Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
Life Care Center of Bardstown, (CCN: 18-5149),	)	Date: July 16, 2008
Petitioner,	)	Docket No. C-07-468
	)	Decision No. CR1818
v.	)	
Centers for Medicare & Medicaid Services.	)	

DECISION

Life Care Center of Bardstown, (Petitioner or facility), was in substantial compliance with Medicare and Medicaid participation requirements based on the survey of Petitioner's facility completed on April 3, 2007. Therefore, there is no basis for the Centers for Medicare & Medicaid Services (CMS) to impose remedies against Petitioner.

I. Background

Petitioner, located in Bardstown, Kentucky, is authorized to participate in Medicare as a skilled nursing facility (SNF) and the Kentucky Medicaid program as a nursing facility (NF). On April 3, 2007, the Division of Health Care Facilities and Services for the State of Kentucky (the state agency) completed a survey of Petitioner's facility, the results of which are reported in a Statement of Deficiencies (SOD) bearing that date. The state agency determined that Petitioner was not in substantial compliance with Medicare and Medicaid participation requirements at the immediate jeopardy level and recommended that CMS impose remedies. CMS notified Petitioner by letter dated April 20, 2007, that it concurred with the state agency findings and recommendations, and that it intended to impose the following remedies: a CMP of $4,050 per day effective January 3, 2007, until Petitioner returned to substantial compliance; a denial of payments for new admissions (DPNA) effective as soon as notification requirements can be met; and termination of the facility's provider agreement effective April 26, 2007, if substantial compliance was not achieved before that date. On April 23, 2007, the state agency completed a revisit survey at Petitioner's facility and determined that immediate jeopardy had been abated as of

March 28, 2007, but that isolated deficiencies continued, and therefore, Petitioner remained out of substantial compliance with participation requirements. By letter dated May 1, 2007, CMS notified Petitioner that the remedies imposed by its letter of April 20, 2007 would continue, but that the CMP would accrue at a lower rate of $100 per day effective March 28, 2007, until substantial compliance is achieved.

The state agency conducted a second revisit at Petitioner's facility on May 11, 2007, and determined that the facility achieved substantial compliance as of April 10, 2007. By letter dated May 25, 2007, Petitioner timely requested a hearing and denied all allegations of non-compliance. The case was assigned to me for hearing and decision on June 12, 2007.

I conducted an in-person hearing in Louisville, Kentucky on February 19-20, 2008. CMS offered exhibits (CMS Exs.) 1 through 26, which were admitted. Petitioner offered exhibits (P. Exs.) 1 through 35, which I admitted into evidence.

CMS elicited testimony from Donna Wherry (Resident 1's granddaughter); Belinda Sue Beard (state surveyor); and Betty Jo Branham, Registered Nurse (R.N.) (state survey nurse consultant/inspector). Petitioner elicited testimony from Misty Morgenson, R.N. (facility director of nursing); Natalie Suffoletta, Licensed Practical Nurse (L.P.N.) (facility nurse); and Susan Lincoln, R.N. (facility nurse consultant).

Both parties submitted a post hearing brief (CMS Br. and P. Br., respectively), and response brief (CMS Reply and P. Reply, respectively) and each party received a copy of the hearing transcript (Tr.).

Based on the applicable law and regulations, the documentary evidence, and the testimony taken at the hearing, the preponderance of the evidence shows that Petitioner was in substantial compliance with applicable federal participation requirements governing nursing homes and, therefore, no enforcement remedy may be imposed.

II. Discussion

A. Issues

The issues in this case are:

> Whether there is a basis for the imposition of enforcement remedies; and, if so,
>
> Whether the remedies imposed are reasonable.

B. Applicable Law

Petitioner is a long-term care facility participating in the federal Medicare program as a SNF and in the state Medicaid program as a NF. The statutory and regulatory requirements for participation by a long-term care facility are found at sections 1819 and 1919 of the Social Security Act (Act) and at 42 C.F.R. Part 483. Sections 1819 and 1919 of the Act vest the Secretary with authority to impose CMPs against a long-term care facility for failure to comply substantially with federal participation requirements.

Facilities that participate in Medicare may be surveyed on behalf of CMS by state survey agencies in order to determine whether the facilities are complying with federal participation requirements. 42 C.F.R. §§ 488.10-488.28, 488.300-488.335. Pursuant to 42 C.F.R. Part 488, CMS may impose a per instance CMP (PICMP) or per day CMP against a long-term care facility when a state survey agency concludes that the facility is not complying substantially with federal participation requirements. 42 C.F.R. §§ 488.406; 488.408; 488.430. The regulations in 42 C.F.R. Part 488 also give CMS a number of other remedies that can be imposed if a facility is not in compliance with Medicare requirements. *Id.*

The regulations specify that a CMP that is imposed against a facility on a per day basis will fall into one of two broad ranges of penalties. 42 C.F.R. §§ 488.408, 488.438. The upper range of CMP, of from $3050 per day to $10,000 per day, is reserved for deficiencies that constitute immediate jeopardy to a facility's residents, and, in some circumstances, for repeated deficiencies. 42 C.F.R. §§ 488.438(a)(1)(i), (d)(2). The lower range of CMP, from $50 per day to $3000 per day, is reserved for deficiencies that do not constitute immediate jeopardy, but either cause actual harm to residents, or cause no actual harm, but have the potential for causing more than minimal harm. 42 C.F.R. § 488.438(a)(1)(ii). There is only a single range of $1000 to $10,000 for a PICMP that applies whether or not immediate jeopardy is present. 42 C.F.R. §§ 488.408(d)(1)(iv), 488.438(a)(2).

The Act and regulations make a hearing before an ALJ available to a long-term care facility against which CMS has determined to impose a CMP. Act, section 1128A(c)(2); 42 C.F.R. §§ 488.408(g), 498.3(b)(13). The hearing before an ALJ is a *de novo* proceeding. *Anesthesiologists Affiliated, et. al*, DAB CR65 (1990), *aff'd*, 941 F.2d 678 (8th Cir. 1991); *Emerald Oaks*, DAB No. 1800, at 11 (2001); *Beechwood Sanitarium*, DAB No. 1906 (2004); *Cal Turner Extended Care Pavilion*, DAB No. 2030 (2006); *The Residence at Salem Woods*, DAB No. 2052 (2006). A facility has a right to appeal a "certification of noncompliance leading to an enforcement remedy." 42 C.F.R. § 488.408(g)(1); *see also,* 42 C.F.R. §§ 488.330(e), 498.3. However, the choice of remedies by CMS or the factors CMS considered when choosing remedies are not subject to review. 42 C.F.R. § 488.408(g)(2). A facility may only challenge the scope and

severity level of noncompliance found by CMS if a successful challenge would affect the amount of the CMP that could be collected by CMS or impact upon the facility's nurse aide training program. 42 C.F.R. §§ 498.3(b)(14), (d)(10)(i). CMS's determination as to the level of noncompliance "must be upheld unless it is clearly erroneous." 42 C.F.R. § 498.60(c)(2). This includes CMS's finding of immediate jeopardy. *Woodstock Care Center*, DAB No. 1726, at 9, 39 (2000), *aff'd, Woodstock Care Center v. U.S. Dept. of Health and Human Services*, 363 F.3d 583 (6th Cir. 2003). The Departmental Appeals Board (the Board) has long held that the net effect of the regulations is that a provider has no right to challenge the scope and severity level assigned to a noncompliance finding, except in the situation where that finding was the basis for an immediate jeopardy determination. *See, e.g.*, *Ridge Terrace*, DAB No. 1834 (2002); *Koester Pavilion*, DAB No. 1750 (2000). Review of a CMP by an ALJ is governed by 42 C.F.R. § 488.438(e).

The Board has addressed the allocation of the burden of persuasion and the burden of production or going forward with the evidence in past cases, in the absence of specific statutory or regulatory provisions. Application of the Board's analysis and approach is not disputed in this case and is appropriate. When a penalty is proposed and appealed, CMS must make a prima facie case that the facility has failed to comply substantially with federal participation requirements. "*Prima facie*" means generally that the evidence is "(s)ufficient to establish a fact or raise a presumption unless disproved or rebutted. *Black's Law Dictionary* 1228 (8th ed. 2004). In *Hillman Rehabilitation Center*, DAB No. 1611, at 8 (1997), *aff'd*, *Hillman Rehabilitation Center v. HHS*, No. 98-3789 (GEB) (D.N.J. May 13, 1999), the Board described the elements of the CMS *prima facie* case in general terms as follows:

> HCFA [now known as CMS] must identify the legal criteria to which it seeks to hold a provider. Moreover, to the extent that a provider challenges HCFA's findings, HCFA must come forward with evidence of the basis for its determination, including the factual findings on which HCFA is relying and, if HCFA has determined that a condition of participation was not met, HCFA's evaluation that the deficiencies found meet the regulatory standard for a condition-level deficiency.

Hillman, DAB No. 1611, at 8. Thus, CMS has the initial burden of coming forward with sufficient evidence to show that its decision to terminate is legally sufficient under the statute and regulations. To make a *prima facie* case that its decision was legally sufficient, CMS must: (1) identify the statute, regulation or other legal criteria to which it seeks to hold the provider; (2) come forward with evidence upon which it relies for its factual conclusions that are disputed by the Petitioner; and (3) show how the deficiencies it found amount to noncompliance that warrants an enforcement remedy.

In *Evergreene Nursing Care Center*, DAB No. 2069 (2007), the Board explained as follows:

> 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 SNF 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. *See Hillman Rehabilitation Center*, DAB No. 1611 (1997), *aff'd*, *Hillman Rehabilitation Ctr. v. HHS*, No. 98-3789 (GEB) (D.N.J. May 13, 1999); *Batavia Nursing and Convalescent Inn*, DAB No. 1911 (2004), *aff'd*, *Batavia Nursing and Convalesent 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*, 537 U.S. 1111, 123 S. Ct. 901 (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. *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). 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. *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." *Id.* at 4 (*quoting Western Care Management Corp.*, DAB No. 1921 (2004)).

C. Findings and Analysis

Below in boldface type are my numbered conclusions followed by the pertinent findings of fact and analysis.

Based upon the survey that ended on April 3, 2007, state agency surveyors cited Petitioner with three immediate jeopardy deficiencies (scope and severity level of "J") of 42 C.F.R. §§ 483.10(b)(11) (Tag F 157)[1], 483.25 (Tag F 309), and 483.75 (Tag F 490). The state agency also cited Petitioner for violations of 42 C.F.R. §§ 483.20(d)(3), 483.10(k)(2) (Tag F 280) at (scope and severity of "D") a level of deficiency that presents no actual harm but has the potential for more than minimal harm that does not amount to immediate jeopardy. Petitioner does not challenge allegations of noncompliance with Tag F 280, and therefore I will not address it in this decision, or the corresponding CMP that CMS determined to impose as a result of the deficiency.

Based on the applicable law and regulations, the documentary evidence, and the testimony taken at the hearing, the preponderance of the evidence shows that Petitioner was in substantial compliance with federal participation requirements governing nursing homes and, therefore, no enforcement remedy may be imposed. I note here that I base my decision on a *preponderance of all the evidence;* although I took under advisement Petitioner's challenge to CMS's *prima facie* case, I here accept that *prima facie* case to have been sufficiently developed to require discussion of all the evidence, and in particular, to require discussion of the persuasive evidence developed by Petitioner. And I add here this emphatic reminder: my evaluation of *all* the evidence, and my specific assignment of weight and credibility to *all* components of that evidence, are informed by my observation of the witnesses as they testified, by their expressed and implied opportunities to observe the events and phenomena they described, their observed care, candor, and completeness in testifying, their training and experience in the subjects on which they gave testimony, and the presence or absence of any interests on their parts that might color or affect the testimony they gave. In short, my evaluation of the entire body of evidence before me is derived from my role as the trial judge in this case, and for it I claim all the deference that such a role historically and legally commands on appellate review.

1. Petitioner established by a preponderance of the evidence that it was in compliance with 42 C.F.R. § 483.10(b)(11) (Tag F 157).

The regulations at 42 C.F.R. § 483.10(b)(11) provide that:

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[1] State surveyors use "Tag" designations that refer to the part of the State Operations Manual (SOM), Appendix P, "Survey Protocol for Long Term Care Facilities," "Guidance to Surveyors" that pertain to the specific regulatory provision allegedly violated.

> Notification of Changes. (i) A facility must immediately inform the resident; consult with the resident's physician; and if known, notify the resident's legal representative or an interested family member when there is—
>
> (A) An accident involving the resident which results in injury and has the potential for requiring physician intervention;
> (B) A significant change in the residents physical, mental, or psychosocial status (i.e., a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications);
> (C) A need to alter treatment significantly (i.e. a need to discontinue an existing form of treatment due to adverse consequenses, or to commence a new form of treatment); or
> (D) A decision to transfer or discharge the resident from the facility as specified in § 483.12(a)

Most of CMS's deficiency allegations from the April 4, 2007 survey stem from events that occurred on January 2-3, 2007 involving Resident 1. I find, for purposes of this discussion, that the evidence is sufficient to establish a *prima facie* case of a violation of 42 C.F.R. § 483.10(b)(11), but that Petitioner proved by a preponderance of the evidence that it was in substantial compliance with applicable regulations.

Resident 1 was an 87-year-old woman who was admitted to Petitioner's facility on July 30, 2006 following hospitalization during which it was determined that she was unable to continue to live alone due to Alzheimer's Disease and deteriorating cognitive ability. P. Ex. 7. She suffered from, among other things, a history of heart problems, stroke, fractures from falls at home, diabetes, hypothyroidism, urinary tract infection, constipation, significant pain, and was generally not oriented to person, time, or place. P. Exs. 6-9; Tr. 46-52.

While there are some specific details in which Petitioner and CMS disagree, the basic facts of what occurred on January 2-3, 2007 are as follows. In the early evening of January 2, Resident 1 received a visit from her granddaughter, Donna Wherry. During the course of the visit, at approximately 8:30 p.m., Resident 1 "threw up" a large volume of vomitus or emesis while in her bed. The nurse on call, L.P.N. Natalie Suffoletta, facility staff, and Ms. Wherry cleaned up the emesis, replaced the soiled sheets and bed covers, and changed Resident 1's clothes. Sometime thereafter, Ms. Wherry left the facility and went home. At about 1:00 a.m. in the morning of January 3, Nurse Suffoletta observed a small amount of emesis on Resident 1's night clothes. At approximately 4:00 a.m., Nurse Suffoletta and two CNAs were conducting bed checks when they discovered that Resident 1 was unresponsive to verbal stimuli, and her vital signs were unstable. Nurse Suffoletta attempted to contact the on-call physician by telephone but was unable

to reach him. Nurse Suffoletta contacted the facility's Director of Nursing (DON) and received an order to have Resident 1 sent to the hospital emergency room. An emergency response ambulance arrived a few minutes later and transported Resident 1 to the hospital. At some point during the early morning, Nurse Suffoletta also placed a call to Resident 1's granddaughter, Ms. Wherry. At approximately 8:10 a.m. staff at the hospital emergency room informed Nurse Suffoletta that Resident 1 had died. Tr. 32-45, 215-221; CMS Ex. 17, at 30-31.

The April 3, 2007 SOD alleges that Petitioner failed to ensure the physician was notified of Resident 1's significant change in condition and/or need to alter treatment, in violation of 42 C.F.R. § 483.10(b)(11) (Tag F 157). Specifically, CMS alleges that Resident 1's condition changed significantly when she vomited *repeatedly* during the evening and early morning hours of January 2-3, 2007, and that Petitioner's staff failed to notify Resident 1's physician as required by the regulations and facility policy, thus placing her in immediate jeopardy. CMS Br. 5-7.

The issue with respect to this deficiency allegation seems to turn on the interpretation of "significant change" as that phrase appears in the regulations at 42 C.F.R. § 483.10(b)(11).

Petitioner maintains that the standard of care or criteria to apply in order to determine if a "significant change" has occurred is the facility policy which it has taken directly from the American Medical Directors Association (AMDA) guidelines. CMS does not challenge the applicability or validity of the policy or guideline. CMS Br. 6-7.

Where a patient presents with vomiting or emesis, Petitioner's policy and the AMDA guidelines require immediate physician notification when:

> 1. The emesis is bloody or coffee ground like in appearance; or
>
> 2. There are repeat episodes of vomiting (i.e. greater than 1 episode within 24 hours); or
>
> 3. The emesis is accompanied by abdominal pain and changes in vital signs.

P. Ex. 29, at 20; P. Ex. 30, at 2.

According to the same standards, a "one time" or "single" episode of vomiting may be reported the next office day. *Id*.

CMS argues that Resident 1 vomited *repeatedly* during the evening and early morning hours of January 2-3, and that these instances indicate *repeat* episodes of vomiting. Therefore, according to CMS, Petitioner's staff should have contacted the physician well before 4:00 a.m. on January 3, to report a significant change in Resident 1's condition. CMS Br. 5-6.

Indeed, CMS contends that Resident 1 vomited as many as four times. It points to the following evidence:

> (1) Nurses notes taken by L.P.N. Suffoletta indicate that on January 2, at approximately 8:30 p.m., Resident 1 vomited in large quantity. CMS Ex. 17, at 30.
>
> (2) Ms. Wherry testified that a short time later she heard a sound in her grandmother's voice and Resident 1 vomited again. Tr. 38.
>
> (3) At approximately 1:00 a.m. on January 3, a small amount of emesis was observed on Resident 1's night clothes. CMS Ex. 17, at 31.
>
> (4) In an interview with surveyors on February 27, 2007, a CNA who was working on January 3, at approximately 4:00 a.m. observed a small amount of vomit on Resident 1's right shoulder. CMS Ex. 3, at 6.

Petitioner argues that Resident 1 vomited only once, and that any other emesis that may have followed shortly thereafter or any "spit up" constitute one episode of emesis. Thus, according to Petitioner, Petitioner's staff was not required to contact Resident 1's physician immediately under the facility policy and applicable regulations. P. Br. 21–22.

I find on balance, that Petitioner established by a preponderance of the evidence that it was in compliance with 42 C.F.R. § 483.10(b)(11). I do not conclude, as CMS urges, that each of the incidents (1)-(4) (above) represents multiple episodes of emesis. I find as a matter of fact that there was one intermittent episode of emesis, extended over a limited time.

The record shows, and there is no dispute between the parties, that Resident 1 vomited a large quantity of emesis at approximately 8:30 p.m. on January 2. CMS Ex. 17, at 30. Clearly, this represents the beginning or the onset of an incident or episode of emesis. However, the other incidents — the second and the third — are much less clear.

The second incident refers to the incident in which Resident 1's granddaughter Ms. Wherry testified that a short time after Resident 1 vomited the first time, she heard a sound in her grandmother's voice and Resident 1 vomited again. The record is not

entirely clear, but it seems that Ms. Wherry's reference to the two vomiting incidents is actually a reference to the first vomiting incident that occurred at approximately 8:30 p.m. I reach this conclusion because the nurse's notes from that evening indicate that the granddaughter came out of Resident 1's room reporting emesis, and a small amount was noted on bed covers. The head of Resident 1's bed was raised and she began vomiting profusely. CMS Ex. 17, at 30. Thus the record indicates that Resident 1 vomited, paused for a very short time, then vomited again in large quantity. This is consistent with Nurse Suffoletta's testimony. She testified in part that:

> I was outside the hall - - I was in the hallway, but outside [Resident 1's] room passing meds, and her granddaughter came and told me that [Resident 1] had thrown up and it was a very small amount. When I went in there, she had a very large amount that she had threw up.

Tr. 215-216.

It is not uncommon that when one vomits, there is an initial release followed by a more significant release shortly thereafter. Although there are two releases, given the short period of time between the two, I consider this to be one episode of vomiting or emesis. This is consistent with the common understanding of the word "episode," which Merriam-Webster's Dictionary defines as, "an event that is distinctive and separate although part of a *larger series*." Merriam-Webster's Collegiate Dictionary (10th ed. 2001).

I also conclude that the third incident, when a small amount of emesis was observed on Resident 1's night clothes at 1:00 a.m. does not amount to a separate episode of emesis at all. It can be fairly characterized only as uncertain of time or nature, but the most likely explanation of it is that it was the final, much-less-serious, manifestation of the episode that had begun earlier in the evening.

Nurse Suffoletta testified that what she observed was a very small "golf ball size" amount of emesis, which she characterized as more of a burp or something coughed up. Tr. 193, 219; CMS Ex. 17, at 31. Nurse Suffoletta did not believe that Resident 1 had vomited again, and there were no reports from the CNAs that Resident 1 had vomited again or that her condition had worsened between the hours of 8:00 p.m. and 4:00 a.m. Tr. 192, 220. Thus, I find that Nurse Suffoletta reasonably — and for purposes of this decision, correctly — concluded both that Resident 1 had not vomited at 1:00 a.m., and that she was not required to notify the physician immediately.

CMS further argues that changes in Resident 1's condition should have prompted Petitioner's staff to immediately notify the physician. CMS Br. 11. CMS offered the testimony of Ms. Wherry who indicated that she observed that her grandmother's

demeanor had changed negatively, that her body had become cold and rigid, and that her legs were discolored. Tr. 33-38.

While I have no intention here of disregarding Ms. Wherry's observations, I reject CMS's argument based on them. Ms. Wherry was by all accounts a very attentive relative, who visited her grandmother on a daily basis. Tr. 28-29, 165. However, while Ms. Wherry certainly seemed to know her grandmother well, she is not a trained health care professional, and thus her observations are that of a lay person. The nurses notes do not indicate that the LPN or CNAs observed any significant change in Resident 1's condition until 4:00 a.m. More importantly, the facility policy requires immediate notification when a resident experiences an episode of emesis *and* a change in vital signs (*i.e.* body temperature, blood pressure, pulse, respiration rate, etc.). Nurse Suffoletta testified that she checked Resident 1's vital signs twice between 8:00 p.m. and 2:00 a.m., and found them to be stable. Tr. 217, 227. CMS complains that Nurse Suffoletta failed to document Resident 1' s vital signs and criticized Petitioner for utilizing a "documentation by exception" system. CMS Br. 11, 14-15. However, CMS never disputed whether Nurse Suffoletta or its staff actually took Resident 1's vital signs and did not dispute that "documentation by exception" is a common practice. CMS Br. 11, 14-15; Tr. 261. I find as a matter of fact that Nurse Suffoleta did take those unrecorded but normal vital signs, and I base my finding on my assessment of Nurse Suffoleta's credibility. That assessment takes into account her demeanor and candor while testifying, the consistency of her testimony with all other written and oral evidence, her own experience and training, and the absence of any impeaching evidence whatsoever on the point.

The record shows that Petitioner thereafter acted in accordance with applicable regulations and facility policy. At 4:00 a.m. on the early morning of January 3, facility staff discovered that Resident 1's vital signs had become unstable. Petitioner's staff recorded Resident 1's vital signs as: pulse 43, blood pressure 125/23, respiration 12, and temperature 94.9. These unstable vital signs *and* Resident 1's prior 8:30 p.m. episode of emesis triggered Petitioner's responsibility to contact the physician immediately. Petitioner's staff called both the attending and on-call physicians as required, but was unable to reach either of them. Petitioner staff was eventually able to reach the DON, and Resident 1 was subsequently transported to the hospital.

Therefore, I find that Petitioner established by a preponderance of the evidence that it was in compliance with 42 C.F.R. § 483.10(b)(11).

2. Petitioner established by a preponderance of the evidence that it was in compliance with 42 C.F.R. § 483.25 (Tag F 309).

This quality of care regulation provides that, "each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable

physical, mental, and psychosocial well being, in accordance with the comprehensive assessment and plan of care." 42 C.F.R. § 483.25

CMS's allegations of noncompliance under Tag F 309 are essentially based on the same set of facts and circumstances involving Resident 1. CMS contends that Petitioner failed to provide the necessary care and services for Resident 1 when she experienced a significant change in condition. Specifically, CMS alleges that Petitioner failed to assess Resident 1's change in condition, failed to monitor her oxygen saturation, and failed to monitor her vital signs according to the physician's orders, and that these failures placed Resident 1 in immediate jeopardy. CMS Ex. 3, at 15.

Petitioner has established that Resident 1 received the necessary care and services in accordance with the regulations. CMS has not demonstrated under this deficiency that Petitioner failed to act based on a particular facility policy or standard of care. Nor has there been any allegation or evidence that Petitioner's care plans, or assessments failed to meet Resident 1's needs. As I have found and concluded above, Petitioner's staff acted in a manner consistent with professional standards of care quality, and there was no failure on the part of Petitioner to properly monitor or assess Resident 1. Therefore, I find that Petitioner was in compliance with 42 C.F.R. § 483.25.

3. Petitioner established by a preponderance of the evidence that it was in compliance with the requirements of 42 C.F.R. § 483.75 (Tag F 490).

The regulation at 42. C.F.R. § 483.75 addresses standards of administration, and provides that a facility must be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each patient.

Again CMS relies on substantially the same facts underlying its claim that the facility did not comply with the notification of changes (Tag F 157) regulation. CMS alleged that this participation requirement was not met because the administrator or executive director failed to: take necessary steps to prevent deficient practices, including investigating contributing events, involving residents who experience a significant change in condition; and ensure all staff where trained properly regarding procedures to effectuate the facilities physician notification policy. I find that Petitioner established that it was in compliance with applicable regulations.

The administration deficiency is a derivative deficiency based on findings of other deficiencies. *Cross Creek Health Care Center*, DAB No. 1665, at 19 (1998).

The gravamen of this deficiency is a facility's failure to have a protocol or procedure in place, not merely the failure of the facility's staff to follow the protocol in a specific instance. CMS has not established that systemic breakdowns on the part of the administration caused deficient facility practice. It might very well be that proof of a series of staff lapses in following the protocol could prove administration ignorance of, or a systemic disregard of, the protocol, which in turn could be seen as an administrative failure to maintain the protocol in an effective and meaningful manner. CMS has not established such proof. Its case, instead, has been refuted as to the predicate issue of the staff's response to Resident 1's episode of vomiting; the failure of the predicate case dooms the derivative citation based on the charged administrative deficiency. Therefore, I find that Petitioner established by a preponderance of all the evidence, that it was in substantial compliance with the requirements of 42. C.F.R. § 483.75.

4. CMP's of $4,050 and $100 per day respectively, are unreasonable based on the facts of this case as there are no violations and therefore no basis for the imposition of CMP's.

The remedy determinations made by CMS in this case are premised on the findings of noncompliance made during the survey period. I have found that Petitioner was in compliance with applicable participation requirements. Consequently, there is no basis for CMS to impose remedies against Petitioner.

III. Conclusion

For all of the reasons set out above, I find and conclude that Petitioner was in substantial compliance with participation requirements at issue in this case, and therefore, no enforcement remedy may be imposed by CMS.

/s/
Richard J. Smith
Administrative Law Judge