Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

The Mary Wade Home, Inc.,
(CCN: 07-5325),

Petitioner

v.

Centers for Medicare and Medicaid Services.

Docket No. C-08-603

Decision No. CR2162

Date: June 23, 2010

DECISION

I find Petitioner, The Mary Wade Home, Inc., violated 42 C.F.R. § 483.25(j) with respect to one resident as an April 16, 2008 survey determined. I therefore find a basis to impose a per instance civil money penalty (PICMP) in the amount of $2,500 against Petitioner.

I. Background

Petitioner is a Medicare certified skilled nursing facility in New Haven, Connecticut. The State of Connecticut Department of Public Health (state survey agency) completed a survey of Petitioner's facility on April 16, 2008, and determined that Petitioner was out of compliance with five Medicare program participation requirements. A Statement of Deficiencies (SOD), dated April 16, 2008, was issued to Petitioner, which outlined the survey findings. CMS concurred with the surveyors' findings of noncompliance, and, by letter dated May 16, 2008, CMS notified Petitioner of the proposed PICMP of $2,500.

On July 12, 2008, Petitioner timely requested a hearing (Request for Hearing) before an administrative law judge (ALJ). The case was assigned to me for hearing and a decision. Although Petitioner was cited for substantial noncompliance with five deficiency tags, Petitioner only challenged its alleged failure to comply with the quality of care requirement specified at 42 C.F.R. § 438.25(j) (Quality of Care-Hydration), which the

SOD identified as tag F327.[1] Request for Hearing at 1-2. As Petitioner does not challenge all the deficiencies cited in the SOD, the uncontested findings and citations are therefore final and binding. 42 C.F.R. § 498.20(b).

A prehearing conference was convened with the parties on November 19, 2008, and a schedule was established for the parties to file written submissions, including proposed witness and exhibit lists and prehearing briefs. The parties completed their prehearing submissions on March 27, 2009.

An in-person hearing was conducted in Hartford, Connecticut on April 7 through 8, 2009. On Petitioner's motion, the hearing was continued and was re-convened on July 20, 2009.[2] The following exhibits were admitted without objection: CMS Exhibits (Exs.) 1 through 22; and Petitioner (P.) Exs. 1 through 18. Transcript (Tr.) at 6-7, 116, 137, 324-25. At hearing, CMS called as witnesses: Surveyor Deborah A. Casinghino, Registered Nurse (R.N.); Suzanne M. Cooney, Resident 14's niece; and Elizabeth R. Cooney, Resident 14's niece and conservator. Petitioner called as its witnesses: Lynn Kinross, R.N.; Jacqueline Henchel, M.D.; Kara Taylor, R.N.; Kathleen Flannigan, Medical Records and Purchasing; and Catherine D'Aniello, R.N., Resident Care Coordinator.

A transcript of the proceedings was prepared, and the parties were provided an opportunity to identify any prejudicial errors. Neither party filed objections or conflicting statement of errata.

The parties submitted post-hearing briefs. The Centers for Medicare and Medicaid Services (CMS) filed its brief on September 21, 2009 (CMS Br.). Petitioner filed its brief on October 30, 2009 (P. Br.), and CMS filed its reply brief on December 14, 2009 (CMS Reply). The record in this matter was closed on December 15, 2009.

This decision is based on the complete record, which includes the parties' arguments, written submissions, all exhibits admitted into the record, and the witness testimony, which I have heard and considered.

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[1] Petitioner does not appeal four deficiency tags cited as: F221 (violation of 42 C.F.R. § 483.13(a)); F281 (violation of 42 C.F.R. § 483.20(k)(3)(i)); F282 (violation of 42 C.F.R. § 483.20(k)(3)(ii)); and F323 (violation of 42 C.F.R. § 483.25(h)).

[2] In response to an issue that CMS raised during the April 2009 hearing, Petitioner requested a continuance of the hearing, which was granted. *See* Tr. at 283, 323; *see also* Order Summarizing Prehearing Conference: Setting Date for Continuance of Hearing and Setting Date for Petitioner to Amend Its Witness List (May 11, 2009).

II. Issues

The issues in this case are whether:

1. Petitioner was in substantial compliance with tag F327 during the April 16, 2008 survey; and

2. CMS's determination of a $2,500 PICMP is reasonable.

III. Applicable Law

Long-term care providers, such as Petitioner, enter into provider agreements with the U.S. Department of Health and Human Services (HHS) to participate in Medicare. Statute and regulation impose requirements of participation. *See* Social Security Act (Act) §§ 1819, 1919; 42 C.F.R. Parts 483, 488, 489. To continue participation in Medicare, providers must remain in 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. "Noncompliance," is defined as "any deficiency that causes a facility to not be in substantial compliance." 42 C.F.R. § 488.301.

If a facility is not in substantial compliance with program requirements, CMS has authority to impose one of the enforcement remedies listed in 42 C.F.R. § 488.406, which includes imposing a civil money penalty (CMP). Act § 1819(h). CMS may impose a CMP for each instance that the facility is not in substantial compliance with one or more program requirements. 42 C.F.R. §§ 488.430(a), 488.440(a)(2). The regulations specify that the CMP imposed against a facility on an instance of noncompliance will range between $1,000 and $10,000. 42 C.F.R. § 488.438(a)(2). The presence of a single deficiency cited at the D-level, or above, is sufficient to establish a facility's noncompliance with applicable regulations and authorizes the imposition of remedies. *Beechwood Sanitarium*, DAB No. 1824 (2002); *see also Glenburn Home*, DAB CR2014 (2009).

The Act and regulations make a hearing before an ALJ available to a long-term facility against whom CMS has determined to impose a CMP. Act § 1128A(c)(2); 42 C.F.R. §§ 488.408(g), 498.3(b)(13). The ALJ's review is generally limited to the general issues, i.e., whether a basis exists to enforce remedies and whether the remedies CMS proposes are reasonable. 42 C.F.R. §§ 488.408(g), 488.438(e), 498.3, 498.5(b). The ALJ's review and decision on these issues is de novo, which the Departmental Appeals Board (Board) has consistently held. *See, e.g*., *Emerald Oaks*, DAB No. 1800, at 11 (2001) (holding ALJ makes no finding regarding how CMS made its determination but makes an independent determination based upon evidence of record); *Beechwood Sanitarium*, DAB No. 1906, at 29 (2004) (finding what CMS knew or how it made its decision is immaterial to the ALJ); *The Residence at Salem Woods*, DAB No. 2052, at 11 n.5 (2006)

(holding ALJ is bound to make an independent determination of reasonableness of remedy based upon evidence developed at hearing); *Cal Turner Extended Care*, DAB No. 2030, at 7 (2006) (noting ALJ does not conduct a quasi-appellate review CMS's determination but makes an independent determination based upon the evidence developed before the ALJ).

A facility has a right to appeal a "certification of noncompliance leading to an enforcement remedy." *See* 42 C.F.R. § 488.408(g)(1); *see also* 42 C.F.R. §§ 488.330(e), 498.3. However, CMS's choice of remedies, 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 that CMS found, if a successful challenge would affect the range of the CMP that CMS could collect or impact 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).

IV. Burden of Proof

The standard of proof, or quantum of evidence, required is a preponderance of the evidence. CMS bears the burden of coming forward with evidence and making a prima facie showing of a basis for imposition of an enforcement remedy. Petitioner bears the burden of persuasion to show by a preponderance of the evidence that it was in substantial compliance with participation requirements or any affirmative defense. *See Batavia Nursing & Convalescent Inn,* DAB No. 1911 (2004); *Batavia Nursing & Convalescent Ctr.,* DAB No. 1904 (2004), *aff'd, Batavia Nursing & Convalescent Ctr. v. Thompson*, 129 F. Appendix 181 (6th Cir. 2005); *Emerald Oaks*, DAB No. 1800; *Cross Creek Health Care Ctr.,* DAB No. 1665 (1998); *Hillman Rehab. Ctr.*, DAB No. 1611 (1997), *aff'd,* No. 98-3789, 1999 WL 34813783 (D.N.J. May 13, 1999).

V. Findings of Fact and Conclusions of Law.

I make findings of fact (Findings) and conclusions of law to support my decision in this case.

A. The evidence establishes that, as of the April 16, 2008 survey, Petitioner was not in substantial compliance with the requirements of 42 C.F.R. § 483.25(j) – Tag F327 (Quality of Care - Hydration).

42 C.F.R. § 483.25(j), governs a facility's quality of care and provides:

> 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.

* * *

> (j) *Hydration*. The facility must provide each resident with sufficient fluid intake to maintain proper hydration and health.

The surveyors allege in the SOD that the facility failed to provide sufficient fluid intake to maintain proper hydration for Resident 14. CMS Ex. 1, at 9. CMS alleges that Petitioner had knowledge that Resident 14 was at risk for dehydration and failed to monitor her signs and symptoms of dehydration and electrolyte imbalance for at least fourteen days in January 2008. CMS Br. at 1, 2.

In its defense, Petitioner maintains that its staff took measures to ensure Resident 14 received sufficient fluid intake to maintain proper hydration and health; however, the resident had a long history of poor oral intake, and she continued to refuse food and fluids while at its facility. P. Br. at 1-2.

As discussed above, when a provider requests review of a CMS enforcement action, CMS has the initial burden of establishing that its determination to impose an enforcement remedy is legally sufficient under the statute and regulations. To establish a prima facie showing of a violation of 42 C.F.R. § 483.25(j), CMS must demonstrate that a facility did not provide a resident proper hydration. Evidence, including signs and symptoms of insufficient fluid intake, abnormal laboratory values, or a diagnosis of dehydration, may establish such a showing. I find that CMS met its burden here and established a prima facie case. I further find that Petitioner has not overcome CMS's showing.

Resident 14 was an 83-year-old female who was admitted to Petitioner's facility on April 25, 2007. P. Ex. 4, at 1; Tr. at 333. She was admitted with the diagnosis of behavioral disturbances, depression, poor oral intake, psychosis, and delirium due to significant electrolyte imbalance. CMS. Ex. 1, at 9; P. Ex. 4, at 1; Tr. at 162. Resident 14's Minimum Data Set (MDS) assessment shows that Resident 14 had severely impaired cognitive skills. CMS Ex. 6, at 2. On August 24, 2001, the probate court determined that Resident 14 was incapable of managing her affairs, and her niece, Elizabeth Cooney, was appointed her conservator. CMS Ex. 22.

Resident 14's care plan listed as a goal that she would be free of signs and symptoms of dehydration in 90 days. CMS Ex. 7, at 1-2; P. Ex. 2, at 1-2. Dietary notes from Petitioner's registered dietician, dated October 17, 2007 to January 14, 2008, establish that Resident 14's recommended fluid intake was 1472 cc per day. The notes also indicate that the resident continued to experience poor oral intake and was losing weight. CMS Ex. 1, at 10; CMS Ex. 8; CMS Ex. 10; Tr. at 40-41. A physician's progress note, dated December 4, 2007, indicates that the resident's conservator did not want Resident 14 to receive any artificial means of nutrition but would agree to intravenous fluids and

hospitalization, should the resident require hydration to help reverse the dehydration process. CMS Ex. 14, at 7. Resident 14's physician's order for January 2008 states under a section identified as "Advanced Directives" that the resident was to have no artificial means of nutrition, including feeding tube or gastrostomy tube. CMS Ex. 17, at 1; P. Ex. 4, at 27; Tr. at 32-33.

From January 11 through January 24, 2008, Petitioner's staff recorded Resident 14's oral intake measurements of less than 1472 cc, for each 24-hour period. For five days of this period, January 17, 21, 22, 23, and 24, 2008, Resident 14 had less than 1000 cc of oral intake. CMS Ex. 9, at 1-2.; CMS Ex. 8, at 2. On January 25, 2008, Resident 14 was transferred to the hospital. Hospital records note the resident: to be alert; in mild distress; disoriented; experiencing labored respirations; having a temperature of 110.5; and excreting cloudy yellow urine. CMS Ex. 13, at 2-3. Resident 14 was diagnosed with dehydration, hypernatremia (electrolyte imbalance), urinary tract infection, probable pneumonia, and required intravenous administration of fluids and antibiotics. CMS Ex. 13, at 9.

The State Operations Manual (SOM), Guidance to Surveyors for Tag F327, provides the surveyor with probes to assess a facility's compliance with the regulation. In this case, the two probe questions are whether: (1) the sampled residents show clinical signs of insufficient fluid intake or abnormal laboratory values; and (2) the facility provided residents with adequate fluid intake to maintain proper hydration and health.

As guidance for the standard of practice for hydration and fluid intake, CMS relies on the American Medical Directors Association's Clinical Practice Guideline for Dehydration and Fluid Maintenance (Guidelines) (CMS Ex. 19). CMS Br. at 12-13. The Guidelines state that nursing practice standards direct nurses to assess for physiological and functional signs and symptoms associated with dehydration and electrolyte imbalance. Table 4 lists signs and symptoms that may be associated with dehydration. These include: dry eyes and/or mouth; urinary tract infections; fever; vomiting; recent rapid weight loss; low blood pressure; rapid pulse; lethargy and weakness; change in mental status; and increased combativeness and confusion. The Guidelines further note that the risk of dehydration can be reduced with: regular rounds of fluid distribution; one-on-one assistance with consuming fluids; recording of fluid intake and output; and reporting of signs. *See* CMS Ex. 19, at 8-9; *see also* Tr. at 52-53, 63-64.

Petitioner's facility policy, titled "Guidelines for Hydration," instructs staff on what to do if a resident's intake is less than 1000 cc per day. The policy requires, in relevant part:

> 3. If a resident's intake is less than 1,000 cc per day, continue to measure intake. If resident takes less than 1,000 cc in a three day period, notify MD. Notify MD of fluid intake and continue to monitor. Nursing may place resident on every 1 hour fluid checks for encouragement to increase fluid intake.

> Note if resident is on “Palliative Care”, continue to monitor intake unless MD discontinues.

CMS Ex. 15, at 1; P. Ex. 11, at 1.

CMS claims that no documentation exists in the record that Petitioner assessed Resident 14’s other signs and symptoms associated with dehydration and electrolyte imbalance, such as eye and mouth dryness, concentrated or discolored urine, and decreased skin turgor. CMS Br. at 13. In further support of its assertion, CMS states that Petitioner’s staff also did not measure Resident 14’s output volume between January 11 and January 24, 2008, but rather, only recorded the number of times per shift (thus every 24-hour period) that Resident 14 had output. *Id.* at 14.

In support of its assertion that adequate steps were taken to ensure that Resident 14 received sufficient fluid to maintain proper hydration and health, Petitioner maintains that Resident 14 was transferred to a psychiatric facility to improve her condition and her willingness to take fluids. However, Resident 14 continued to refuse food and fluids. P. Br. at 7-8; Tr. at 169, 336-37; P. Ex. 5. Petitioner asserts that after Resident 14’s fluids intake dropped below 1000 cc per day for three consecutive days, Petitioner’s staff, in accordance with its policy, notified Resident 14’s conservator and physician. Once the conservator provided permission, the facility staff arranged for the resident to be transferred to the hospital. P. Br. at 2, 15-16.

1. Petitioner failed to monitor Resident 14’s signs and symptoms of dehydration and electrolyte imbalance for at least fourteen days in January 2008.

The Board has held that where a resident has been found to be at risk for dehydration, the compliance analysis must begin with what the facility did to mitigate that risk. *Cmty. Skilled Nursing Ctr.,* DAB No. 1987 (2005). The parties do not dispute Petitioner’s knowledge of Resident 14’s risk of dehydration and electrolyte imbalance nor does Petitioner dispute that Resident 14 consumed less liquid than Petitioner’s registered dietician had recommended. Rather, CMS maintains that Petitioner failed to monitor and respond to signs and symptoms of dehydration and electrolyte imbalance for Resident 14 during the period from January 11 to January 24, 2008. CMS Br. at 12-13.

Petitioner states that its staff followed Resident 14’s initial care plan of increasing fluid intake. Petitioner argues that Resident 14 clearly exercised her right to refuse the food and fluids that several staff administered, even after being informed of the consequences. P. Br. at 4-14. Petitioner claims that dehydration resulted from Resident 14’s refusal to accept fluids that Petitioner offered. Thus, Petitioner maintains it had taken all reasonable steps to maintain Resident 14’s hydration and health. P. Br. at 24. Petitioner also argues that the regulation does not address any failure to assess dehydration or to record intake and output as a requirement to maintain hydration and health. P. Br. at 25.

Petitioner's argument that it took reasonable steps to mitigate Resident 14's hydration fails. As noted above, assessing hydration, or recording intake and output, is consistent with the professional standards of care and Petitioner's own policy. Petitioner must establish these specific actions to show that it mitigated Resident 14's risk for dehydration. The facility has to prove that the resident became dehydrated despite the fact that the facility provided care consistent with professional standards of care for preventing dehydration in someone with Resident 14's medical condition. *Cmty. Skilled Nursing Ctr.,* DAB No. 1987. While the nurse's notes in P. Ex. 3, and the physician's progress notes in P. Ex. 4, show that Petitioner's staff tried to administer fluids and food to Resident 14, they do not contain the close monitoring that would establish compliance with 42 C.F.R. § 483.25(j). Specifically, Petitioner has not presented either documentary or testimonial evidence to illustrate the continual monitoring of Resident 14 for signs or symptoms of dehydration, as the nursing practice standards and the facility's policy require.

First, the resident's nurse's notes provide no mention of any efforts by staff to monitor Resident 14 for common signs of dehydration during the period between January 11 and 24, 2008. Tr. at 55-56. As noted above, the Guidelines require that dehydration risk reduction include assessing and reporting signs and symptoms of dehydration, such as dry eyes and or mouth, urinary tract infection, vomiting, low blood pressure, rapid pulse and decreased skin turgor. CMS Ex. 19, at 8-9. Although the evidence does show that Petitioner recorded some of Resident 14's temperature readings, its staff only recorded the resident's blood pressure readings on January 15 and January 22, 2008. CMS Ex. 10, at 2; CMS Ex. 11, at 6-12; Tr. at 56-57. The evidence establishes that the resident's signs and symptoms of dehydration were only assessed and documented when Resident 14 was transferred to the hospital. CMS Ex. 13, at 1-3.

The evidence also demonstrates that Petitioner's staff failed to record the resident's output volumes between January 11 and January 24, 2008.[3] CMS Ex. 9, at 1-2. The Guidelines clearly require the recording of intake and outputs of a resident to mitigate the risk of dehydration. CMS Ex. 19, at 9. Moreover, Petitioner's own facility policy for resident hydration requires staff to measure all fluid intakes and output on each shift for residents with dehydration problems, such as Resident 14. CMS Ex. 15, at 3. Although the nurse's notes contain recordings of Resident 14's intake, no record exists of her output. CMS Ex. 9.

Section 1819(b) of the Act outlines requirements for skilled nursing facilities in the provision of services to its residents. The Board has consistently held that section 1819(b), as well as the statute and the regulations as a whole, are based on the premise that a facility has the expertise to plan for and provide care and services to maintain a resident's highest practicable functional level. *Woodland Vill. Nursing Ctr.*, DAB 2053,

[3] Surveyor Casinghino testified that staff could have monitored Resident 14's fluid output volume by weighing an absorbent brief before and after use, or by manually expunging fluid from the brief and then weighing the expunged fluid. Tr. at 45-47.

at 9 (2006) (citing *Spring Meadows Health Care Ctr.*, DAB No. 1966, at 20 (2005)) ([W]hen a facility adopts a policy that calls on the nursing staff to take affirmative actions to safeguard resident health and safety, it is reasonable to infer (in the absence of evidence to the contrary) that the facility did so because such actions are necessary to attain or maintain resident well-being.). The Board has also held that a facility's failure to comply with a physician's orders or to follow its own facility policy, as well as a facility's failure to provide services in accordance with a resident's plan of care based on a resident's comprehensive assessment, can constitute a deficiency under section 483.25. *Lakeridge Villa Health Care Ctr.*, DAB No. 1988, at 22 (2005) (citing *The Windsor House*, DAB No. 1942, at 55-56 (2004); *Batavia Nursing & Convalescent Ctr.*, DAB No. 1904, at 35-36 (2004)).

After reviewing all of the evidence in this case, I find that Petitioner failed to monitor Resident 14 for signs and symptoms of dehydration and electrolyte imbalance between January 11 and 24, 2008.

2. Resident 14 was hospitalized on January 25, 2008 and diagnosed with dehydration, an electrolyte imbalance, and a urinary tract infection.

CMS maintains that Resident 14 was dehydrated at the time of her January 25, 2008 hospitalization. CMS Br. at 14. Hospital documentation, which identifies the hospital emergency room physician's diagnosis of dehydration, supports CMS's position. Specifically, the evidence establishes that, upon Resident 14's arrival at the hospital, she was diagnosed with dehydration, hyponatremia (electrolyte imbalance), and a urinary tract infection. CMS Ex. 13, at 15. Furthermore, the evidence indicates that Resident 14 had a temperature of 101.5, altered mental status, and her urine had cloudy yellow coloration. CMS Ex. 15, at 3-5. The hospital's diagnosis of Resident 14's dehydration supports CMS's allegation that Petitioner was not in compliance with the participation requirement of 42 C.F.R. § 483.25(j).

I find that Petitioner has not provided sufficient documentary and testimonial evidence to sustain its burden in showing that its staff made reasonable steps to maintain Resident 14's hydration and health. I find that during the period January 11 through January 24, 2008, Resident 14 consumed less liquid than Petitioner's registered dietician recommended. On January 25, 2008, Resident 14 was transferred to the hospital from Petitioner's facility, and she was diagnosed as suffering from a urinary tract infection and dehydration. Petitioner knew that Resident 14 was at risk for dehydration, Petitioner had care planned for the risk, and Petitioner's records reflect Resident 14's decreased consumption of liquids prior to her hospitalization on January 25, 2008. Resident 14 suffered actual harm from dehydration. *See Woodland Vill. Nursing Ctr.*, DAB No. 2053, at 14 ([D]ehydration on its face can constitute actual harm . . . where . . . the dehydration is so severe that it requires hospitalization, the conclusion that harm has occurred appears unassailable.).

Accordingly, I conclude that the evidence establishes that, as of the April 16, 2008 survey, Petitioner was not in substantial compliance with 42 C.F.R. § 483.25(j), at a scope and severity level of G, indicating actual harm that is not immediate jeopardy.

B. A PICMP of $2,500 is reasonable.

Petitioner has not contested the reasonableness of the PICMP that CMS proposed due to the finding of noncompliance with the program requirements at 42 C.F.R. § 483.25(j). However, even if Petitioner had challenged the PICMP, having already concluded that Petitioner was in violation of 42 C.F.R. § 483.25(j) and in applying the factors specified at 42 C.F.R. § 488.438(f), I determine that the $2,500 PICMP that CMS imposed is reasonable.

VI. Conclusion

After reviewing all of the evidence in this case and for the reasons discussed in this decision, I find that CMS established that Petitioner was not in substantial compliance with 42 C.F.R. § 483.25(j) with respect to Resident 14. I further conclude that a $2,500 PICMP is reasonable.

/s/

Alfonso J. Montaño
Administrative Law Judge