological problems that placed him or her at great risk for falls. Some of them had a history of falling. The interventions that Petitioner adopted to address this problem included tying the residents to their wheelchairs with non self-releasing seatbelts. CMS argues that Petitioner's use of involuntary restraints was wrong, both as a matter of law and as a matter of sound nursing practice. It contends that involuntary restraints are never appropriate tools for dealing with fall risks. In fact, according to CMS, the use of such devices actually increases the likelihood that residents will sustain injurious falls.

I find CMS's arguments to be well-supported by the evidence. There simply was no legitimate justification for Petitioner's use of involuntary restraints as a protective measure.

These residents shared common characteristics and the care that Petitioner provided to them had similar features. Each of these residents was an elderly individual with debilitating physical and/or mental impairments. Resident # 1 was 73 years old and suffered from congestive heart failure, a below-the-knee amputation of his right leg, Parkinson's disease, and depression. CMS Ex. 16, at 7; CMS Ex. 18, at 1-4; CMS Ex. 19, at 2. Resident # 2 was aged 71 years, and had diagnoses of late stage Parkinson's disease, diabetes, stroke, renal insufficiency, and ambulatory dysfunction. CMS Ex. 16, at 20; CMS Ex. 21, at 2. Resident # 3 was 78 years old and had suffered a stroke, mental status change, and depression. CMS Ex. 16, at 22; CMS Ex. 22, at 7. Resident # 4 was 92 years old and had diagnoses including dementia, anxiety, and depression. CMS Ex. 16, at 23.

Each of the four residents was prone to sustaining falls. Resident # 1 experienced several falls during the approximately three weeks that he resided in Petitioner's facility. CMS Ex. 18, at 7, 12, 16, 17, 26. Resident # 2 was identified by Petitioner's staff as being at risk for falling. CMS Ex. 21, at 11. Resident # 3 had been identified by the staff as being a fall risk and, in fact, the resident sustained a fall from her wheelchair on March 26,

2007. CMS Ex. 22, at 7; CMS Ex. 23, at 9. Resident # 4 was identified as having an unsteady gait which put her at risk for sustaining falls. CMS Ex. 24, at 3.

The evidence establishes further that Petitioner's staff attempted various interventions with each of these residents in order to protect them against falling. However, the staff decided that each required an involuntary physical restraint. Petitioner obtained a physician's order for involuntary physical restraints for each of the four residents. CMS Ex. 18, at 10-11; CMS Ex. 21, at 54, 56; CMS Ex. 23, at 1, 9; P. Ex. 18, at 7-8. Petitioner's staff tied all of these residents to their wheelchairs with non self-releasing seat belts. CMS Ex. 18, at 24-25; CMS Ex. 21, at 63; CMS Ex. 23, at 9; CMS Ex. 24, at 1-2.

The use of involuntary restraints by skilled nursing facilities has long been a controversial issue. More than 20 years ago, experts reached a consensus that the overuse of physical restraints and the harm caused by their use constituted a major problem in such facilities. CMS Ex. 50, at 1-2.[3] I take notice that the Secretary's principal purpose in adopting 42 C.F.R. § 483.13(a) was to assure that facilities used restraints only in circumstances where residents' medical conditions made their use absolutely necessary. *See id.*

That intent is restated in a policy memorandum, issued on June 22, 2007, from the director of CMS's survey and certification group to State survey agency directors. CMS Ex. 35. The purpose of the memorandum is to describe the circumstances where use of physical restraints may be appropriate. The memorandum reiterates the Secretary's policy that restraints may be used by a facility under only the most limited circumstances. It states that a resident may not be restrained unless he or she has a specific medical symptom that cannot be addressed by another, less restrictive intervention. *Id*. at 2. Furthermore, the restraint must be required to treat a resident's symptom, to protect his or her safety, and help him or her attain or maintain his or her highest level of physical or psychological well-being.

[3] The clinical literature about restraints, some of which I discuss in this decision, focuses on the risks that these devices pose for residents as opposed to the possible benefits that they may produce. The dry tone of these analyses fails at times to capture the essential nature of a restraint. When a nursing facility resident is restrained involuntarily that individual is subjected to limitations on his or her freedom of movement which exceed those which are imposed by our prisons on their inmates.

The memorandum additionally makes it clear that a heavy burden lies on a facility that seeks to justify using a restraint. A physician's order does not justify a facility using a restraint where that measure is not supported by the resident's entire medical record. CMS Ex. 35, at 2.

Most pertinent to this case is that the memorandum proscribes using restraints as a mechanism for protecting residents against falling:

> *Falls do not constitute self-injurious behavior or a medical symptom that warrants the use of a physical restraint.* Although restraints have been traditionally used as a falls prevention approach, they have major, serious drawbacks and can contribute to serious injuries. There is no evidence that the use of physical restraints . . . will prevent or reduce falls. Additionally, falls that occur while a person is physically restrained often result in more severe injuries.

Id. at 3 (emphasis added).

Thus, and as a matter of policy, involuntary restraints may not be used as a falls protection device. The risks to residents of physical and psychological injury resulting from the use of restraints outweigh any possible benefits that may be obtained from their use.

This policy is supported by the professional literature. The policy memorandum rests on journal articles which find that restraints do not protect residents against sustaining falls. CMS Ex. 35, at 3 n.1. The weight of professional opinion is that restraints do not reduce the likelihood that residents will sustain falls but, rather, increase that likelihood. CMS Ex. 52, at 5

The fact that Petitioner, by its own admission, used involuntary restraints as a falls prevention measure establishes Petitioner not to be compliant with regulatory policy. Petitioner's actions were improper as a matter of law. They contravened professionally recognized standards of care. And, they were also ineffective.

The ineffectiveness of Petitioner's use of restraints is demonstrated by the history at Petitioner's facility of Resident # 1, who is one of the four residents whose care is at issue. This resident was at a very high risk for falls while at Petitioner's facility. He was at times agitated, he manifested irrational behavior, and he fell often from his wheelchair. Petitioner's solutions to the problems posed by the resident's propensity to fall included

tying him to his wheelchair with a non self-releasing restraint. The consequences of restraining the resident were not beneficial. The resident's propensity for sustaining falls did not diminish as a consequence of being restrained. His level of agitation increased. And, in fact he fell at least twice after Petitioner's staff restrained him.

On July 10, 2007, Petitioner's staff obtained an order from a physician for a non self-releasing seatbelt to be applied to Resident # 1. CMS Ex. 18, at 10. The evidence establishes that the resident became increasingly agitated after being restrained and he continued to fall. On July 14, 2007, the resident was observed to be very agitated. He loosened his seatbelt and attempted to pull it over his head. CMS Ex. 18, at 14. He remained agitated on the following day. *Id.* at 15. On July 16, 2007, at about 5:30 p.m., the resident was found to be lying in front of his wheelchair on the floor of Petitioner's dining room. P. Ex. 11, at 89. The stitching on his seatbelt had broken. The resident was put back in his wheelchair and tied in with a new non-releasing belt. At about 9:00 p.m. on that same evening, Petitioner's staff found the resident lying on the floor on his right side, having tipped over the wheelchair in an evident attempt to free himself from his restraint. *Id.* Petitioner's staff restrained the resident in a "rock and go" wheelchair in an effort to prevent the resident from tipping his chair over. On July 17, 2007, the staff noted that the resident's agitation had increased. He was observed to be grasping at the facility's walls and on wall safety rails and jerking on them. *Id.* The staff administered Ativan, a tranquilizer, to the resident, with little effect. *Id.* On the evening of July 17, the resident was found sitting on the floor of Petitioner's TV room. CMS Ex. 18, at 17.

The resident was briefly hospitalized on July 17, 2007. He returned to Petitioner's facility on July 18, at which time he was again restrained and provided with continuous monitoring. However, on July 22, 2007, the resident became extremely agitated and attempted to scoot out of his restraint and the "rock and go" wheelchair. CMS Ex. 18, at 21.

I have considered the arguments that Petitioner makes in support of its restraining the four residents whose care is at issue here. I find these arguments to be unpersuasive.

Petitioner argues that "the crux of the dispute" between it and CMS is that Petitioner believes that the circumstances pursuant to which a skilled nursing facility may use involuntary restraints includes protection of residents who are at high risk for sustaining falls. Petitioner's final brief at 6. According to Petitioner skilled nursing facilities have traditionally and appropriately used restraints to protect residents against sustaining falls and its use of these restraints in the cases of Residents #s 1, 2, 3, and 4 is consistent with such allegedly traditional use. In its eyes, the policy memorandum that I discuss above represents a departure from tradition and from professionally recognized standards of care. Petitioner adds that, even if the memorandum now constitutes the Secretary's

binding policy precluding use of restraints for falls protection, it should not be held accountable for violating that policy inasmuch as this allegedly new policy was effectuated only weeks before the July survey took place.

I disagree with Petitioner's assertions that the policy prohibiting involuntary restraints as a falls prevention measure states a new policy or is a departure from professionally recognized standards of care governing the use of restraints. The memorandum captures the weight of professional opinion that has accumulated over decades of experience. As I discuss above, the policy memorandum is grounded on numerous journal articles which hold that using restraints as a falls protection measure is never in the interest of residents. CMS Ex. 35, at 3 n.1.

Additional long-standing professional opinion not cited in the memorandum supports the policy prohibiting use of involuntary restraints as a falls prevention measure. In 1994, thirteen years prior to the July survey, two physicians who studied the issue of restraints use in nursing homes stated:

> The most common and apparently misguided use of restraints is to prevent falls. The risk factors for being restrained and for falling substantially overlap. Falls are very common in restrained patients. *There is evidence that restraints do not decrease fall-related injuries*.

Steven H. Miles, M.D., and Roberta Meyers, M.D., *Untying the Elderly, 1989 to 1993 Update*, CLINICS IN GERIATRIC MEDICINE, Vol. 10, No. 3, August 1994, at 513 (emphasis added) (citations omitted). Dr. Miles, whose expert testimony was provided by CMS, testified that:

> [S]cientific literature has long dispelled the notion that restraints are effective in preventing falls. Not only are restraints not effective in preventing falls but studies have shown that restraints can increase the risk of serious injuries from falling.

CMS Ex. 52, at 5.

Petitioner argues that CMS's ban on the use of restraints to prevent falls depends on a rationale which is inapplicable to a specific subgroup of residents. According to Petitioner these residents comprise precisely the type of residents whose care is at issue here. They are those residents who are confused, elderly, and non-ambulatory or who are unable to transfer or ambulate safely without staff assistance, and who lack the judgment to seek necessary assistance. Petitioner's final brief at 10. Petitioner contends that while others may not benefit from the use of restraints the residents who are part of this

subgroup do benefit from such measures. Consequently, according to Petitioner, its restraining the four residents whose care is at issue, all asserted to be members of the subgroup that benefits from restraints, was consistent with professionally recognized standards of care.

As support for this contention Petitioner cites a single journal article, Capezuti et al., *Physical Restraint Use and Falls in Nursing Home Residents*, 44 JOURNAL OF THE AMERICAN GERIATRIC SOCIETY, 627-633, 631 (1996). Petitioner relies on the following statement in that article:

> Restraint use with nonambulatory residents, both confused and nonconfused, was associated with a lower risk of falls and injuries.

Id. Petitioner did not supply this article nor did it explain the methodology used for its purported conclusion. I do not find the single citation relied on by Petitioner to be persuasive in the absence of any explanation of the article's contents and methodology. At most it comprises an outlier analysis that contradicts a large body of literature which states a different conclusion. Petitioner did not buttress this article with any empirical evidence or expert testimony which refutes the mass of expert opinion provided by CMS or which shows that the policy prohibiting use of restraints for falls protection is unsupported.

I take notice also that the article's principal author co-authored another article in 1998 which states a conclusion that is entirely consistent with mainstream thought about the benefits of restraints as a falls prevention measure:

> Based on the multiple logistic regression analysis, there was no indication of increased risk of falls or injuries with restraint removal. Moreover, restraint removal significantly decreased the chance of minor injuries due to falls . . . CONCLUSIONS: Physical restraint removal does not lead to increases in falls or subsequent fall-related injury in older nursing home residents.

Capezuti et. al, *The Relationship Between Physical Restraint Removal and Falls and Injuries Among Nursing Home Residents*, 53 JOURNALS OF GERONTOLOGY SERIES A: BIOLOGICAL SCIENCES AND MEDICAL SCIENCES, Issue 1, at M47-M52 (1998).

But, even assuming that the regulation governing the use of restraints hypothetically permits these devices to be used by a facility to protect a resident or residents against falling, I do not find that Petitioner established that restraining its residents was a

necessary element of their care. Petitioner has not made a credible showing that any of the residents whose care is at issue actually benefitted by being restrained.

Petitioner's case boils down to contending that it had tried every other intervention its staff could think of to protect the residents whose care is at issue without obtaining an effective level of protection. Consequently, according to Petitioner, it restrained these residents as an intervention of last resort. I find that to be an inadequate justification for the use of restraints. Restraining residents because other interventions have not worked to protect them is not justified given the great mass of professional opinion and empirical evidence to the effect that restraining falls prone residents actually *increases* their risk of falling.

While I have no doubt that these residents' propensities for falling were caused by underlying medical conditions and that their instability and lack of judgment merited aggressive care by Petitioner and its staff, I do not find that Petitioner established that restraining the residents was an appropriate intervention.[4] Petitioner has simply not adduced evidence showing why, as a matter of logic and sound nursing care, restraining these residents would have helped them.

Indeed, the weight of the evidence in this case establishes that, at least insofar as Resident # 1 is concerned, the resident did not benefit from the use of restraints. Resident # 1 became *more* agitated after he was restrained. He fought against his restraints and he fell at least twice after he was restrained. Notwithstanding, Petitioner's staff made no effort to reassess their determination to restrain him, did not ask the resident's physician to reconsider his order to restrain the resident, and did not contemplate removing the restraints.[5] That evidence is sufficient, standing alone, to sustain a finding of

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[4] CMS argues at length that none of the residents manifested "symptoms" that would have justified restraining them. It is unnecessary that I decide this argument because it is clear that Petitioner did not establish that restraining the residents comprised appropriate care to treat the residents' instability and/or poor judgment.

[5] Petitioner asserts that putting the resident in a "rock and go" wheelchair after his second post-involuntary restraint fall on July 16, 2007, was an appropriate intervention in response to the resident's problems. Petitioner's pre-hearing brief at 33. I disagree. The "rock and go" chair may have been somewhat more stable than the chair previously used by the resident. But, it did not ameliorate the resident's increased agitation nor did it eliminate the risk that the resident might fall. In fact, the resident came out of the chair on July 17, 2007. CMS Ex. 18, at 17.

noncompliance even if, as a matter of law, the use of restraints as a falls prevention technique was not prohibited.

Petitioner introduced the testimony of the physician who ordered that Residents #s 2, 3, and 4 be restrained as support for its contention that it acted reasonably to restrain these residents. P. Ex. 18.[6] With respect to Resident # 2, the physician avers that the use of an involuntary restraint was appropriate in order to protect the resident due to the failure of other protective measures attempted by Petitioner and due also to the resident's progressively deteriorating condition. *Id.* at 3-4. He contends that it was appropriate to restrain Residents #s 3 and 4 involuntarily, essentially for the same reasons. *Id.* at 4-9.

I do not find this testimony to be persuasive. The physician does not explain how restraining any of these residents against their will would have provided any of them with enhanced protection against falls. Use of restraints is not justified by saying that the residents were at great risk for falling and that their medical conditions were deteriorating. Assuming the accuracy of the physician's assessment of these residents' physical and mental conditions, that does not justify the use of involuntary restraints in the absence of clear evidence that the residents would benefit from being restrained.

Finally, I am not persuaded that Petitioner established that there were no alternatives to restraining the four residents whose care I have discussed. Each of these residents shared a common characteristic. Their many physical and mental impairments rendered them incapable of standing and walking safely without close supervision. But, these common problems suggest a common solution, enhanced supervision of the residents. Petitioner has not shown that these residents would not have benefitted simply by being watched more closely by facility staff in lieu of being tied to their wheelchairs.

The regulation forbids a facility from restraining residents for purposes of its own convenience and that, I find, is the true crux of this case. When challenged with problems that would have been financially daunting to solve or which required possibly more intensive dedication of staff resources, Petitioner opted instead to restrain the residents. Petitioner's administrator comes close to admitting that, in fact, its use of restraints was,

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[6] Petitioner did not provide a physician's testimony explaining the reasons for restraining Resident # 1 against his will.

at bottom, premised on reasons of convenience rather than as treatment for residents' conditions:

> As the facility Administrator at Britthaven of New Bern, I am of the opinion that it would be operationally and financially unfeasible to provide 24 hour one to one monitoring for all residents who are at risk for falls.

P. Ex. 19, at 2.

Petitioner argues that it would have had to hire as many as eight additional employees in order to have provided the residents with the intensive one-on-one supervision that might have obviated the need for restraints. Which is to say that Petitioner asserts that it might have been quite costly for it to give these residents care that effectively protected them. I am not persuaded that any of these residents needed "24 hour one to one monitoring" in order to be kept safe (for example, Petitioner did not tie the residents to their beds when they were out of their wheelchairs and the residents evidently slept without continuous observation) and I find no evidentiary support for Petitioner's assertion that it would require eight additional employees to protect the residents adequately. But, even if a significant augmentation of staff resources would have been necessary to safeguard these residents from falling, that does not excuse Petitioner from failing to provide such care. Providing necessary care was an obligation which it assumed when it applied to participate in Medicare and when it accepted the four residents.

b. Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.25(h)(1).

The regulation which is at issue here states that a facility must ensure that its residents' environment remain as free of accident hazards as is possible. The regulation imposes on a facility the duty of accounting for all hazards that it knows or should know pose a threat for resident safety and well-being and it requires the facility to take every reasonable measure to eliminate such hazards.

CMS's allegations of noncompliance derive from the care that Petitioner provided to Resident # 1, the resident whose care I discussed in detail at subpart a. of this Finding. In essence, CMS alleges that restraining the resident constituted a hazard to his well-being because it created the likelihood that the resident would fall. The gravamen of CMS's case against Petitioner is that, once Petitioner restrained Resident # 1, it had the obligation

to assure the resident's safety, either by eliminating the restraint or by providing the resident with intensive supervision at all times. CMS Ex. 16, at 24-48.[7]

I find CMS's argument to be well-founded. As I discuss above, the accepted professional literature holds that restraining residents increases the likelihood of falls. Petitioner should have known that the resident was at an increased risk for falling after he was restrained against his will.

The increased risk to Resident # 1 was not only apparent from the accepted professional literature, of which Petitioner's nursing staff should have been aware, but it was made evident by the resident's behavior and the consequences of that behavior after he was restrained. The record unequivocally establishes that the resident strongly resisted being restrained and struggled more or less continuously against his restraint after it was applied by Petitioner's staff. In the wake of being restrained, the resident suffered two falls on July 16, 2007.[8] Petitioner argues that the first of these falls is attributable solely to a defective restraint, contending that the restraint broke, thus allowing the resident to become unstable and to fall. However, there is no evidence to prove that there was a defect in the restraint and it is equally possible that the restraint broke simply as a consequence of the resident's struggles against it. And, even if the restraint was defective, I infer from the evidence that the resident would not have fallen but for his struggles after being restrained.

In any event, whether the resident's first fall was as a consequence of a defective restraint or the consequence of his vigorous resistance to being restrained, that fall coupled with the resident's heightened agitation and efforts to escape put Petitioner's staff on notice that restraining the resident enhanced the resident's risk of falling. The staff knew that the resident was resisting his restraint and that his struggling increased the likelihood of a fall. The second fall that occurred on July 16 was a foreseeable consequence of the resident's continued struggles to free himself from his restraints.

Petitioner argues that, whatever hazards may have contributed to the resident's July 16 falls, they were eliminated by placing the resident in a "rock and go" wheelchair. That intervention, according to Petitioner, gave the resident enhanced stability and eliminated

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[7] In stating this argument CMS does not concede that restraining the resident was appropriate.

[8] I cite to the exhibits which describe these events above, at subpart a. of this Finding.

the likelihood that he would tip the chair over. I do not find this argument to be persuasive.

Placing the resident in the "rock and go" chair did not do anything to ameliorate the resident's increased agitation. He continued to struggle afterwards, to the extent that, on numerous subsequent occasions, the staff administered Ativan to the resident in an attempt to calm him. P. Ex. 11, at 89-92. Nor did placing the resident in the "rock and go" chair eliminate the likelihood that the resident would fall as a consequence of his agitation and his struggling. On July 17, 2007, after the resident had been placed in the "rock and go" wheelchair he was found to be sitting on the floor of Petitioner's TV room, having come out of the chair as a result of his struggling against his restraints.

2. Petitioner remained noncompliant with a Medicare participation requirement as of the August survey.

CMS's allegations of continuing noncompliance by Petitioner as of the August survey again are based on the provisions of 42 C.F.R. § 483.25(h). CMS Ex. 26, at 1-4. CMS contends that Petitioner failed to provide adequate supervision to a resident who is identified as Resident # 1 in the report of the August survey.[9]

The undisputed facts establish that the resident was an individual with a history of falls who was unsteady even when she was seated. CMS Ex. 26, at 1. The resident had been given a seat belt known as a "lap buddy" to wear while she was in her wheelchair as a supportive device.[10] On July 14, 2007, Petitioner's hairdresser found the resident to be lying on the floor of the facility's dining room. The resident was transferred to a hospital for assessment of complaints of leg pain and was diagnosed to be suffering from a left hip fracture. *Id.* at 2.

CMS asserts – and I agree – that the prima facie evidence shows that Petitioner was remiss in supervising Resident # 1. This resident was an individual who was known to be

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[9] In its briefs, CMS refers to this resident as "Resident # 5" ostensibly in order to avoid confusing this resident with the different resident who is identified as Resident # 1 in the report of the July survey and whose care I have discussed in detail in Finding 1. I find that there is no need to change the identification of this resident from that which is used in the August survey report and, so, I refer to the resident as "Resident # 1" throughout this Finding.

[10] CMS does not allege, nor do I find, that the seatbelt given to this resident was an involuntary restraint.

unstable and who was at a risk for falling even when seated in a wheelchair. Consequently, the resident needed to be supervised closely. Petitioner failed to provide this resident with the requisite close supervision on July 14, 2007 and, consequently, she fell. The evidence shows that Petitioner's staff was not really aware of the resident's whereabouts just prior to her sustaining her fall. CMS Ex. 26, at 3; CMS Ex. 27, at 11. For example, Petitioner's hairdresser averred that, prior to the resident's fall, she had provided services to the resident and returned her to her room. CMS Ex. 26, at 3; CMS Ex. 27, at 11; P. Ex. 23, at 1-2. But, somehow, and inexplicably unobserved, the resident traveled to another part of Petitioner's facility where she fell.

There is also evidence to show that someone on Petitioner's staff improperly positioned Resident # 1 in her wheelchair prior to the resident sustaining her fall. The resident had been given a tilt wheelchair that was designed to minimize the possibility that the resident might lean forward and fall out of the chair. CMS Ex. 26, at 2. However, at the time of the fall someone had left the chair back in a vertical position. *Id.*

Thus, the evidence offered by CMS strongly supports a conclusion that Resident # 1 was inadequately supervised by Petitioner's staff. The resident had a history of falls and was known to be unstable even while in her wheelchair. Yet, on July 14, 2007 the resident was left unsupervised with the chair improperly positioned long enough so that the resident fell and was injured.

Petitioner's response to this evidence is to assert that the accident occurring to Resident # 1 was the first and only such incident involving the resident. It contends that this allegedly isolated event should not be viewed as evidence of overall deficient care. Moreover, according to Petitioner, it promptly addressed the situation by providing training to its staff.

I am not persuaded by this argument that Petitioner was compliant. There is clear and unrebutted evidence that Petitioner's staff was remiss in supervising Resident # 1. The accident sustained by the resident may have been unanticipated in the sense that every accident comes as a surprise when it occurs. But, staff had every reason to know that failing to closely supervise Resident #1 and failing to assure that she was properly positioned in her wheelchair put her at great risk for an injury-producing accident.

3. CMS's determinations of immediate jeopardy are not clearly erroneous.

The burden falls on Petitioner to prove that a finding by CMS of an immediate jeopardy level deficiency is clearly erroneous. CMS's findings of immediate jeopardy attach to the two deficiencies identified at the July survey which I address at Finding 1 of this decision.

There is ample evidence in the record to show that there was a likelihood that these deficiencies would cause residents to suffer serious injury, harm, impairment or death. All four of the residents who were restrained against their will were exposed to the likelihood of grave physical and/or psychological harm. Indeed, the reaction of one of them, Resident # 1, to being restrained is graphic evidence of how the imposition of restraints can cause both agitation and falls. That conclusion is buttressed by the professional literature and opinion evidence offered by CMS showing that restraints as a falls reduction technique actually increase the likelihood that residents will suffer serious falls.

Petitioner has not offered rebuttal evidence which proves CMS's findings of immediate jeopardy to be clearly erroneous. Indeed, Petitioner has not offered argument or identified evidence which it purports to show that its deficiencies – assuming them to be established – were at a level of scope and severity that is less than immediate jeopardy.

4. Petitioner's non-immediate jeopardy level noncompliance persisted through August 30, 2007.

Once noncompliance is established the burden falls on the facility to prove that it has corrected its deficiencies. In this case, CMS determined that Petitioner's non-immediate jeopardy level noncompliance with the requirements of 42 C.F.R. § 483.25(h), identified at the August survey as commencing on July 14, 2007 with Resident # 1's fall, persisted through August 30, 2007.[11] Petitioner has not offered persuasive proof to establish that it attained compliance at an earlier date.

Petitioner asserts that it addressed the circumstances surrounding the fall of Resident # 1 by providing its staff with in-service training on proper positioning of residents. Petitioner's pre-hearing brief at 36. Petitioner contends also that it gave one-on-one inservice training to its hairdresser on July 16, 2007.

Petitioner's records show that it did not complete its staff in-service training relative to the deficiency identified at the August survey prior to at least August 31, 2007. That is the date on which Petitioner's staff received training on monitoring residents for safety. CMS Ex. 32, at 5. And, indeed, the plan of correction submitted by Petitioner addressing the August survey deficiency does not represent that training relating to that deficiency was completed before October 15, 2007. This evidence satisfies me that Petitioner did

[11] I refer here to the resident who was identified as Resident # 1 at the August survey and not to the resident who was identified as Resident # 1 at the July survey.

not prove that it attained compliance prior to August 30, 2007, the correction date determined by CMS.

5. CMS's remedy determinations are reasonable.

CMS determined to impose civil money penalties of $4050 per day for July 16-18, 2007 to remedy Petitioner's immediate jeopardy level noncompliance. It determined to impose penalties of $250 per day to remedy Petitioner's non-immediate jeopardy level noncompliance on July 14-15, 2007 and $200 per day for each day from July 19 through August 30, 2007, also to remedy Petitioner's non-immediate jeopardy level deficiencies. I find these determinations to be reasonable.

a. Civil money penalties of $4050 per day are reasonable to remedy Petitioner's immediate jeopardy level noncompliance.

Per-diem civil money penalties imposed to remedy immediate jeopardy level noncompliance must fall within a range of from $3050 to $10,000 per day. 42 C.F.R. § 488.438(a)(1)(i). There are regulatory criteria for deciding what amount within this range may be a reasonable remedy for an immediate jeopardy level deficiency. These criteria include: the seriousness of a facility's noncompliance; its compliance history; its culpability; and its financial condition. 42 C.F.R. §§ 488.438(f)(1) - (4); 488.404 (incorporated by reference into 42 C.F.R. § 488.438(f)(3)).

The immediate jeopardy level civil money penalty amount that CMS determined to impose in this case is extremely modest, being at the bottom end of the range of penalties that may be imposed to remedy immediate jeopardy level noncompliance. I find that, in this case, a daily penalty amount of $4050 is justified by the seriousness of the noncompliance. Petitioner has offered no evidence to prove that it lacks the financial wherewithal to pay penalties in this daily amount.

As I discuss above, at Finding 3, Petitioner's noncompliance was extremely serious. It put residents who were restrained involuntarily at great risk for severe physical and psychological harm. Petitioner restrained these residents for reasons of convenience and not as a medically justified form of treatment. I find that penalties of $4050 per day are amply justified in light of that.

Petitioner argues that, if it is liable for an immediate jeopardy level deficiency, the penalty should be assessed at $3050, and not $4050, per day. Petitioner asserts that it is the victim of a new and allegedly non-traditional interpretation of the regulation governing restraints and that it should not be penalized heavily for following what it contends was a traditional interpretation of the regulation. I do not accept this

characterization. As I discuss above, at Finding 1, the consensus in the nursing profession for many years has been that restraints should not be used as a falls prevention measure. CMS's policy as to restraints is not new but, rather, it is simply a restatement of that consensus. Moreover, it is apparent that Petitioner's primary reason for restraining these residents was not so much to protect them as it was to save itself the expense associated with providing them with a greater degree of supervision and security.

b. Penalties of $250 and $200 per day are reasonable to remedy Petitioner's non-immediate jeopardy noncompliance.

The permissible range of non-immediate jeopardy level civil money penalties is from $50 to $3000 per day. 42 C.F.R. § 488.438(a)(1)(ii). The same regulatory criteria for determining what is reasonable within this range apply here as apply to immediate jeopardy level penalties. 42 C.F.R. §§ 488.438(f)(1) - (4); 488.404 (incorporated by reference into 42 C.F.R. § 488.438(f)(3)).

The non-immediate jeopardy level penalties that CMS determined to impose are extremely modest and lie at the low end of the permissible range of non-immediate jeopardy level civil money penalties. They comprise significantly less than ten percent of the maximum non-immediate jeopardy level penalty amount.

I find that they are strongly supported by the seriousness of Petitioner's non-immediate jeopardy level deficiency. CMS determined – and the evidence supports this determination – that Resident # 1 sustained serious injuries as a consequence of Petitioner's failure to protect her adequately against accident hazards.[12] In light of that a minimal level daily civil money penalty, either of $250 or $200 per day, is certainly appropriate.

/s/
Steven T. Kessel
Administrative Law Judge

[12] Here I refer to the Resident # 1 who is identified in the report of the August survey.