Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
The Cottage Extended Care (CCN: 37-5489),	)	Date: July 31, 2007
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-06-410
	)	Decision No. CR1629
Centers for Medicare & Medicaid Services.	)	
	)	

DECISION

Petitioner, The Cottage Extended Care Center (Petitioner or facility), is a long term care facility certified to participate in the Medicare program as a provider of services. Petitioner challenges the Centers for Medicare & Medicaid Services' (CMS's) determination that, from January 12 – February 13, 2006, it was not in substantial compliance with program participation requirements, and that on January 12, 2006, its deficiencies posed immediate jeopardy to resident health and safety. The parties have agreed that this matter be decided on the written record, without an in-person hearing.

For the reasons set forth below, I find that the facility was not in substantial compliance with program participation requirements during the period in question, and that on January 12, 2006, its deficiencies posed immediate jeopardy to resident health and safety. I sustain the $3300 civil money penalty (CMP) for the day of immediate jeopardy. For the period of noncompliance that was not immediate jeopardy, the penalty imposed ($50 per day) is the mandatory minimum per day CMP so it must also be sustained.

I. Background

The Social Security Act (Act) sets forth requirements for nursing facility participation in the Medicare and Medicaid programs, and authorizes the Secretary of Health and Human Services to promulgate regulations implementing the statutory provisions. Act §§ 1819 and 1919. 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. Immediate jeopardy exists if the facility's noncompliance has caused or is likely to cause "serious injury, harm, impairment or death to a resident." 42 C.F.R. § 488.301. CMS's determination as to the level of a facility's noncompliance – which includes its immediate jeopardy finding – must be upheld unless it is "clearly erroneous." 42 C.F.R. § 498.60(c).

The Secretary contracts with state survey agencies to conduct periodic surveys to determine whether skilled nursing facilities are in substantial compliance with program participation requirements. Act § 1864(a); 42 C.F.R. § 488.20. The regulations require that each facility be surveyed once every 12 months, and more often, if necessary, to ensure that identified deficiencies are corrected. Act § 1819(g)(2)(A); 42 C.F.R. §§ 488.20(a); 488.308.

Here, following a complaint investigation/survey conducted January 9, 11, and 12, 2006, surveyors from the Oklahoma State Department of Health (State Agency) concluded that the facility was not in substantial compliance with federal requirements for nursing homes participating in the Medicare and Medicaid programs. Specifically, it found that the facility did not meet federal requirements under:

- 42 C.F.R. § 483.13(c) (Tag F-224 - Staff Treatment of Residents) at a "K" level of scope and severity (pattern of immediate jeopardy to resident health and safety);

- 42 C.F.R. §§ 483.20(d); 483.20(k)(1) (Tag F-279 - Comprehensive Care Plans) at a "D" level of scope and severity (isolated instance of noncompliance that causes no actual harm with the potential for more than minimal harm);

- 42 C.F.R. § 483.20(k)(3)(ii) (Tag F-282 - Comprehensive Care Plans) at an "E" level of scope and severity (pattern of noncompliance that causes no actual harm with the potential for more than minimal harm).

CMS Exhibit (Ex.) 2, at 1, 8, 10.

Following an informal dispute resolution proceeding, the State Agency generally upheld the deficiency findings for 42 C.F.R. § 483.13(c) (staff treatment of residents), but lowered the scope and severity findings from "K" to "J," reflecting that the deficiency posed immediate jeopardy but involved an isolated instance rather than a pattern of noncompliance. Petitioner (P.) Ex. 11, at 1-2. The other findings were undisturbed.

CMS has agreed with the State Agency's recommendations and imposed a CMP of $3300 per day for one day of immediate jeopardy (January 12, 2006) plus $50 per day for the period of noncompliance that did not pose immediate jeopardy (January 13 through February 13, 2006) (32 days x $50 = $1600). CMS Ex. 1, at 2, 4.

Petitioner timely requested a hearing, and the case was assigned to me. On November 3, 2006, I held a prehearing telephone conference, at which the parties agreed that this matter would be decided based on written submissions, without an in-person hearing. During the conference, I noted that the facts alleged, if true, suggested substantial noncompliance with two additional regulations – 42 C.F.R. §§ 483.25 (quality of care) and 483.10(b)(11) (notification of changes). I advised the parties that, pursuant to 42 C.F.R. § 498.56, I would add, as new issues, the facility's compliance with §§ 483.25 and 483.10(b)(11). Neither party objected so those issues are also before me. *See* Order (Nov. 8, 2006); 42 C.F.R. § 498.56; *Alden Town Manor Rehabilitation & HCC*, DAB No. 2054, at 17, *et seq.* (2006).

The parties filed initial (opening) briefs (CMS Op. Br. and P. Op. Br.) and submissions. Following the prehearing conference, they filed closing briefs (CMS Cl. Br. and P. Cl. Br.) and additional witness declarations. CMS filed a reply brief (CMS Reply). CMS has filed 12 exhibits (CMS Exs. 1-12), which, in the absence of objection, I admit as CMS Exs. 1-12. Petitioner has filed 41 exhibits (P. Exs. 1-41). In the absence of any objections, I admit P. Exs. 1-41.

II. Issues

As a threshold matter, Petitioner has not appealed CMS's determination that, from January 12 through February 13, 2006, the facility was not in substantial compliance with Medicare requirements for comprehensive care plans, 42 C.F.R. §§ 483.20(d), 483.20(k)(1), and 483.20(k)(3)(ii). This justifies the imposition of a penalty. 42 C.F.R. § 488.438(a)(1)(ii). (See discussion, below).

The sole issues remaining are:

- Whether, from January 12 through February 13, 2006, the facility was in substantial compliance with 42 C.F.R. §§ 483.13(c) (staff treatment of residents); 483.25 (quality of care); and 483.10(b)(11) (notification of changes);

- If the facility was not in substantial compliance on January 12, 2006, did its deficiencies pose immediate jeopardy to resident health and safety?

III. Discussion

A. CMS's determinations on the unchallenged deficiencies (42 C.F.R. §§ 483.20(d), 483.20(k)(1), and 483.20(k)(3)(ii)) are final and binding and provide a sufficient basis for imposing a penalty.

CMS's findings of noncompliance that result in the imposition of a remedy are considered initial determinations that an affected party, such as Petitioner, may appeal. The regulations governing such actions dictate that CMS send notice of the initial determination to the affected party, setting forth the basis for and effect of the determination, and the party's right to hearing. 42 C.F.R. §§ 498.20(a)(1); 498.3; 498.5. The affected party may then challenge the determination by filing a hearing request within 60 days of its receiving the notice. 42 C.F.R. § 498.40. An initial determination is final and binding unless reversed or modified by a hearing decision, or under circumstances not applicable here. 42 C.F.R. § 498.20(b).

In this case, CMS sent the appropriate notice, and Petitioner requested a hearing. Petitioner's very broad hearing request lists all of the cited tags and contends that they "should not have been cited based on the facts and to the extent stated."[1] However, Petitioner's closing brief makes clear that it "is not appealing the deficiencies cited under F 279, § 483.20(k)(1) or F 282, [§ 483.20(k)(3)(ii)]."[2] P. Cl. Br. at 2. CMS's

---

[1] Petitioner's hearing request does not satisfy the specificity requirements of 42 C.F.R. § 498.40 (the hearing request must identify the specific issue and the findings of fact and conclusions of law with which the affected party disagrees, and must specify the bases for contending the findings and conclusions are incorrect). Nevertheless, Petitioner had the opportunity to remedy those shortcomings in its subsequent submissions. See *The Carlton at the Lake*, DAB No. 1829 (2002); *Alden Nursing Center – Morrow*, DAB No. 1825 (2002).

[2] Petitioner did not cite 42 C.F.R. § 483.20(d), which the surveyors included under tag F-279. I consider this a mere oversight since Petitioner has not argued substantial compliance with that regulation. Further, although the hearing request cites

determinations on the F-279 and F-282 tags are therefore final and binding, and Petitioner was not in substantial compliance with the regulation governing comprehensive care plans, 42 C.F.R. §§ 483.20(d), 483.20(k)(1), and 483.20(k)(3)(ii). Because we have a final and binding determination that the facility was not in substantial compliance, CMS has the discretion to impose one or more of the enforcement remedies listed in 42 C.F.R. § 488.406, which include the imposition of a CMP. Act § 1819(h); 42 C.F.R. § 488.402. So long as CMS has a basis for imposing a remedy, I have no authority to review its determination to do so. 42 C.F.R. § 488.438(e). Nor may I review CMS's choice of remedy. 42 C.F.R. § 488.408(g)(2). CMS has chosen a per day CMP, which must be at least $50 per day. 42 C.F.R. § 488.438(a)(1)(ii).

B. The facility was not in substantial compliance with 42 C.F.R. §§ 483.13(c) (staff treatment of residents), 483.25 (quality of care), nor 483.10(b)(11) (notification of changes).

Resident Number 7 (R7) was a 54-year-old woman, admitted to the facility on November 11, 2005, suffering from insulin dependent diabetes mellitus, congestive heart failure, polyneuropathy, peripheral vascular disease, hypertension, and hypothyroidism. She had a physician order for hospice care due to end stage diabetes mellitus. P. Ex. 39, at 1; CMS Ex. 2, at 3.

R7's care plan identified as potential problems complications attributable to her hypertension. To prevent such complications, the plan directed that staff monitor her blood pressure and report any abnormal readings, monitor and report any shortness of breath, drowsiness, confusion, numbness, or tingling, and notify her physician of any signs or symptoms of hypertensive crisis. P. Ex. 37, at 1; CMS Ex. 7, at 1. The plan noted that she had a history of cerebral vascular accident (CVA or stroke) and was at risk for another. Among other approaches, staff were directed to monitor lab values, blood pressure, and to monitor "closely" changes in cognitive or functional level. The plan directed them to report to the physician any signs or symptoms of a repeat CVA. P. Ex. 37, at 4; CMS Ex. 7, at 4.

The plan also identified R7's risk for hypo/hyperglycemic reactions related to her diabetes, and, among other approaches, directed staff to monitor and report to her physician any abnormal lab values or other signs or symptoms of hypo/hyperglycemic reactions, such as moist clammy skin, blurred vision, headache, and weakness (hypoglycemia) or dry skin, fruity smelling breath, hypotension, and lethargy (hyperglycemia). P. Ex. 37, at 2; CMS Ex. 7, at 2.

"483.20(k)(ii)" instead of "483.20(k)(3)(ii)," this is plainly a typographical error.

A nurses note dated January 2, 2006, at 11:30 a.m., indicates that staff observed R7 having a seizure. Calls were placed to the on-call physician, and, according to a 12:05 p.m. note, to the hospice. With the first entry, documenting the call to the physician, the nurse wrote "waiting for return call." CMS Ex. 2, at 3; CMS Ex. 5, at 4-5; P. Ex. 15, at 1; P. Ex. 34, at 3. But nothing in the nurses notes or elsewhere establishes that the call was returned or that any other action was taken over the next two days, aside from a hospice nurse visit the afternoon of January 3 to treat R7's necrotic right big toe. P. Ex. 15, at 4. Indeed, documentation suggests minimal staff monitoring until the afternoon of January 4, when R7 suffered a second seizure.

Nurses notes dated January 4, 2006, describe finding R7 at 4:30 p.m., lying in bed, displaying "seizure-like activity" (eyes fluttering, hand tremors, facial twitching). The nurse measured her blood sugar (which was low – 64), took vital signs and notified the hospice of her change in status. Hospice staff advised giving R7 sugar, attributing the seizure to low blood sugar. At 6:00 p.m., R7's blood sugar was 70, but she remained unresponsive, her pupils non-responsive. The nurse gave her more sugar and called the hospice back, asking them to come out. CMS Ex. 2, at 3-4; CMS Ex. 5, at 4-5; P. Ex. 34, at 3-4. A hospice employee apparently came to the facility, but the record does not indicate the time. P. Ex. 15, at 5. In any event, at 7:00 p.m., R7's blood sugar was up to 80, but then fell back to 63. Facility staff notified R7's friend (who had power of attorney), and spoke to the hospice nurse about sending R7 to the hospital. Some time thereafter, facility staff notified the on-call physician. At 9:30 p.m., the emergency medical services team arrived, and R7 was transferred to the hospital. Facility staff also attempted, unsuccessfully, to contact R7's sister. CMS Ex. 2, at 3-4; CMS Ex. 5, at 5-6; P. Ex. 34, at 3-4.

R7 arrived at the emergency room at 9:35 p.m. Her blood sugar level was 60; she was confused, had difficulty talking and was partially paralyzed. CMS Ex. 10, at 1. Remarkably, hospital staff were not aware of the seizure R7 was reported to have suffered on January 2; according to the hospital intake records, R7 experienced a seizure at 4:30 p.m. on January 4, but had no other recent history of seizures. The hospital physicians diagnosed a stroke and R7 was admitted to the hospital in poor but stable condition. CMS Ex. 10, at 1-3; *see also* CMS Ex. 6, at 1; P. Ex. 38, at 1 ("in her usual state of health up until the day of admission when she had a tonic and clonic seizure").

At the time of the survey, the surveyors discovered alcohol in R7's room, and several staff members reported seeing alcoholic eggnog, wine, and vodka in her room prior to January 2, 2006. CMS Ex. 2, at 2-3; CMS Ex. 9.

1. The facility was not in substantial compliance with 42 C.F.R. § 483.13(c) (staff treatment of residents).

"Neglect means failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness." 42 C.F.R. § 488.301. A facility must develop and implement written policies and procedures that prohibit resident neglect. 42 C.F.R. § 483.13(c). This regulation governing staff treatment of residents "addresses a deficiency related to lack of an effective policy as opposed to one directed at the occurrence of neglect itself." *Emerald Oaks*, DAB No. 1800, at 12 (2001). However, the drafters of the regulation characterized as "inherent in § 483.13(c)" the requirement that "each resident should be free from neglect as well as other forms of mistreatment." 59 Fed. Reg. 56130 (November 10, 1994). The drafters also deliberately rejected the suggestion that the regulations require evidence of a negative outcome to support the finding of neglect:

> We do not accept this comment because neglect may be determined even if no apparent negative outcome has occurred. The potential for negative outcome must be considered.

Id.

Petitioner has produced a somewhat meager set of written documents, which it characterizes as its written policies and procedures prohibiting resident neglect and abuse. The documents seem to focus on abuse, offering little that directly addresses the issue of neglect. P. Exs. 19-21. The first of these, titled "Abuse and Neglect Policy," is dated March 18, 2005, and says that residents will be protected "against all forms" of neglect, that allegations will be immediately investigated, and that the resident's representative/family member and physician will immediately be notified of possible neglect. P. Ex. 19.

A second document, labeled "Abuse and Neglect Prohibition Policy," is undated and Petitioner has not said whether it was in effect at the time of the survey. The document repeats that all alleged violations of neglect "are reported immediately to the administrator or other officials in accordance with State law through established procedures within five (5) working days of the incident." P. Ex. 20, at 1. The document includes the regulatory definition of neglect ("failure to provide goods and services

necessary to avoid physical harm, mental anguish or mental illness") and offers some examples, such as "failure to answer call lights to provide needed assistance." P. Ex. 20, at 2.[3]

A third document, also undated (with no indication as to when it went into effect), is titled "Resident Abuse, Neglect, or Mistreatment Policy and Procedure." This document repeats that residents will be free from neglect. It says that "[a]ll staff, on an ongoing basis, shall monitor resident care and treatments, to assure residents are free from abuse, neglect, or mistreatment," and that all instances of neglect will be reported, thoroughly investigated, and the physician will be notified. P. Ex. 21.[4]

CMS has not argued that the written documents themselves are inadequate. However, the regulation requires that policies be "implemented," and implementing a policy requires more than maintaining a paper file of documents without actually regulating staff actions. Examples of neglect can demonstrate that the facility has not implemented an anti-neglect policy. *Barn Hill Care Center*, DAB No. 1848, at 9-12 (2002); *Emerald Oaks,* DAB No. 1800, at 18; *see* 59 Fed. Reg. 56130.

In CMS's view, the facility's failure to respond appropriately to R7's medical needs establishes that it had not developed and implemented policies and procedures to prohibit the neglect of its residents. I agree that on January 2 and 4, 2006, the facility did not provide R7 with services necessary to avoid physical harm, and therefore neglected her.

During the morning of January 2, R7 unquestionably experienced serious symptoms that should have been assessed, monitored, and reported. The January 2 nurses note indicates that staff observed R7 having a seizure, although it does not describe her specific symptoms. According to her care plan, staff should have notified her physician and closely monitored her condition. Staff placed one call to the on-call physician, but nothing suggests that call was ever returned, and I see no evidence of staff efforts to follow-up. Nor is there any evidence that staff thereafter monitored her for signs or symptoms of stroke, or hypertensive crisis, as required by her care plan. As CMS's nurse consultant, Daniel J. McElroy, R.N., observes, neurological assessments were not performed; no vital signs were taken. Indeed, for at least 10 hours, from 11:30 a.m. on

---

[3] This provision reflects language found in the preamble to the regulations. In explaining that neglect may be determined in the absence of a negative outcome, the drafters set forth this and the other examples listed in Petitioner's policy. 59 Fed. Reg. 56130.

[4] An additional document instructs staff in first aid techniques for seizure victims. P. Ex. 23. ("Protect tongue if can. Prevent from hitting head. Don't interfere, only protect.")

January 2 until 9:30 p.m., only two "assessments" were performed: 1) the observation of R7's seizure; and 2) an observation of her level of consciousness. CMS Ex. 12, at 6 (McElroy Decl.); CMS Ex. 5, at 4-5.

As to testing for hyper/hypoglycemia, the record is ambiguous. At best, five hours elapsed before facility staff recorded a finger-stick blood glucose reading. CMS Ex. 12, at 6 (McElroy Decl.); *but see* CMS Ex. 5, at 4-5. According to RN McElroy, at least five hours elapsed between the 11:30 a.m. seizure and the first recorded finger-stick test, which occurred at 4:30 p.m. CMS Ex. 12, at 6 (McElroy Decl.). But the medical records include *no* record of a finger-stick test on January 2. The only 4:30 p.m. finger-stick test occurred on *January 4*. I nevertheless give the facility the benefit of the doubt and assume that R7's blood was tested approximately five hours after her first seizure. R7's glucose was then "slightly low," 64, which, in RN McElroy's view, was not significant. The other two readings were normal (70 and 80), suggesting that the problem was not blood sugar, but something else. But no one then followed up to identify and treat that "something else." CMS Ex. 12, at 6 (McElroy Decl.); CMS Ex. 5.

On the afternoon of January 3, the hospice nurse treated R7's necrotic toe, but her note says nothing about R7's having suffered a seizure the day before, suggesting that she was not aware of it. P. Ex. 15, at 4.[5]

More than two days after the first seizure, when R7 presented with symptoms of a second seizure (in fact, she had a stroke), staff delayed notifying her physician until hours after the onset of symptoms.

Also troublesome, no evidence suggests that the facility timely investigated these failures to monitor and report.

Petitioner asserts that its staff consistently monitored R7 "throughout the three (3) day period from 1-01-06 through 7:00 pm on 1-4-06." Citing generally to four exhibits, Petitioner claims 73 contacts in fewer than 96 hours, including two physician telephone orders and eight nurses note entries. P. Cl. Br. at 4, 8 (citing P. Exs. 15, 32, 39 and 41). P. Ex. 15 consists of nurses notes from January 1 through 4, 2006.[6] I find that the entries prior to R7's January 2 seizure (P. Ex. 15, at 1, 3) are irrelevant to the deficiency cited. Further, the bulk of the entries discuss hospice treatment for R7's necrotic right toe, which is also irrelevant to the deficiency cited. P. Ex. 15, at 1, 3, 4.

---

[5] I note also that the facility personnel did not sign off on the January 3, 2006 hospice nurse's report. P. Ex. 15, at 4.

[6] Petitioner has omitted at least one critical page of the actual nurses notes. *Compare* P. Ex. 15, *with* CMS Ex. 5.

With respect to the remaining exhibits upon which Petitioner relies, P. Ex. 32 is an unsigned report, dated September 10, 2006, prepared by Petitioner's nurse consultant, Linda Wilkerson, R.N. It includes RN Wilkerson's conclusions, based on her review of the medical records, but does not provide any independent evidence of the facility's actions. Moreover, RN Wilkerson's conclusions as to staff's assessing R7's condition following the January 2 seizure are not supported. She notes that at 11:30 a.m. on January 2, 2006, R7 suffered a seizure. She then conflates the minimal January 2 nurses note entry ("resident was having a seizure," "inform them of. . .seizure activity,") with the somewhat more detailed January 4 descriptions ("seizure like activity noted," "eyes fluttering," "tremors to hands. . .facial twitching. . ." "Remains unresponsive with pupils nonresponsive") to conclude that her review of the nurses notes demonstrates "that the facility sufficiently assessed the resident's condition and described a change in the resident's condition as seizure activity." P. Ex. 32, at 2. The simple statement that the resident had a seizure does not establish that staff properly assessed or monitored her symptoms following the January 2 seizure.

P. Ex. 39 is a set of physician orders. There are no physician orders at all for January 2 or 3, 2006. Only one order is dated January 4, 2006 – the telephone order (which does not indicate the time received) directing that R7 be transferred to the hospital. P. Ex. 39, at 2.

The final exhibit cited, P. Ex. 41, consists of CMS survey documents used for gathering facility census information, and seems unrelated to this issue.

Thus, between the morning of January 2, when R7's first seizure was reported, and the evening of January 4, when staff finally sent her to the emergency room, multiple staff members had multiple opportunities to provide and document the care R7 needed. Staff failure to monitor R7 following the report of her initial seizure, staff failure to follow-up with her physician about that seizure, the January 4 delay in notifying her physician about her second seizure, and the absence of any facility investigation of these instances of neglect establish that the facility failed to implement its own policies to prevent neglect. I find this sufficient to establish that the facility was out of compliance with 42 C.F.R. § 483.13(c); *see also* 59 Fed. Reg. 56130 ("A delay in providing needed services for a resident has the potential to cause physical harm and/or mental anguish. Such a delay (or lack of timeliness) can be considered neglect under the definition we are incorporating.").

2. The facility was not in substantial compliance with 42 C.F.R. § 483.25 (quality of care).

Under the statute and the "quality of care" regulation, each resident must receive and the facility must 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. Act § 1819(b)(2); 42 C.F.R. § 483.25.

Failure to follow care plan. The medical professionals who drafted R7's plan of care recognized that she was at risk for stroke – which, even if not fatal, could seriously compromise the quality of her remaining life – as well as complications related to her hypertension and diabetes. So they set the following goals:

- 1) that she be able to function at her then-current level without complications and that all signs and symptoms of a possible CVA be recognized;
- 2) that she not have complications of hypertension; and
- 3) that her diabetes be managed and that she not have complications from her diabetes. P. Ex. 37, at 1, 2, 4.

To meet those goals, the plan calls for careful monitoring and keeping the physician apprised of all suspicious signs and symptoms. I have discussed in some detail the facility staff's failure to follow that plan of care. Because it did not follow that plan, the facility did not provide R7 the services its own medical professionals had identified as necessary "to maintain her highest practicable physical, mental, and psychosocial well-being." On this basis alone, the facility was not in substantial compliance with 42 C.F.R. § 483.25.

Petitioner, however, justifies its failure to provide the services called for in R7's care plan by pointing to R7's receipt of hospice care and the purported "advance directive," by which she declined life-sustaining treatment. P. Exs. 14, 16, 17. But nothing in the hospice agreement nor what Petitioner submits as R7's "advance directive" instructs staff to ignore her care plan. The hospice agreement talks about the focus of its care being to "relieve pain and symptoms and not to cure the disease," and allows for inpatient services in an acute care setting when necessary to stabilize the patient. P. Ex. 14, at 1. Under its terms R7 waives "further *aggressive* treatment for [her] *terminal illness*," (emphasis added) but she does not waive all treatment. P. Ex. 14, at 4.

With respect to R7's "advance directives," one calls for withholding life-sustaining treatment "if such treatment would only prolong my process of dying." P. Ex. 16, at 1, 5. A second document, dated November 1, 2001 (more than four year earlier) simply directs that, if her heart stops beating or she stops breathing, "no medical procedure to restore breathing or heart function. . .be instituted by any health care provider." The document also says that her decision will not prevent her from receiving "other health care such as the Heimlich maneuver or oxygen and other comfort care measures." P. Ex. 17, at 1.[7] R7's care plan, which did not purport to cure her illnesses but was designed to maintain the quality of her life, was fully consistent with these directives and should have been followed.

Failure to consider alcohol consumption. Facility staff also fell short of providing necessary care and services with respect to R7's alcohol consumption. Multiple staff members knew about and reported R7's possession and consumption of alcohol – which obviously presents serious risks for someone with her diabetic condition. On the other hand, no one seemed to know how to respond to the situation. *See* P. Ex. 35; CMS Ex. 9. Alcohol was not discussed in R7's care plan.

Inexplicably, R7's physician, Terrance Grewe, D.O., who was also the facility's medical director, was not aware that R7 had access to alcohol. Nevertheless, he now opines that, had he known, he would not have prohibited its consumption since her condition was terminal. P. Ex. 10, at 3; CMS Ex. 2, at 6. He also opines that "the alcohol found in the subject resident's room played no role in the resident's decline or the cerebrovascular

---

[7] This record does not conclusively establish that R7 had in place a valid and unambiguous advance directive. By its terms, the hospice agreement does not require an advance directive, and no boxes were checked to indicate that an advance directive had been executed. P. Ex. 14, at 2. According to the facility's own assessment forms, R7 had no advance directive. CMS Ex. 8, at 2 (among a check-off list of possible advance directives, only "NONE OF THE ABOVE" is checked). According to the hospital emergency room records, R7 was "full code." CMS Ex. 10, at 1. On January 7, 2006, three days after her hospital admission, a physician (apparently not Dr. Grewe, R7's nominal treating physician) signed a do-not-resuscitate order, based apparently on the 2001 document. P. Ex. 18.

event which led to her hospitalization." P. Ex. 10, at 3.[8] The regulations do not require evidence of actual harm, so whether her stroke was related to alcohol consumption does not determine the facility's compliance with 42 C.F.R. § 483.25.[9]

The issue here is not whether R7 was entitled to consume alcohol (she was, so long as she was informed of the risk), but whether the facility planned for it, and whether her physician knew about it. Alcohol affects blood sugar, so its consumption must be factored into any efforts to control diabetes. Equally significant, R7 had a prescription for the narcotic pain reliever, morphine (also not mentioned in R7's care plan). P. Ex. 39, at 2, 3 (MS Contin is a brand name for morphine). As RN McElroy points out, alcohol and morphine combined pose significant dangers, and R7's physician needed to balance the amount of morphine given with the amount of alcohol consumed, which he obviously could not do since he was not aware that she was consuming alcohol. CMS Ex. 12, at 6 (McElroy Decl.).

Thus, based on the facility's failure to consider, in its care-planning, R7's alcohol consumption, as well as its failure to advise her physician that she was consuming alcohol, I conclude that it was not in substantial compliance with the quality of care regulation, 42 C.F.R. § 483.25.

3. The facility was not in substantial compliance with 42 C.F.R. § 483.10(b)(11) (notification of changes).

The facility must immediately consult with the resident's physician when there is a significant change in a resident's physical, mental, or psychosocial status (i.e., a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications). 42 C.F.R. § 483.10(b)(11)(i). Petitioner concedes that R7's seizures constituted a "significant change." Although staff placed a call to the on-call physician following R7's January 2 seizure, no evidence suggests that the call was

---

[8] I assume Dr. Grewe means that any alcohol *she may have consumed at the facility* played no role in her subsequent decline. Obviously, she had not consumed the alcohol the surveyors later found in her room, so it could not have affected her.

[9] Petitioner also relies on the ALJ opinion in *Alden Town Manor Rehabilitation & HCC*, DAB CR1398 (2006) to argue that CMS must prove that the facility's actions adversely affected the resident. P. Cl. Br. at 16. That decision was reversed on appeal. DAB No. 2054 (2006); *see also Liberty Commons Nursing and Rehab - Alamance*, DAB No. 2070, at 10, *aff'd*, No. 06-1868, 2007 WL 2088703 (4th Cir. July 20, 2007) (case name on appeal *Liberty Commons Nursing and Rehab Center - Johnston v. Leavitt*).

returned or that staff ever "consulted" with the physician. And the uncontroverted evidence establishes that, on January 4, staff delayed for hours contacting R7's physician, even though her condition was rapidly declining.

Petitioner's own witness, Linda Wilkerson, R.N., explains that "a new onset of seizure activity, continuing seizure activity and/or unresponsiveness would be considered potentially life-threatening and meeting the definition of a significant change in condition." P. Ex. 32, at 4. RN Wilkerson agrees with CMS that facility staff failed to consult with R7's physician as required on four occasions: 1) following R7's seizure at 11:30 a.m. on January 2, 2006; 2) following R7's seizure at 4:30 p.m. on January 4, 2006; 3) at 6:00 p.m. on January 4, when R7 became unresponsive; and 4) at 7:00 p.m. on January 4, when R7's finger stick blood sugar level measured 63. P. Ex. 33, at 6-7; P. Ex. 32, at 3-4. *Accord* CMS Ex. 12, at 5-6 (McElroy Decl.).

The facility was thus not in substantial compliance with the requirement that it consult with the residents' physician when there is a significant change in a resident's physical, mental, or psychosocial status, 42 C.F.R. § 483.10(b)(11).

C. On January 12, 2006, the facility's deficiencies posed immediate jeopardy to resident health and safety.

I next consider whether CMS's immediate jeopardy finding was "clearly erroneous." 42 C.F.R. § 498.60(c)(2). The Board has observed repeatedly that the "clearly erroneous" standard imposes on facilities a "heavy burden" to show no immediate jeopardy, and has sustained determinations of immediate jeopardy where CMS presented evidence "from which '[o]ne could reasonably conclude' that immediate jeopardy exists." *Barbourville Nursing Home*, DAB No. 1962, at 11 (2005); *Florence Park Care Center*, DAB No. 1931, at 27-28 (2004), *citing Koester Pavilion*, DAB No. 1750 (2000).

Immediate jeopardy exists if the facility's noncompliance has caused or is likely to cause "serious injury, harm, impairment, or death to a resident." 42 C.F.R. § 488.301.[10]

---

[10] Citing some unofficial source (*The Facility Guide to OBRA Regulations and the Long-Term Care Survey Process*, Heaton Resources, Revised June 2006), Petitioner claims that, in order to find immediate jeopardy, "**the threat must be present when [the surveyors] are onsite**." P. Cl. Br. at 10. Petitioner has not provided a copy of the exact document upon which it relies, so I am not able to review its provisions. I seriously doubt that any reputable source would provide this level of misinformation. Immediate jeopardy exists if the facility's noncompliance *has caused* or is likely to cause "serious injury, harm, impairment, or death to a resident" (42 C.F.R. § 488.301) and surveyors need not be present at the time of the noncompliance in order to find immediate jeopardy.

I recognize the seriousness of R7's underlying condition, and I do not know whether her very negative outcome – seizure, stroke, paralysis – could have been avoided (although her care plan suggests that possibility). Nevertheless, the regulation does not require that a resident suffer actual harm; the *likelihood* of serious injury or harm establishes immediate jeopardy. *Liberty Commons Nursing and Rehab - Alamance*, DAB No. 2070, at 10, *aff'd*, No. 06-1868, 2007 WL 2088703 at *3 (4th Cir. July 20, 2007). That the facility's actions (or inactions) were likely to cause R7 serious injury, harm, or even death is well-supported by this record. First, with respect to staff's failure to follow R7's care plan in responding to her seizures, Petitioner's own consulting nurse characterized as "potentially life-threatening" the onset of a seizure, continuing seizure, and the resident's subsequent unresponsiveness. P. Ex. 32, at 4. Yet, the facility failed to monitor and failed to report those significant changes in her condition.

Second, the facility did not consider R7's alcohol consumption in its care planning, and did not report to her physician that she consumed alcohol. Yet, the physician prescribed morphine. I find that combination of diabetes, morphine, and alcohol consumption – in the absence of planning – is potentially lethal, creating the likelihood of serious harm.

In light of these significant facts, I do not find "clearly erroneous" CMS's immediate jeopardy determination.

D. I find reasonable the imposition of a $3300 per day CMP for the period of immediate jeopardy.

Having found a basis for imposing a CMP, I now consider whether the amount imposed is reasonable. CMS imposed a penalty of $3300 per day for one day of immediate jeopardy, which is barely above the mandatory minimum ($3050) for immediate jeopardy situations.

I determine whether the amount imposed 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. 42 C.F.R. § 488.438(f). 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; 3) the facility's prior history of noncompliance in general and specifically with reference to the cited deficiencies.

CMS does not contend that facility history is a factor here, and Petitioner does not claim that its financial condition would be compromised if it were compelled to pay this fairly minimal CMP. With respect to the other factors, however, I find that the deficiencies were serious and the facility was culpable. R7's well-being was seriously jeopardized by multiple instances of staff neglect. In light of these factors, I find reasonable this relatively minimal CMP.

IV. Conclusion

For the reasons discussed above, I uphold CMS's determination that, from January 12 – February 13, 2006, the facility was not in substantial compliance with program participation requirements, specifically 42 C.F.R. §§ 483.13 and 483.20. I also find that, on January 12, 2006, its deficiencies posed immediate jeopardy to resident health and safety. I sustain, as reasonable, the $3300 per day CMP for the period of immediate jeopardy. Finally, since the penalty imposed from January 13 through February 13, 2006 ($50 per day), is the statutory minimum CMP, I also sustain that amount.

/s/

Carolyn Cozad Hughes
Administrative Law Judge