Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Life Care at Hilton Head,	)	Date: February 27, 2009
(CCN: 42-5147),	)	
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-08-168
	)	Decision No. CR1908
Centers for Medicare & Medicaid	)	
Services.	)	
	)	

DECISION

Petitioner, Life Care at Hilton Head (Petitioner or facility), is a long term care facility located on Hilton Head Island, South Carolina, that is certified to participate in the Medicare program. The Centers for Medicare & 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. Petitioner appealed.[1]

I conclude that, from September 21 through October 24, 2007, the facility was not in substantial compliance with program requirements and that, from September 21 through October 11, 2007, its deficiencies posed immediate jeopardy to resident health and safety. I find reasonable the civil money penalty (CMP) imposed – $4550 per day for 21 days of immediate jeopardy, plus $100 per day for 13 days of substantial noncompliance that was not immediate jeopardy.

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

[1] As discussed below, because Petitioner did not appeal deficiencies cited under 42 C.F.R. § 483.35(d)(3) (dietary services – food) or 42 C.F.R. § 483.75(l)(1) (clinical records), the facility was not in substantial compliance with Medicare requirements. P. Ex. 1, at 16-24; *see* Hearing Request. I address here the deficiencies that allegedly posed immediate jeopardy.

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 with program participation requirements. 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), 488.308.

Here, following an annual survey, completed October 11, 2007, CMS determined that the facility was not in substantial compliance with Medicare participation requirements, specifically, 42 C.F.R. §§ 483.20(k) (Tag F282 – comprehensive care plans); 42 C.F.R. § 483.25 (Tag F309 – quality of care); 42 C.F.R. § 483.35(d)(3) (Tag F365 – dietary services, food); 42 C.F.R. § 483.75(i) (Tag F501 – medical director); and 42 C.F.R. § 483.75(l)(1) (Tag F514 – clinical records). CMS also determined that the facility's substantial noncompliance began on September 21, 2007, and that its deficiencies resulted in substandard quality of care and posed immediate jeopardy to resident health and safety. CMS Ex. 1; P. Exs. 1, 2. CMS subsequently determined that the immediate jeopardy abated effective October 12, 2007, and that the facility returned to substantial compliance on October 25, 2007. P. Exs. 4, 5.

CMS has imposed against the facility a CMP of $4550 per day for 21 days of immediate jeopardy ($95,550), and $100 per day for 13 days of substantial noncompliance that was not immediate jeopardy ($1300). ($96,850 total). CMS has also imposed a Denial of Payment for New Admissions (DPNA) from October 21 through October 24, 2007. P. Exs. 3, 4, 5.

I held a hearing by telephone on August 5, 2008. Joseph Bianculli appeared on behalf of Petitioner and Heather Horton appeared on behalf of CMS. I have admitted into evidence CMS Exhibits (Exs.) 1-22 and P. Exs. 1-73 (including P. Ex. 21A). Tr. 3. The parties have filed opening briefs (Br.), closing briefs (Cl. Br.) and reply briefs (Reply).

II. Issues

In its request for hearing, Petitioner explicitly and emphatically limited its appeal to the findings underlying CMS's determinations of immediate jeopardy and substandard quality of care. ("**This Request for Hearing does not address the 'non-jeopardy' deficiencies cited following the October 11, 2007 survey, nor the $100 per day CMP associated with those deficiencies.**") Petitioner repeated this assertion in its pre-hearing

and post-hearing briefs. P. Br. at 3; P. Cl. Br. at 5. I therefore conclude that, from September 21 through October 24, 2007, the facility was not in substantial compliance with 42 C.F.R. § 483.75(l)(1) (clinical records) and 42 C.F.R. § 483.35(d)(3) (dietary services – food), and affirm as reasonable the $100 per day penalty from October 12 through 24, 2007 ($1300) and the DPNA in effect from October 21 through 24, 2007.[2]

I consider here the following issues:

- from September 21 through October 24, 2007, was the facility in substantial compliance with 42 C.F.R. §§ 483.20(k), 483.25, and 483.75(i);

- if the facility was not in substantial compliance from September 21 through October 11, 2007, did its deficiencies then pose immediate jeopardy to resident health and safety;

and

- if the facility was not in substantial compliance, was the penalty imposed ($4550 per day for 21 days of immediate jeopardy) reasonable?

III. Discussion

A. The facility was not in substantial compliance with 42 C.F.R. §§ 483.20(k) and 483.25 because the facility did not assure that its residents' dialysis shunt sites were monitored daily and facility staff failed to follow resident care plans with respect to monitoring shunt sites.[3]

The facility must develop a comprehensive care plan for each resident. The plan must include measurable objectives and time-tables to meet the resident's identified needs, and must describe the services to be furnished. Those services must meet professional standards of quality and be provided by qualified persons in accordance with the care plan. 42 C.F.R. § 483.20(k). The facility must then provide to each resident the care and services necessary to allow him/her to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the resident's comprehensive assessment and care plan. Act, section 1819(b); 42 C.F.R. § 483.25. The facility's medical director (who must be a physician) is ultimately responsible for implementing resident care policies and coordinating medical care in the facility. 42 C.F.R. § 483.75(i).

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[2] A facility may not appeal CMS's choice of remedy. 42 C.F.R. § 488.408(g).

[3] My findings of fact and conclusions of law are set forth, in italics and bold, in the discussion captions.

In this case, six facility residents required regular kidney dialysis treatment, which was provided by an outside dialysis center. Each resident had in place a dialysis shunt, also known as a fistula or graft. A dialysis shunt is a surgically-created connection between an artery and a vein that provides a location for dialysis needle access. P. Ex. 69, at 2 (Perez Decl.); P. Ex. 72, at 3 (Parris Decl.). According to Marjorie Grant-Lewis, R.N., the facility's director of nursing (DON), facility policies require "routine" monitoring of each shunt site for complications, "such as tenderness, redness, clotting, and the like . . . that could be indications of infection, a clogged shunt, etc." P. Ex. 70, at 3 (Grant-Lewis Decl.).

In addition, each resident's care plan addressed his/her need for dialysis and included among its goals: dialysis treatment "without complications." CMS Ex. 5, at 1; CMS Ex. 7, at 1; CMS Ex. 9, at 1; CMS Ex. 11, at 1; CMS Ex. 13, at 1; CMS Ex. 15, at 1. To achieve this goal, each care plan required that staff monitor the resident's shunt site:

- Resident 13: "Assess shunt site for bruit and thrill,"[4] and "Observe for bleeding at site of shunt." CMS Ex. 5, at 1; P. Ex. 12.

- Resident 20: "Assess the dialysis shunt site daily," and "Assess area for any drainage or bleeding." CMS Ex. 7, at 1.[5]

- Resident 21: "Observe for bleeding at site of shunt." CMS Ex. 9, at 1; P. Ex. 31, at 3.

- Resident 22: "Assess the dialysis shunt site daily," and "Assess area for any drainage or bleeding." CMS Ex. 11, at 1; P. Ex. 41, at 1.

- Resident 23: "Observe for bleeding at site of shunt." CMS Ex. 13, at 1; P. Ex. 59, at 4.

- Resident 24: "Observe for bleeding at site of shunt." CMS Ex. 15, at 1.

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[4] A "bruit" is a whooshing sound heard through a stethoscope. "Thrill" is pulsation felt over the access site by feeling with fingers. CMS Ex. 16, at 2 (Phillips Decl. ¶ 18).

[5] Petitioner has submitted a care plan for Resident 20 that is dated April 9, 2008, which calls for even closer monitoring (assess shunt every eight hours, verify peripheral pulses distal to shunt site every eight hours, verify presence of bruit or thrill at shunt site every eight hours). P. Ex. 21A, at 6. Because it was generated months after the period of substantial noncompliance, the document is not relevant to what was going on in the facility at the time of the survey (although the revised plan arguably undermines Petitioner's suggestion that its residents required little to no site monitoring beyond that provided by the dialysis center).

The facility thus recognized the importance of monitoring the shunt sites for bleeding, infection or other complications.

Standard of care. The parties seem to agree that the standard of care requires staff to monitor a shunt site for complications once a day. The facility's medical director, Dr. Gaston Perez, M.D., opines that "the standard of care is for a nursing facility's staff to monitor a shunt site for complications once a day . . . ." P. Ex. 69, at 3 (Perez Decl.). DON Grant-Lewis agrees: "I agree with Dr. Perez and Nurse [Parris] that daily monitoring is completely appropriate and adequate for residents who go out to dialysis at an outside center three times per week." P. Ex. 70, at 3 (Grant-Lewis Decl.). According to the facility's administrator, James Hardy, "[D]aily monitoring of the shunt site is adequate and appropriate." P. Ex. 71, at 2 (Hardy Decl.). The outside dialysis center's clinical manager, Lelia Wirt, R.N., says the same: "[D]aily monitoring of the shunt site for clots, redness, infection, and the like, is . . . the standard of care in the dialysis industry." P. Ex. 73, at 1-2 (Wirt Decl.). And Derek Parris, the R.N. Regional Director of Clinical Services for Petitioner's parent company, appears to agree: "[T]he shunt site shall be checked on a daily basis with physician notification for any known or suspected problem." P. Ex. 72, at 4 (Parris Decl.).[6] State Surveyor, Karen Phillips, initially testified that compliant facilities should monitor shunt sites "every eight hours, or[,] at a minimum, once a day." CMS Ex. 16, at 2 (Phillips Decl. ¶ 20). Under cross-examination, she agreed that "it's okay to do it once a day." Tr. 15, 24;[7] *see also* CMS Ex. 21, at 4 ("Daily Checks of Vascular Access").

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[6] *But see* P. Ex. 72, at 3 (Parris Decl.) ("Our pertinent Policy and Procedure . . . provides that the shunt site should be covered by a dressing, and that our nursing staff should not even change the dressing unless necessary.") And Petitioner claims that "FMC Hilton Head Dialysis instructs Petitioner's staff that they ordinarily should not even touch or change dressings at the shunt site . . . ." P. Cl. Br. at 9. In fact, I found no indication in the record of such instructions from the dialysis center. Clinical Manager Wirt's declaration does not say it. P. Ex. 73. The opinion is attributable solely to Regional Director Parris. P. Ex. 72, at 1, 3. Moreover, Petitioner's written policies and procedures instruct staff to change dressings when certain complications arise, which seems inconsistent with Petitioner's suggestion that only dialysis center staff address such problems. CMS Ex. 17, at 2.

[7] Petitioner claims that Surveyor Phillips "considered 'daily' monitoring of the shunt site to be inadequate, either in general, or in the cases of the residents she cited." P. Cl. Br. at 15. This is simply incorrect. Although she expressed a preference for monitoring every shift, she agreed that daily monitoring is acceptable. CMS Ex. 16, at 2 (Phillips Decl. ¶ 20); Tr. 15, 24.

Even though the facility recognized the importance of observing the shunt sites daily for bleeding, infection or other complications, Petitioner has come forward with no reliable evidence to establish that it followed the care plans and met the standard of care by monitoring the shunt site daily.[8]

Resident 13 (R13): ("Assess shunt site for bruit and thrill"; "Observe for bleeding at site of shunt.") Nurses notes reflect that staff assessed R13's shunt site for bruit and thrill on the day of her admission, August 20, 2007. CMS Ex. 5, at 3; P. Ex. 16, at 1. Thereafter, however, her records include no reference to any other observation or assessment of her shunt site until the time of the survey, when, on October 10, 2007, staff again assessed her shunt site for bruit and thrill. CMS Ex. 5, at 21.

Resident 20 (R20): ("Assess the dialysis shunt site daily"; "Assess area for any drainage or bleeding.") R20 was admitted to the facility on April 10, 2007. An April 20, 2007 nursing note says "no side effects from dialysis noted" but does not mention the shunt site. CMS Ex. 7, at 6; P. Ex. 25, at 5. In fact, R20's medical records include no references to any observations or assessments of her shunt site from the time of her admission until July 2, 2007. On that date, a nurse reports "[no] bleeding noted after returning from dialysis." CMS Ex. 7, at 19; P. Ex. 25, at 18. For the following two weeks, nurses sporadically report monitoring the shunt site. On July 10, 2007, the nurse writes "thrill felt/bruit heard [at] graft site." CMS Ex. 7, at 22; P. Ex. 25, at 21. On July 11, 2007, the nurse writes "dialysis site ok [no] bleeding." CMS Ex. 7, at 22; P. Ex. 25, at 21. On July 14, the nurse reports "graft site in tact." CMS Ex. 7, at 23; P. Ex. 25, at 22.

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[8] In its reply brief, Petitioner claims that CMS has impermissibly raised, as a new issue, the adequacy of the care actually provided. P. Reply at 3-6. But, from the issuance of the statement of deficiencies through the submission of its reply brief, CMS has consistently maintained that staff were not monitoring resident shunt sites as required. *See*, *e.g.*, P. Ex. 1, at 1, 3 ("[T]he facility failed to follow the plan of care for 6 of 6 dialysis residents related to checking dialysis shunts/access sites."); CMS Br. at 8 ("[N]one of the six dialysis residents surveyed had their vascular access sites assessed every eight hours, or even daily."); CMS Cl. Br. at 4 ("The nursing home's failures with regard to providing six of six dialysis residents with necessary care and services, in violation of 42 C.F.R. § 483.25, constituted substandard quality of care and posed immediate jeopardy to all these residents.") Moreover, Petitioner has consistently recognized that the issue is adequacy of care. In its hearing request, for example, it writes: "The most serious allegations, which support the 'immediate jeopardy' findings, all essentially allege that the Center's staff and Medical Director failed to implement certain care plan interventions to monitor the dialysis access sites of several residents." Hearing request at 3; *see also* P. Ex. 1, at 2 (as part of its plan of correction, inservice instructing staff "what to assess regarding the resident's shunt").

An entry dated July 18, 2007, indicates that the dialysis center called to report a possible blockage in R20's shunt. CMS Ex. 7, at 26; P. Ex. 25, at 24. The information apparently had no effect on the staff's performance, inasmuch as they did not start checking the shunt site daily as required. The next reference to checking R20's shunt site is three days later, and then nothing for three months. On July 21, 2007, a nurses note says "[Dressing] to [left] thigh intact[;] no signs of bleeding noted this shift." CMS Ex. 7, at 27; P. Ex. 25, at 25.

On September 12, 2007, the notes indicate that the resident returned from dialysis "with blood all over clothes." CMS Ex. 7, at 30; P. Ex. 25, at 28. Staff apparently changed her clothes, but nothing suggests that they then checked her shunt site. On September 21, 2007, R20 again returned from dialysis with blood "all over clothes and wheel chair." CMS Ex. 7, at 34; P. Ex. 25, at 32. The nurse reports that she cleaned her up, but still does not mention checking the shunt site. In fact, the record contains no suggestion that anyone monitored R20's shunt site again until October 3, 2007, when the nurse writes that R20 "[r]eturned from dialysis, checked dialysis site, noted some previous bleeding, no active bleeding noted." CMS Ex. 7, at 38; P. Ex. 25, at 36. On October 10 (the time of the survey) staff next document checking the site ("[positive for] bruit [and] thrill"). CMS Ex. 7, at 39; P. Ex. 25, at 37.

Resident 21 (R21): ("Observe for bleeding at site of shunt.") R21 was admitted to the facility on May 17, 2007. No evidence suggests that anyone checked her shunt site until two days later. A nurses note dated May 19 describes the graft as "intact," and says "thrill and bruit heard." P. Ex. 35, at 3. On June 12, 2007, a nurse writes "shunt D & I." P. Ex. 35, at 14. Otherwise R21's records include no additional indication that staff observed the site for bleeding, as called for in her care plan.

Resident 22 (R22): ("Assess the dialysis shunt site daily"; "Assess area for any drainage or bleeding.") R22 resided in the facility from April 4, 2007 until May 21, 2007. No entry even mentions the shunt site until May 11, 2007, when a nurses note describes the site as "clean and dry" and notes "bruit/thrill present." P. Ex. 45, at 18. The following day, the nurse reported "shunt site clean and dry thrill/bruit present." P. Ex. 45, at 19. On May 13, a nurse describes the shunt site as "clean" and "bruit/thrill present." P. Ex. 45, at 19. Several days pass without mention of the site. Then, on May 17, the nurse writes "thrill felt[;] bruit heard [without] difficulty." P. Ex. 45, at 21. Staff next note "shunt in place[,] thrill felt[,] bruit heard" on May 20. P. Ex. 45, at 22.

Resident 23 (R23): ("Observe for bleeding at site of shunt.") R23 was admitted to the facility on March 20, 2007, but his treatment records indicate that staff first checked his shunt on March 27, noting "left arm shunt pos[itive] for bruit [and] pulsating[;] [dressing] dry [and] intact. P. Ex. 54, at 2. The next day, staff noted "shunt thrill felt, bruit heard." P. Ex. 54, at 3. His records contain no other mention of monitoring. R23 stopped dialysis treatment about May 7, 2007, and entered hospice care. P. Ex. 54, at 13.

Resident 24 (R24): ("Observe for bleeding at site of shunt.") R24 was a short-term placement, admitted to the facility on April 13, 2007. P. Ex. 57; P. Ex. 64, at 1. Notwithstanding his care plan, his treatment record contains not a single instance of staff observing his shunt site.

Thus, review of the facility's own treatment records establishes that, at most, staff only sporadically monitored the resident shunt sites, neither meeting the standard of care nor following these residents' individual care plans. *See Universal Healthcare/King*, DAB No. 2215, at 23 (2008) (ALJ reasonably relied on facility's failure to document.). Nor did any treating nurse or other employee testify that, in fact, (s)he checked shunt sites daily, but then simply failed to document having done so.

Petitioner, however, argues that the absence of documentation does not mean that its staff failed to monitor the shunt sites as required, but instead means that their doing so was too inconsequential to merit documentation. According to Petitioner, facility policy was to "document by exception," which means that nurses were required to document care provided for acute conditions, but not for treatment of chronic conditions, like end stage renal disease. For these less serious chronic conditions, staff need only report abnormal findings.[9]

The Departmental Appeals Board has appropriately rejected such reasoning. In *The Laurels at Forest Glen*, DAB No. 2182 (2008), the treatment records of a diabetic resident lacked documentation of blood glucose test results. As here, the facility argued that, because the resident's diabetes was a chronic condition, staff appropriately focused its attention on treating the significant injuries that had necessitated the resident's admission. The Board found it "not reasonable" to focus on recent injuries "to the exclusion of addressing [the resident's] diabetes, his . . . hypoglycemia, and the consequent need to monitor [his] blood sugar levels . . . ." A facility is responsible for ensuring that each resident receives *all* necessary care and services. *Id.* at 17.

Further, the facility's own documentation policies require that "nursing care that is based on the interdisciplinary care plan" be documented in the clinical record. This documentation requirement specifically includes reporting the care provided and the resident's "current status." P. Ex. 6, at 6. So, inasmuch as each resident's care plan

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[9] Although some people live many years with end stage renal disease, it is nevertheless a serious condition, and the dialysis-related problems for at least four of the six residents in this case were especially significant. Among R20's primary diagnoses were end-stage renal disease and diabetes, and she had demonstrated susceptibility to bleeding at her shunt site. P. Ex. 20; P. Ex. 70, at 3 (Grant-Lewis Decl.). In addition to his end stage renal disease, R22 had demonstrated that he was susceptible to serious infections. P. Ex. 44, at 1. R23 had suffered kidney failure secondary to acute sepsis. P. Ex. 70, at 6 (Grant-Lewis Decl.). R24 was admitted to the facility with "acute renal failure." P. Ex. 70, at 6 (Grant-Lewis Decl.).

required shunt site monitoring, the facility policy mandated that staff document whenever they provided it. A second document, titled "Medicare *Documentation* Guidelines," (emphasis added) specifically instructs staff to address "thrill and bruit" in "daily nursing." CMS Ex. 7, at 53. CMS may reasonably rely on the provider's policies as "evidence of the standard of care the facility expect[s] its staff to provide" as well as evidence of the professional standards of care. *The Laurels at Forest Glen*, DAB No. 2182, at 18 (quoting *Oxford Manor*, DAB No. 2167, at 5-6 (2008)).[10]

Finally, no member of the facility's staff testified that the facility policy was to "document by exception" their monitoring of shunt sites. Presumably, the DON would be most familiar with the facility's practices with respect to documenting nursing care, and DON Grant-Lewis said nothing about documentation by exception. P. Ex. 70 (Grant-Lewis Decl.). Neither Medical Director Perez (P. Ex. 69) nor Administrator Hardy (P. Ex. 71) made any claims regarding documentation by exception. Only Regional Director Parris, who did not actually work in the facility, defends the practice. But even he does not say that "document by exception" was the facility policy. P. Ex. 72, at 7-9.[11]

Thus, the residents' care plans and the standard of care require that facility staff monitor the resident shunt sites daily, but they did not do so. The facility was therefore not providing services in accordance with its care plans or professional standards of quality, in violation of 42 C.F.R. § 483.20(k). It was not providing to those residents who had shunt sites the care and services needed to allow them to attain or maintain the highest practicable physical well-being, in accordance with their care plans. This failure puts the facility out of substantial compliance with 42 C.F.R. § 483.25.

Because the facility's medical director is ultimately responsible for implementing resident care policies, staff failure to follow the care plans arguably implicates the regulation governing medical directors, 42 C.F.R. § 483.75. However, inasmuch as the deficiencies cited directly violate sections 483.20(k) and 483.25, I need not consider the somewhat closer question as to whether they also violated section 483.75.

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[10] Petitioner also points out that its staff regularly recorded their routine observation and care of chronic conditions, documenting normal findings for blood sugar levels (CMS Ex. 5, at 4- 21; P. Ex. 16, at 2-19; CMS Ex. 7, at 2-39; P. Ex. 35, at 2-3, 4, 5; P. Ex. 45; P. Ex. 64); vital signs (CMS Ex. 7, at 3, 6); and wound care (CMS Ex. 5, at 4-9, 11-13, 15-19; P. Ex. 35, at 1-5; P. Ex. 45). While this fact does not address the deficiency actually cited – that they were not monitoring the shunt sites – it seems to undermine Petitioner's claim that facility policy was to "document by exception" its monitoring of chronic conditions.

[11] If, in fact, Regional Director Parris meant to imply that "documentation by exception" was the facility policy for monitoring shunt sites, I would reject that testimony as inconsistent with the facility's written policy, P. Ex. 6, at 6.

Finally, although, as Petitioner points out, CMS has not alleged that any resident was harmed by the facility's deficiencies, I need not find actual harm in order to sustain the finding of substantial noncompliance. Whenever a deficiency poses the potential for more than minimal harm, the facility is not in substantial compliance, and CMS has the authority to impose a remedy. Act, section 1819(h); 42 C.F.R. §§ 488.301, 488.402, 488.406. Failing to monitor a shunt site for symptoms of bleeding, clotting, or infection, as required by the resident care plan and standard of care, poses the potential for more than minimal harm. *See* discussion below.

B. CMS's determination that the facility's deficiencies posed immediate jeopardy to resident health and safety is not clearly erroneous.

I next consider whether CMS's immediate jeopardy finding was "clearly erroneous."

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 would include an immediate jeopardy finding) must be upheld unless it is "clearly erroneous." 42 C.F.R. § 498.60(c).

As a general principle, the facility that disregards patient care plans plays a dangerous game. The plan is in place because health care professionals have identified the resident's needs and come up with ways to address them. Here, the plans recognize the vulnerabilities of those in dialysis, particularly with regard to potential complications at the shunt sites. And those concerns are well taken. *See*, *e.g.*, CMS Exs. 19, 20. Shunt sites are susceptible to bleeding, clotting, infection, and other complications.

Petitioner, however, minimizes the potential danger. Dr. Perez acknowledges that a shunt may clog, and that bleeding is "not unusual." He also acknowledges that "serious and even fatal hemorrhaging from dialysis has been reported," but characterizes such results as "very rare," particularly if the dialysis center is providing appropriate treatment and observations. He also says that "[i]t would be extremely unusual . . . for such a clot to cause any significant problem within a day or two." P. Ex. 69, at 2-4 (Perez Decl.). Thus, in Petitioner's view, the facility's failure to monitor shunt sites poses little risk to its dialyzed residents so long as the staff *at the dialysis center* are doing their jobs properly.

First, while I agree that dialysis center staff are responsible for monitoring their patients, that does not eliminate the facility's independent responsibility under the regulations to follow resident care plans and to provide services necessary to insure that each resident achieve or maintain the highest practicable well-being. *See Transitional Health Services of Fremont*, DAB CR1833, at 10 (2008). Moreover, even assuming the staff at the dialysis center were monitoring appropriately, they saw the residents just three times per

week (Monday, Wednesday and Friday). Assuming a resident never missed a dialysis treatment, his/her shunt site would be monitored only every two to three days unless the facility was also checking it. Neither Dr. Perez nor anyone else has suggested that clotting/bleeding/infection would present no significant problems if undetected for up to three days.

Second, immediate jeopardy does not require an imminent medical emergency. Rather, Petitioner must show that the potential harm or injury "did not meet any reasonable definition of 'serious.'" *Daughters of Miriam Center*, DAB No. 2067, at 9 (2007); *Hallmark House Nursing Center*, DAB No. 2226, at 6 (2009). And these residents had demonstrated that they were particularly vulnerable to complications. When the dialysis center contacted facility staff about possible blockage to R20's shunt, it should have alerted staff to the need for increased vigilance in monitoring, but it had no such effect; staff still did not adhere to the care plan nor meet the standard of care. The next reference to checking R20's shunt site is two days later, and then nothing for three months. R20's repeated incidents of bleeding elicited a similar lack of response. Both R22 and R23 had demonstrated a disturbing susceptibility to serious infection. Yet staff were not ensuring that their shunt sites were free of symptoms of infection.

I consider this disregard likely to cause serious injury. I therefore do not find clearly erroneous CMS's immediate jeopardy determination.[12]

C. The amount of the CMP is reasonable.

I next consider whether the CMP was 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.

It is well-settled that, in reaching a decision on the reasonableness of the CMP, I consider whether the evidence presented on the record concerning the relevant regulatory factors 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

[12] Petitioner also accuses CMS of arbitrarily selecting October 11 as the date the immediate jeopardy ended. P. Reply at 21. In fact, CMS selected the date that the facility alleged it removed the immediate jeopardy by providing its nursing staff with inservice training on requirements for monitoring shunt sites, specifically what to assess, potential complications, and documentation requirements. P. Ex. 1, at 3.

of the other factors involved (financial condition, facility history, culpability). 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. 1683, at 8.

CMS has imposed a penalty of $4550 per day for the period of immediate jeopardy, which is at the low end of the penalty range ($3050-$10,000). 42 C.F.R. § 488.438(a)(1).

The parties have provided me little assistance on this issue. I have no information as to the facility history. Petitioner has not argued that its financial condition affects its ability to pay the penalty. With respect to the remaining factors, I note that the scope of the facility's noncompliance, by itself, justifies imposing a penalty above the minimum. Moreover, the facility is culpable for almost totally disregarding its obligations to follow care plans and to monitor daily the shunt sites of its residents undergoing kidney dialysis. I find that these factors justify the penalty imposed.

IV. Conclusion

For all of the reasons discussed above, I uphold CMS's determination that, from September 21 through October 24, 2007, Petitioner was not in substantial compliance with program participation requirements, and that from September 21 through October 11, 2007, its deficiencies posed immediate jeopardy to resident health and safety. I find that the CMP imposed – $4550 per day for 21 days of immediate jeopardy – was reasonable.

/s/
Carolyn Cozad Hughes
Administrative Law Judge