Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Haven Health Center of Windham	)	
(CCN: 07-5425),	)	Date: September 24, 2007
	)	
Petitioner,	)	Docket No. C-04-213
	)	Decision No. CR1656
- v. -	)	
	)	
Centers for Medicare & Medicaid	)	
Services.	)	
	)	

DECISION

Petitioner, Haven Health Center of Windham, Willimantic, Connecticut, is certified to participate in the Medicare and Medicaid programs as a provider of services. Petitioner challenges the Centers for Medicare & Medicaid Services' (CMS) determination that it was not in substantial compliance with program participation requirements and CMS's imposition of a per instance civil money penalty (CMP) of $2000. For the reasons discussed below, I find that CMS did not make a *prima facie* case that Petitioner was out of substantial compliance with participation requirements and, thus, CMS's determination to impose the $2000 per instance CMP is not supported by the record.

I. Background

The Connecticut Department of Public Health, Division of Health Systems Regulation (State Agency) completed a complaint survey at Petitioner's facility on October 17, 2003. The State Agency determined that Petitioner was out of compliance with the Medicare participation requirement at 42 C.F.R. § 483.10(b)(11) (F Tag 157 on the statement of deficiencies (SOD or 2567)) and that the noncompliance was an isolated deficiency that constituted actual harm not amounting to immediate jeopardy (a scope and severity level G). By letter dated December 18, 2003, CMS imposed a per instance CMP of $2000 based on the State Agency determination.

By letter dated February 6, 2004, Petitioner requested a hearing. The case was assigned to me for hearing and decision. On May 3, 2004, the parties submitted stipulations with CMS's readiness report (Stip.). I held a hearing in Hartford, Connecticut, on July 12, 2005.[1] I heard the testimony of three witnesses: Deborah Casinghino, the State Agency surveyor who conducted the complaint survey in this case; Petitioner's current Director of Nursing (DON) Karen Parry; and Petitioner's expert witness, Frederick Rowland, M.D., Ph.D. I admitted into evidence CMS Exhibits (CMS Exs.) 1-44 (Transcript (Tr.) at 9)[2] and Petitioner's Exhibits (P. Exs.) 1-4. Tr. at 10. Both parties submitted briefs (CMS Br. and P. Br.).

II. Issues

1. Whether Petitioner was out of substantial compliance with participation requirements.

2. If Petitioner was out of substantial compliance with participation requirements, whether the $2000 CMP imposed by CMS against Petitioner is reasonable.

III. Statutory and Regulatory Background

The Social Security Act (Act) sets forth requirements for nursing facilities participating in the Medicare and Medicaid programs, and authorizes the Secretary of Health and Human Services to promulgate regulations implementing the statutory provisions. Act, sections 1819 and 1919. The Secretary's regulations governing nursing facilities participating in the Medicare program are found at 42 C.F.R. Parts 483, 488, and 489.

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[1] At the conclusion of CMS's case, Petitioner moved for a directed verdict, alleging CMS had not established its *prima facie* case. I informed the parties I would consider whether CMS had established a *prima facie* case in my decision. Tr. at 45-48.

[2] CMS Ex. 11 was not included in the stack of documents CMS provided me at the hearing and which I took into evidence and brought back to my office. During the parties' prehearing exchange, CMS provided me with two copies of CMS Ex. 11. I am placing one of those copies in the record as CMS Ex. 11 in order to complete the record. I have not, however, relied on CMS Ex. 11 in making my decision in this case. I note also that CMS's Exhibits, other than CMS Exs. 43 and 44, were marked as Docket No. C-04-121. The correct docket number for this case is Docket No. C-04-213. I am not, however, re-marking CMS's exhibits.

To participate, 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.

If a facility is not in substantial compliance with program requirements, CMS has the authority to impose one or more of the enforcement remedies listed in 42 C.F.R. § 488.406, which include imposing a CMP. *See* Act, section 1819(h). CMS may impose a CMP for the number of days that a facility is not in substantial compliance with one or more program requirements, or for each instance that a facility is not in substantial compliance. 42 C.F.R. § 488.430(a); 488.440. If CMS imposes a per instance CMP, the CMP will be in the range of $1000-$10,000. 42 C.F.R. § 488.438(a)(2).

IV. Burden of Proof

As an evidentiary matter, CMS has the burden of coming forward with evidence related to disputed findings that is sufficient (together with any undisputed findings and relevant legal authority) to establish a *prima facie* case of noncompliance with a regulatory requirement. If CMS makes this *prima facie* showing, then the petitioner must carry its ultimate burden of persuasion by showing, by a preponderance of the evidence, on the record as a whole, that it was in substantial compliance during the relevant period. *Evergreene Nursing Care Center,* DAB No. 2069, at 7 (2007); *Hillman Rehabilitation Center,* DAB No. 1611 (1997), *aff'd, Hillman Rehabilitation Ctr.,* No. 98-3789 (GEB) (D. N.J. May 13, 1999); *Batavia Nursing and Convalescent Inn,* DAB No. 1911 (2004), *aff'd, Batavia Nursing and Convalescent Center v. Thompson,* No. 04-3687 (6th Cir. 2005); *Guardian Health Care Center,* DAB No. 1943 (2004); *Fairfax Nursing Home, Inc.*, DAB No. 1794 (2001), *aff'd, Fairfax Nursing Home v. Dep't of Health & Human Srvcs*, 300 F.3d 835 (7th Cir. 2002), *cert. denied*, 2003 WL 98478 (Jan. 13, 2003).

CMS makes a *prima facie* showing of noncompliance if the evidence CMS relies on is sufficient to support a decision in its favor absent an effective rebuttal. *Evergreene,* DAB No. 2069; *Hillman Rehabilitation Center,* DAB No. 1663, at 8 (1998), *aff'd*, *Hillman Rehabilitation Ctr. v. HHS,* No. 98-3789 (GEB) (D. N.J. May 13, 1999); *see also Guardian Health Care Center,* DAB No. 1943. A facility can overcome CMS's *prima facie* case either by rebutting the evidence upon which that case rests, or by proving facts that affirmatively show substantial compliance. *Evergreene Nursing Care Center,* DAB No. 2069, at 7; *Tri-County Extended Care Center,* DAB No. 1936 (2004). "An effective rebuttal of CMS's *prima facie* case would mean that at the close of the evidence the provider had shown that the facts on which its case depended (that is, for which it had the burden of proof) were supported by a preponderance of the evidence." *Evergreene Nursing Care Center,* DAB No. 2069, at 7-8; *Tri-County Extended Care Center,* DAB No. 1936, at 4 (quoting *Western Care Management*, DAB No. 1921 (2004)).

V. Stipulations

The parties stipulated to the following facts (as set forth in CMS's readiness report and noted in Petitioner's readiness report), and their stipulations are set forth verbatim below:

1. The resident care plan dated 2/10/03 indicated that the resident was insulin dependent with interventions that included monitoring for signs and symptoms of hypoglycemia which included cold, clammy skin, shallow respirations, mental confusion, double vision and nervousness. (CMS 2567)

2. Review of the physician's order dated 2/25/03 directed finger sticks four times a day on Thursdays for one month. (CMS 2567)

3. Review of the resident's glucose monitoring flow sheet dated 3/20/03 at 6:30 AM indicated that the resident's finger stick was 52, and a repeat of 73 after a snack had been given.

4. Review of the clinical record indicated that there was no documentation to reflect that the physician was notified of the low blood sugar as per policy. Subsequently the glucose monitoring flow sheet dated 3/20/03 at 11:30 AM indicated that the resident's finger stick was 46 with a repeat of 69 after orange juice and glucose had been given.

5. Although nurse's notes of 3/20/03 did not identify that the physician was notified of the 11:30 AM fingerstick of 46, the 24 hour report indicated that the physician was called about the 11:30 AM sugar and was told of the 6:30 AM and 11:30 AM results and blood work was ordered, however no change in insulin orders were made. (CMS 2567)

6. Review of a physician's order dated 3/26/03 directed staff to monitor Resident #1 blood pressure and pulse every week on Thursdays on the 3-11 shift. (CMS 2567)

7. Review of the nurse's note dated 3/27/03 on the 11-7 shift, indicated that the resident had a pulse rate of 46, and the resident's color was pale, with an oxygen saturation level of 94% on two liters of oxygen. (CMS 2567)

8. Although the nurse's note dated 3/27/03 on the 11-7 shift indicated that the resident had the Holter monitor in place, the facility was unable to provide documentation that the physician had been notified of the resident's low pulse rate. (CMS 2567)

9. Review of the facility's policy on Physician Notification indicated that the physician and/or medical director is to [be] notified in a timely fashion of a change in the resident's condition/status. (CMS 2567)

10. LPN #2 on 10/16/03 stated that she was unable to recall if the physician and/or supervisor had been notified of the resident's low pulse on 3/27/03 on the 11-7 shift. (CMS 2567)

VI. Findings of Fact, Conclusions of Law, and Discussion

I make findings of fact and conclusions of law to support my decision in this case. I set forth my findings below, in italics, as separate headings.

1. CMS has not made a prima facie case that Petitioner was out of substantial compliance with the participation requirement at 42 C.F.R. § 483.10(b)(11) (F Tag 157 on the SOD dated October 17, 2003) at the relevant times.

The regulation at 42 C.F.R. § 483.10(b)(11) is entitled "notification of changes" and provides, at section 483.10(b)(11)(i)(B), that a facility must immediately inform a resident's physician when there is a significant change in the 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). According to the Guidance to Surveyors, State Operations Manual, Appendix PP, under F Tag 157, a "life threatening condition" is a condition such as a heart attack or stroke. "Clinical complications" are conditions such as development of a stage II pressure sore, onset or recurrent periods of delirium, recurrent urinary tract infection, or the onset of depression. The preamble to the final rule implementing this regulatory provision acknowledges that "judgment must be used in determining whether a change in the resident's condition is enough to warrant notification." 56 Fed. Reg. 48826, 48833 (Sept. 26, 1991).

CMS alleges that Petitioner was not in substantial compliance with the participation requirement at 42 C.F.R. § 483.10(b)(11)(i)(B) because it failed to immediately notify Resident 1's physician when the resident had a low blood sugar at 6:30 a.m. on March 20, 2003, and a low pulse rate on March 27, 2003. CMS maintains that these two instances required immediate consultation with Resident 1's attending physician. To establish a *prima facie* case of noncompliance, CMS must establish that on either March 20, 2003, or on March 27, 2003, there was a "significant" change in Resident 1's health status and that the significant change be in either a "life-threatening" condition or constitute a clinical complication.[3]

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[3] CMS has also inferred that the March 20, 2003 blood sugar and the March 27, 2003 pulse contributed to the resident's March 29, 2003 hospitalization. CMS has put in no evidence to connect the event of March 29, 2003, to the events of March 20 and 27, 2003, and I thus do not consider the events surrounding the March 29, 2003 hospitalization here.

To establish its *prima facie* case, CMS relies on the SOD, the declaration (CMS Ex. 43) and hearing testimony of Ms. Casinghino, the admitted exhibits offered by CMS, and the memorandum of Albert L. Geetter, M.D. (CMS Ex. 44). I note first that I am giving no weight to Dr. Geetter's memorandum. It is not a sworn affidavit, is unsigned and is undated. Moreover, Petitioner objected to it, arguing that if Dr. Geetter did not appear to testify and be subjected to cross examination the statement was hearsay. CMS did not call Dr. Geetter, and asserted only that his memorandum was prepared in the usual course of his employment. CMS counsel did not present any testimony to establish that this document was a business record prepared in the usual course of business, other than her own representation on the record. *See* Tr. at 6-9, 45; CMS Br. at 8. While I admitted CMS Ex. 44 into evidence, as noted above, I have given it no weight. Thus, in deciding whether CMS has made its *prima facie* case, I consider only the testimony of Ms. Casinghino, her declaration, CMS's exhibits, and the SOD.

CMS presented no expert medical testimony from a physician regarding the resident's baseline condition and what changes cited in the resident's blood sugar or pulse rate might mean to the resident's condition. Instead, CMS submitted Ms. Casinghino's written declaration and called her to testify at hearing. CMS Ex. 43; Tr. at 17-44. Ms. Casinghino testified that her review of Resident 1's medical records did not indicate that the low finger stick blood glucose tests at 6:30 and 11:30 a.m. on March 20, 2003, were reported to Resident 1's physician. She testified that her discussions with Resident 1's physician and advanced practice registered nurse (APRN) indicated that they did not recall being informed of the finger stick results and that had they been they might have made changes in the resident's treatment. However, the 24-hour report notes that the physician was apprised of both finger stick results and I accept, based on the 24-hour report, that the physician was, in fact, notified of the two finger stick results. CMS did not call either the physician or the APRN as a witness, and the record does not reflect that either told Ms. Casinghino that they were not informed of the results, just that they did not recall whether they were so informed.

With regard to the resident's blood sugar, the SOD notes that "no change[s] in insulin orders were made" by the physician or APRN after the physician and APRN were informed of the finger stick results. CMS Ex. 6, at 2; Stip. 5. While Ms. Casinghino testified that the physician or APRN told her they might have done things differently if they had been so informed (Tr. 25, 31, 35), the physician and the APRN apparently did not find the change significant enough to change the resident's insulin treatment.

Ms. Casinghino also testified that Petitioner did not follow its own policies and that pursuant to facility policy a low blood sugar required immediately contacting the resident's physician. Tr. 30; CMS Ex. 18. The failure to follow an internal protocol or policy is not in and of itself a failure to comply with a participation requirement. *See Lake City Extended Care*, DAB No. 1658, at 6 (1998); *Manor Care of Largo*, DAB

CR746 (2001). What is important here is that even if reporting the two results together was not "immediate" or "timely," the physician or APRN did not consider the change significant enough to change the insulin dosage given the resident. This convinces me that the blood sugars noted on the morning of March 20, 2007 were not "significant" changes.

CMS also does not explain how the low pulse detected on March 27, 2003, constitutes a significant change to Resident 1's condition. Ms. Casinghino testified that Resident 1's normal pulse rate was between 58 and 70. Tr. 31. She does not explain why a pulse rate of 46 on March 27, 2003, is significant, or how it might lead to a life-threatening condition or clinical complication. CMS advanced no other evidence to show why the low pulse was significant or how it might lead to a life-threatening condition or clinical complication. It is only when a change causes a medically significant deterioration that the notification requirement is triggered.

In sum, CMS did not present evidence to establish that the resident's baseline condition relative to the blood sugar levels or pulse rate in issue constituted a significant change in her condition. Although CMS insinuates that the potential for more than minimal harm is evident from low blood sugar readings or pulse rate, CMS never explains why or how minimal harm is evident. CMS has not even met the first essential element of a deficiency under this section of the regulations, as CMS has not established that a significant change occurred. Since there is no evidence before me that a significant change occurred, there is no need for me to address whether the change was a life-threatening condition or constituted a clinical complication. I find that CMS has not established a *prima facie* case that Petitioner was out of substantial compliance with participation requirements. Thus I must find Petitioner to be in substantial compliance with participation requirements.

2. CMS's imposition of the $2000 CMP is not supported by the record.

The only remedy imposed by CMS on Petitioner is a $2000 CMP. As I have found Petitioner in substantial compliance with participation requirements, the imposition of the CMP is not supported by the record.

VII. Conclusion

At all relevant times, Petitioner was in compliance with participation requirements. Accordingly, CMS's imposition of a $2000 CMP is not supported by the record.

/s/
Alfonso J. Montano
Administrative Law Judge