Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Cedar Lake Nursing Home,	)	Date: June 24, 2009
(CCN: 67-5898),	)	
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-08-500
	)	Decision No. CR1967
Centers for Medicare & Medicaid	)	
Services.	)	
	)	

DECISION

Petitioner, Cedar Lake Nursing Home (Petitioner or facility), is a long term care facility located in Malakoff, Texas, that participates in the Medicare program. Following a survey completed March 5, 2008, the Centers for Medicare and Medicaid Services (CMS) determined that the facility was not in substantial compliance with Medicare requirements, and that its deficiencies posed immediate jeopardy to resident health and safety. CMS imposed a $5000 per instance civil money penalty (CMP). Petitioner appeals, and CMS now moves for summary judgment.

For the reasons discussed below, I find that summary judgment is appropriate. Based on the undisputed evidence, I conclude that the facility was not in substantial compliance with Medicare requirements governing accident prevention, 42 C.F.R. § 483.25(h).

I. Background

The Social Security Act (Act) sets forth requirements for nursing facility participation in the Medicare program, and authorizes the Secretary of Health and Human Services to promulgate regulations implementing those statutory provisions. Act, section 1819. The Secretary's regulations are found at 42 C.F.R. Part 483. To participate in the Medicare program, a nursing facility must maintain substantial compliance with program

requirements. To be in substantial compliance, a facility's deficiencies may pose no greater risk to resident health and safety than "the potential for causing minimal harm." 42 C.F.R. § 488.301.

The Secretary contracts with state survey agencies to conduct periodic surveys to determine whether skilled nursing facilities are in substantial compliance. Act, section 1864(a); 42 C.F.R. § 488.20. The regulations require that each facility be surveyed once every twelve months, and more often, if necessary, to ensure that identified deficiencies are corrected. Act, section 1819(g)(2)(A); 42 C.F.R. §§ 488.20(a), 499.308.

Here, following a survey completed March 5, 2008, CMS determined that the facility was not in substantial compliance with Medicare participation requirements, specifically, 42 C.F.R. § 483.25 (h) (Tag F323 – accident prevention), as well as physical environment (42 C.F.R. § 483.70(c)(2)), pharmacy services (42 C.F.R. § 483.60(b)(d) and (e)), and administration (42 C.F.R. § 483.75). CMS also determined that the facility's deficiencies under § 483.25(h) posed immediate jeopardy to resident health and safety, and has imposed a $5,000 per instance CMP for that deficiency alone. CMS Exs. 1, 3. It imposes no penalties for the remaining deficiencies.[1]

Petitioner timely requested a hearing and the matter was assigned to another administrative law judge (ALJ) for resolution. CMS moved for summary judgment, which Petitioner opposed. With its motion and brief (CMS Br.), CMS submitted 13 exhibits (CMS Exs. 1-13). With its response (P. Br.), Petitioner submitted 14 exhibits (P. Exs. 1-14). Petitioner subsequently filed a document labeled "Petitioner's Response to CMS's Motion for Summary Judgment" (P. MSJ Response) along with two affidavits labeled P. Exs. A and B. CMS objected to that late submission. Although the ALJ did not explicitly rule on CMS's objections, in a brief order dated December 29, 2008, he denied CMS's motion for summary judgment. Shortly thereafter, he left the agency, and the matter was re-assigned to me.

The December 29 order did not identify or discuss any material fact in dispute. On March 17, 2009, I vacated that order, set forth the criteria for evaluating the appropriateness of summary judgment, and invited the parties to submit any additional arguments as to why CMS's motion should or should not be granted. In response, the parties filed supplemental briefs (CMS Supp. Br. and P. Supp. Br.).

[1] Petitioner asserts that CMS rescinded a deficiency citation under 42 C.F.R. §483.75 (Tag F490 – administration). P. Br. at 1. In fact, CMS rescinded the *penalty* imposed for that deficiency, but did not say that it had rescinded the deficiency finding itself. CMS Ex. 1, at 4.

II. Issues

I consider first whether summary judgment is appropriate. On the merits, the issues are: 1) whether the facility was in substantial compliance with 42 C.F.R. § 483.25(h); and 2) whether the $5000 per instance CMP is reasonable.

Although Petitioner challenges CMS's finding of immediate jeopardy, I have no authority to review that issue. An ALJ may review CMS's scope and severity findings (which include a finding of immediate jeopardy) only if a successful challenge would affect the range of the CMP, or if CMS has made a finding of substandard quality of care that results in the loss of approval of a facility's nurse aide training program. 42 C.F.R. § 498.3(b)(14); *See*, *Evergreen Commons*, DAB No. 2175 (2008); *Aase Haugen Homes*, DAB No. 2013 (2006). Here, the penalty imposed is a per instance CMP, for which the regulations provide only one range ($1000 to $10000), so the level of noncompliance does not affect the range of the CMP. 42 C.F.R. § 488.438(a)(2). Nor does CMS's scope and severity finding affect approval of the facility's nurse aide training program. Even without the immediate jeopardy finding, the facility's nurse aide training program could not be approved because the facility has been assessed a $5000 CMP, and a state may not approve a facility's nurse aide training program if, within the last two years, the facility has been assessed a CMP of $5000 or more. Act, § 1819(f)(2)(B); 42 C.F.R. § 483.151(b)(2)(iv).

III. Discussion

A. CMS is entitled to summary judgment because the undisputed evidence establishes that the facility did not follow its own elopement prevention policies nor take alternative steps to ensure that an elopement-prone resident was adequately supervised and provided assistance devices designed to mitigate foreseeable risks of harm from accidents, as required by 42 C.F.R. § 483.25(h).

Summary Judgment. Summary judgment is appropriate if a case presents no genuine issue of material fact. "To defeat an adequately supported summary judgment motion, the non-moving party may not rely on the denials in its pleadings or briefs, but must furnish evidence of a dispute concerning a material fact . . . ." *Livingston Care Center*, DAB No. 1871, at 5 (2003). The moving party may show the absence of a genuine factual dispute by presenting evidence so one-sided that it must prevail as a matter of law, or by showing that the non-moving party has presented no evidence "sufficient to establish the existence of an element essential to [that party's] case, and on which [that party] will bear the burden of proof at trial." *Livingston Care Center v. Dep't of Health & Human Services*, 388 F.3d 168, 173 (6th Cir. 2004) (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 323-24 (1986)). To avoid summary judgment, the non-moving party must then act affirmatively by tendering evidence of specific facts showing that a dispute exists. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 n.11

(1986); s*ee also Vandalia Park*, DAB No. 1939 (2004); *Lebanon Nursing and Rehabilitation Center*, DAB No. 1918 (2004). In examining the evidence for purposes of determining the appropriateness of summary judgment, I must draw all reasonable inferences in the light most favorable to the non-moving party. *Brightview Care Center*, DAB 2132, at 2, 9 (2007); *Livingston Care Center*, 388 F.3d at 172; *Guardian Health Care Center*, DAB No. 1943, at 8 (2004); *but see*, *Brightview*, DAB 2132, at 10 (entry of summary judgment upheld where inferences and views of non-moving party are not reasonable). Moreover, drawing factual inferences in the light most favorable to the non-moving party does not require that I accept the non-moving party's legal conclusions. *Cf. Guardian Health Care Center*, DAB No. 1943, at 11 ("A dispute over the conclusion to be drawn from applying relevant legal criteria to undisputed facts does not preclude summary judgment if the record is sufficiently developed and there is only one reasonable conclusion that can be drawn from those facts.").[2]

Citing a Sixth Circuit opinion, *Baily v. Floyd City Bd. of Educ.*, 106 F.3d 135 (6th Cir. 1997), Petitioner argues that, under Rule 56(e) of the Federal Rules of Civil Procedure (Fed. R. Civ. P.), CMS's motion for summary judgment must be supported by affidavits. According to Petitioner, CMS's motion fails because it was not accompanied by witness affidavits. P. MSJ Response, at 3. Petitioner has interpreted Rule 56 and the *Baily* decision exactly backwards. Rule 56(a) and (b), Fed. R. Civ. P., says that either party may move for summary judgment "with or without supporting affidavits." Consistent with this rule, the *Baily* court held:

> A moving party need *not* support its motion with evidence disproving the nonmoving party's claim, but need only show that "there is an absence of evidence to support the nonmoving party's claim." *Michigan Protection and Advocacy Serv., Inc. v. Babin*, 18 F.3d 337, 341 (6th Cir. 1994) (quoting *Celotex Corp. v. Carrett*, 477 U.S. 317, 325 (1986)). The nonmovant then must counter with more than a scintilla of evidence in support of his or her position; the evidence must be such that a jury could reasonably find for

[2] Petitioner repeatedly mischaracterizes, as disputes of fact, disputes over conclusions to be drawn from applying relevant legal criteria to undisputed facts, *e.g*. whether a resident's elopement was beyond the facility's control; whether Petitioner did what was reasonably within its control to prevent accidents; whether staff properly supervised and monitored an elopement-prone resident; whether the facility remained as free of accident hazards as possible. *See*, P. Supp. Br. at 3-5. A conclusion does not become a fact simply because it is incorporated into a witness declaration. Rather than repeatedly concluding that it acted properly, a facility avoids summary judgment by coming forward with evidence establishing what it actually did in the way of supervision and accident prevention. *See*, discussion, below.

> that party. *Michigan Protection and Advocacy Serv., Inc.*, 18 F. 3d at 341 (citing *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252, 106 S.Ct. 2505, 2512, 91 L. Ed. 2d 202 (1986)); *accord Harrow Prods., Inc., v. Liberty Mut. Ins. Co.*, 64 F.3d 1015, 1019 (6th Cir. 1995).

(emphasis added) *Baily v. Floyd City Bd. Of Educ.*, at 3. Thus, where the defendant moved for summary judgment on the grounds that the plaintiff lacked evidence of an element essential to her case, the Sixth Circuit held that the district court appropriately granted summary judgment because the *nonmoving* party failed to present evidence "of evidentiary quality" (such as admissible documents, attested testimony) demonstrating the existence of a genuine issue of material fact, as required by Rule 56. *Id.* at 7.

Undisputed Facts. CMS's case centers around facility efforts to protect from accidents one of its residents, identified as R10. R10 was a 92-year-old woman suffering from a long list of ailments, including chronic obstructive pulmonary disease, dementia, anxiety, and agitation. CMS Ex. 9, at 1, 3. CMS has come forward with evidence – unchallenged by Petitioner – establishing that:

- R10 had a history of wandering, was at high risk for elopement, and repeatedly attempted to leave the facility. CMS Ex. 9, at 1-2, 9, 10, 17, 46, 50, 75, 77, 83; P. Ex. 1, at 17.

- R10 had a history of falls, and fell multiple times in January 2008. CMS Ex. 9, at 14, 15.

- The facility developed a care plan, dated September 19, 2007, to address the problem it identified as "resident occasionally wanders from facility." The plan required staff to place the resident in an area "where constant observation is possible" and to "approach the resident warmly and positively." CMS Ex. 9, at 50; P. Ex. 1, at 26.

- Plan amendments dated January 15 and January 27, 2008 added social services intervention, WanderGuard placement,[3] frequent observation, door alarm and administration of ordered medications as needed for insomnia and restlessness. The plan also directed staff to intervene when the resident ambulated up and down the halls, offering her a drink or snack, and assisting her back to her room. CMS Ex. 9, at 50; *see*, P. Ex. 1, at 18.

[3] A WanderGuard system attaches sensors to exit doors and/or windows, causing them either to lock or sound an alarm when approached by a resident wearing a corresponding bracelet/anklet.

- An additional plan, dated January 27, 2008 (and reviewed periodically thereafter) directed all staff to monitor the resident location every two hours, notify the interdisciplinary team of any attempts to leave the facility, monitor the resident's location every fifteen minutes if an attempt to leave occurs "until an action plan and protective measures are in place," redirect resident from wandering in and out of other residents' rooms, encourage participation in activities, and refer to the social worker if R10 has trouble coping with placement. CMS Ex. 9, at 54; P. Ex. 1, at 17.

- R10's physician ordered a Wanderguard CMS Ex. 9, at 8; P. Ex. 3, at 3.

- Social services assessments dated January 7, January 31, and February 7, 2008, indicate that R10 became combative when staff attempted to redirect her as she tried to leave the facility. CMS Ex. 9, at 72, 83-84.

- On February 20, 2008, a visitor reported that she saw R10 out of the facility, walking along the shoulder of Highway 31. Staff found her and returned her to the facility, tired and thirsty, but unharmed. CMS Ex. 9, at 17, 75, 78; P. Ex. 5, at 1; P. Ex. 11, at 2.

- Incident reports dated February 20, 2008, reiterate that a visitor "said there was an elderly woman in a pink sweat suit walking down the highway and wondered if she belonged here." Staff ran after her and returned her to the facility unharmed. CMS Ex. 9, at 78, 79; P. Ex. 5, at 1, 2.

- According to the incident report, on the day of R10's elopement, new alarms were being installed and the previous alarms had been turned off for rewiring. CMS Ex. 9, at 78; P. Ex. 5, at 1.

- Staff explained to surveyors that the door alarms had not sounded when R10 exited the facility because workers installing a new alarm system had turned off the existing system, and no workers were at the front door when she left. CMS Ex. 6, at 80.

- Following her safe return, the facility implemented one-on-one supervision of R10 pending completion of the new alarm system. CMS Ex. 9, at 17, 78, 80.

- At least three other facility residents were equipped with WanderGuard bracelets or anklets at the time of R10's elopement. CMS Ex. 12, at 7.

Petitioner has not challenged any of these facts, and CMS argues that it is entitled to summary judgment because these undisputed facts establish the facility's substantial noncompliance with 42 C.F.R. § 483.25(h) (quality of care -- accidents), which mandates that each resident receive and that the facility provide the necessary care and services to allow a resident 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. *See also*, Act, section 1819(b). The regulation also requires that the resident environment remain as free of accident hazards as possible and that the facility "take reasonable steps to ensure that a resident receives the supervision and assistance devices designed to meet his assessed needs and to mitigate foreseeable risks of harm from accidents." *Briarwood Nursing Center*, DAB No. 2115, at 5 (2007); *Guardian Health Care Center*, DAB No. 1943, at 18 (2004). The facility must anticipate what accidents might befall a resident and take steps to prevent them. A facility is permitted the flexibility to choose the methods it uses to prevent accidents, but the chosen methods must constitute an "adequate" level of supervision under all the circumstances. *Briarwood*, at 5; *Windsor Health Care Center*, DAB No. 1902, at 5 (2003).

As a threshold matter, Petitioner characterizes as "a material fact in dispute" whether an elopement may properly be considered an accident hazard within the meaning of 42 C.F.R. § 483.25(h).[4] P. Supp. Br. at 3. Whether an elopement falls within the ambit of 42 C.F.R. § 483.25(h) is not a factual dispute, but a legal conclusion that has been resolved by the Departmental Appeals Board. Preventing injury from accidents includes preventing elopements because when a resident elopes, he is entirely without facility supervision or support for his personal safety. *Brightview Care Center*, DAB 2132, at 13, *citing Woodstock Care Center v. Thompson*, 363 F.3d at 583, 589 (6th Cir. 2003).

And, based on the undisputed facts, I find that Petitioner failed to take all reasonable steps to prevent R10's elopement. For summary judgment purposes, I accept Petitioner's claim that the alarm installation company "never advised anyone at the facility that they would be disconnecting the old alarm system for a few hours while the new system was being connected." P. MSJ Response, Ex. A at 1. But I reject the conclusions that Petitioner reaches based on this fact. It does not follow that the alarm system issues were "totally unforeseeable," nor that "the facility's actions or lack thereof" created "no known or foreseeable danger," nor that R10's elopement was "completely beyond the facility's control." P. Br. at 2-3; *See*, P. Supp. Br. at 3, 4. P. MSJ Response, Ex. A, at 1, 2 (Humble Decl.).[5] To the contrary, staff well knew that R10 would attempt to leave the facility if

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[4] Rather than citing the relevant regulation, Petitioner cites the tag number used by the survey agency on the survey report form. As discussed below, tag numbers may be useful tools, but they have no particular legal significance.

[5] Petitioner did not timely submit its declarations in response to CMS's Motion for Summary Judgment. However, inasmuch as I accorded the parties an additional

given the opportunity. Any reasonable person could anticipate the need for heightened supervision when strangers, who are neither familiar with resident behavior nor responsible for resident welfare, are working in and around the facility exit doors. That those strangers were working with the facility alarm systems makes even more foreseeable the increased risk to R10 and the facility's other elopement-prone residents.

Moreover, although an alarm system may be a useful tool, no system is fail-safe; alarms are no substitute for adequate staff supervision, particularly where, as here, that system is under repair/replacement. *See*, *Asbury Center at Johnson City*, DAB No. 1815, at 13 (2002). Thus, in addition to the WanderGuard, R10's care plan required that she be placed in an area "where constant observation is possible"; that she be observed "frequently"; that staff intervene when she ambulated up and down the halls; and that her location be monitored every two hours. CMS Ex. 9, at 50, 54; P. Ex. 1, at 17, 18, 26. Yet, notwithstanding the conclusory and imprecise claims that R10 was monitored "on a regular basis," and that "the facility provided proper supervision," Petitioner has come forward with no evidence as to the frequency and means by which staff supervised R10 prior to the time her elopement was discovered (at about 4:15 p.m. on February 20, 2008). P. MSJ Response, Ex. A, at 2; P. MSJ Response, Ex. B, at 2, 4; CMS Ex. 9, at 17, 78; P. Ex. 5, at 1; P. Ex. 11, at 2.

Nursing notes for February 20 say nothing about R10 until 4:15 p.m., when they describe the visitor's report that R10 was out on the highway shoulder. P. Ex. 11. Neither the incident report nor any other document in this record suggests that any employee or employees were responsible for monitoring R10's location prior to her elopement. Nothing suggests that the facility tried to figure out where and when R10 was last observed before 4:15 p.m., much less where she had been placed to assure "constant observation." Indeed, the record before me suggests a staff oblivious to the supervisory aspects of R10's care plan, relying solely on its alarm system to protect her. Certainly, staff investigators did not move beyond the failings of the alarm system when it tried to determine what went wrong.

Because the undisputed evidence establishes that the facility did not provide R10 with the supervision and assistance devices she needed, and did not take reasonable steps to ensure that her environment remained free of accident hazards, it was not in substantial compliance with 42 C.F.R. § 483.25(h), and CMS is entitled to summary judgment on that issue.

Petitioner raises two additional arguments, neither of which has any merit.

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opportunity to address the issues raised, CMS was not prejudiced by the lateness of the submission.

F-Tag numbers. Petitioner complains that on the Statement of Deficiencies CMS listed the alleged deficiency under the wrong "F-tag" number.

The State Operations Manual (SOM) includes guidance to surveyors for completing a Statement of Deficiencies (Standard Form 2567). Each deficiency is listed under a separate F-tag number, which corresponds to a specific regulatory provision. Under each F-tag, the survey team cites the applicable regulation, lists factual findings relating to that deficiency and assesses the deficiency's scope and severity. In the past, according to Petitioner, deficiencies relating 42 C.F.R. § 483.25(h)(1) (requiring that the environment remain as free of accident hazards as possible) corresponded to tag F323. Deficiencies relating to 42 C.F.R. § 483.25(h)(2) (requiring adequate supervision and assistive devices) corresponded to tag F324. But here, CMS includes both (h)(1) and (h)(2) deficiencies under one tag F323. For reasons not fully explained, Petitioner argues that CMS's use of that F-tag precludes it from citing a deficiency under section 483.25(h)(2).[6] I disagree.

While no doubt a useful shorthand device, F-tags have no legal significance. Their use does not even rise to the level of survey guidance generally provided by the SOM, which itself does not have the force and effect of law. *Aase Haugen Homes, Inc*., DAB No. 2013, at 15 (2006), *citing*, *Beverly Health & Rehabilitation Services, Inc. v. Thompson*, 223 F. Supp. 2d 73, 99, 100 (D.D.C. 2002) and *Cmty. Nutrition Institute v. Young*, 818 F. 2d 943, 949 (D.C.Cir.1987) (recognizing that agencies may develop written guidelines without the risk of "having a court transmogrify those guidelines into binding norms."). The Act and regulations govern these proceedings, and, so long as Petitioner had adequate notice of the deficiencies cited – which review of the Statement of Deficiencies and notice letters demonstrate it plainly did – it has no basis for complaint about the F-tag numbers. CMS Ex. 1; CMS Ex. 3, at 1.

Quality Assurance Committee. Finally, Petitioner argues that CMS is precluded from citing a deficiency because the facility's quality assurance committee (QAC) was addressing the elopement problem. Inasmuch as the evidence establishing the facility's substantial noncompliance here is wholly independent of any QAC study, I reject this contention.

A facility must maintain a quality assessment and assurance committee to identify quality issues and to develop and implement appropriate plans of action to address those issues. The committee's good faith attempts to identify and correct deficiencies will not be used as a basis for sanctions. 42 C.F.R. § 483.75(o).

[6] Inasmuch as CMS did not address the issue, the reason for this apparent change in practice, while inconsequential, remains unexplained.

Nothing in this record suggests that CMS learned of R10's elopement based on its review of QAC documents. To the contrary, the facility was required to report the incident to the State Agency, to investigate and to prepare an incident report, independent of any QAC involvement. While an elopement or similar incident would likely (and should) trigger QAC scrutiny, that fact does not preclude CMS from finding a deficiency and imposing remedies. That the incident report is also reviewed by the QAC does not make it a privileged document. If that were the case, any facility could prevent surveyor scrutiny of incriminating documents by providing them to the QAC; and it could avoid penalties simply by referring its deficiencies to the QAC for study.[7]

C. The penalty imposed is reasonable.

I next consider whether the CMP is reasonable by applying the factors listed in 42 C.F.R. § 488.438(f): 1) the facility's history of noncompliance; 2) the facility's financial condition; 3) factors specified in 42 C.F.R. § 488.404; and 4) the facility's degree of culpability, which includes neglect, indifference, or disregard for resident care, comfort or safety. The absence of culpability is not a mitigating factor. The factors in 42 C.F.R. § 488.404 include: 1) the scope and severity of the deficiency; 2) the relationship of the deficiency to other deficiencies resulting in noncompliance; and 3) the facility's prior history of noncompliance in general and specifically with reference to the cited deficiencies.

In reaching a decision on the reasonableness of the CMP, I consider whether the evidence supports a finding that the amount of the CMP is at a level reasonably related to an effort to produce corrective action by a provider with the kind of deficiencies found, and in light of the above factors. I am neither bound to defer to CMS's factual assertions, nor free to make a wholly independent choice of remedies without regard for CMS's discretion. *Barn Hill Care Center*, DAB No. 1848, at 21 (2002); *Community Nursing Home*, DAB No. 1807, at 22 *et seq*. (2002); *Emerald Oaks*, DAB No. 1800, at 9 (2001); *CarePlex of Silver Spring*, DAB No. 1638, at 8 (1999).

CMS has imposed a per-instance penalty of $5000. CMS does not contend that the facility history justifies a higher CMP. Petitioner has not argued that its financial condition affects its ability to pay the penalty. With respect to the remaining factors, I find that, although $5000 is at the mid-range for per instance penalties ($1000 -- $10000), it is nevertheless a relatively small amount of money; any lesser amount would be highly unlikely to induce corrective action. Moreover, the facility recognized R10's vulnerability, but disregarded her safety when it failed to provide the level of supervision that she needed, for which it is culpable.

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[7] Petitioner has not asked that any QAC documents be excluded; in fact, Petitioner, not CMS, has submitted QAC documents. P. Br. at 7. CMS has not relied on any QAC document to make its case, and neither do I. P. Ex. 6.

The CMP is therefore reasonable.

IV. Conclusion

For the reasons discussed above, I find that the facility was not in substantial compliance with Medicare requirements governing accident prevention (42 C.F.R. § 483.25(h)), and affirm as reasonable the $5000 per instance CMP.

/s/
Carolyn Cozad Hughes
Administrative Law Judge