Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Affectionate Home Health Care
(CCN: 14-7989)

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-13-510

Decision No. CR3638

Date:

DECISION

Petitioner, Affectionate Home Health Care, was not in compliance with 42 C.F.R. § 484.18,[1] on December 3, 2012, a condition of participation for a home health agency (HHA) participating in the Medicare program. There is a basis for termination of Petitioner's participation in the Medicare program pursuant to 42 C.F.R. § 489.53(a)(3) effective December 21, 2012.

I. Background

Petitioner is a HHA located in Homewood, Illinois that participated in the Medicare program as a provider of services (provider). Petitioner was subject to surveys by the Illinois Department of Public Health (state agency) on August 23, 2012, October 3, 2012, and December 3, 2012. The findings and conclusions of the surveys are discussed in greater detail later in this decision. The Centers for Medicare & Medicaid Services (CMS) notified Petitioner on January 3, 2013, that Petitioner's participation as a HHA in

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[1] References are to the 2012 revision of the Code of Federal Regulations (C.F.R.), unless otherwise stated.

the Medicare program was terminated effective December 21, 2012. CMS Exhibit (Ex.) 5; Joint Stipulation of Undisputed Facts (Jt. Stip.).

Petitioner timely requested a hearing before an administrative law judge (ALJ) on March 1, 2013. Jt. Stip. ¶ 5. On March 15, 2013, the case was assigned to me for hearing and decision and an Acknowledgement and Prehearing Order (Prehearing Order) was issued at my direction. On November 5, 2013, I set this case for hearing on December 17 and 18, 2013. On December 9, 2013, Petitioner filed a waiver of oral hearing; CMS did not oppose; and, on December 13, 2013, I set a final briefing schedule.

The parties filed post-hearing briefs (CMS Br. and P. Br.) and CMS filed a post-hearing reply brief (CMS Reply). Petitioner waived a reply brief on March 25, 2014. CMS offered CMS Exs. 1 through 37; Petitioner did not object to my consideration of the CMS exhibits; and they are admitted and considered as evidence. Petitioner offered Petitioner's exhibits (P. Exs.) 1 through 23. On August 12, 2013 and January 23, 2014, CMS filed objections to P. Ex. 6, page 1; P. Ex. 11, pages 1 through 4; and P. Ex. 18, page 1. Petitioner did not respond to the objections. CMS argues that the copies of the documents to which it objects are different in material respects from copies of the same documents obtained by surveyors from the facility during the surveys. CMS argues that the documents are not properly authenticated and should not be considered as substantive evidence. Under Fed. R. Evid. 901(a) which establishes the federal-court requirement to authenticate, that is, to identify an item of evidence; the party offering the evidence must produce evidence sufficient to support a finding that the item is what the proponent claims it is. There is no authentication problem with the documents to which CMS objects because there is no problem identifying the documents for what they are. Indeed, CMS concedes that the documents to which it objects are copies of documents, of which copies were obtained by the surveyors during the surveys. The CMS objection is that the copies now offered by Petitioner include additional entries or alterations not visible on the copies offered in evidence by CMS. There is no issue that the documents are relevant. The CMS objection goes to the weight or probative value of Petitioner's exhibits, not their admissibility. Accordingly, the CMS objection is overruled and P. Exs. 1 through 23 are admitted. Petitioner submitted with its brief three declarations that were not marked as evidence. CMS did not object to my consideration of the declarations and they are marked and admitted as evidence as follows:

P. Ex. 24	Declaration of Atilana Rivera, dated January 13, 2014
P. Ex. 25	Declaration of Eddie Geredine, dated January 13, 2014
P. Ex. 26	Declaration of Sheree Luckie, dated January 13, 2014

II. Discussion

A. Applicable Law

The Social Security Act (Act) sets forth requirements for HHAs participating in the Medicare and Medicaid programs, and authorizes the Secretary of Health and Human Services to promulgate regulations implementing the statutory provisions. Act §§ 1861(m) and (o), and 1891 (42 U.S.C. §§ 1395x(m) and (o), 1395bbb). The Secretary's regulations governing HHA participation in the Medicare program are found at 42 C.F.R. pt. 484. The conditions for participation are established by 42 C.F.R. pt. 484, subpts. B and C.

In order to participate in the Medicare program and obtain reimbursement for its services, a HHA must be in compliance with all applicable conditions of participation specified in the Act, including sections 1861(o) and (z) and 1891(a), and 42 C.F.R. pt. 484. 42 C.F.R. § 488.3(a)(2); *A.M. Home Health Services, Inc.*, DAB No. 2354 at 1 (2010); *Aspen Grove Home Health*, DAB No. 2275 at 1-2 (2009). Periodic review of compliance with the conditions of participation is required and accomplished through surveys by the state agency. Based upon its survey, the state agency either certifies compliance or noncompliance of the surveyed provider. 42 C.F.R. §§ 488.20, 488.24, 488.26.

The state agency certifies that a HHA is not in compliance with the conditions of participation when "the deficiencies are of such character as to substantially limit the provider's . . . capacity to furnish adequate care or which adversely affect the health and safety of patients." 42 C.F.R. § 488.24(b). Whether or not there is compliance with a condition of participation depends upon the "manner and degree to which the provider . . . satisfies the various standards within each condition." 42 C.F.R. § 488.26(b); *CSM Home Health Services*, DAB No. 1622 at 6-7 (1997).

CMS is authorized to terminate a provider agreement when the provider no longer meets the requirements of the Act or fails to meet the conditions of participation, among other grounds listed in the regulation. Act §§ 1861(o)(6), 1866(b)(2), 1891(e) (42 U.S.C. §§ 1395x(o)(6), 1395cc(b)(2), 1395bbb(e)); 42 C.F.R. § 489.53(a)(3). CMS has the discretion and is authorized to terminate a HHA's provider agreement based on a single condition-level deficiency. *United Medical Home Care*, DAB No. 2194 at 13-14 (2008). CMS has the authority to terminate a HHA where there are repeated standard-level violations, none of which rise to a condition-level violation either singly or collectively, if the provider does not timely submit a plan of correction acceptable to CMS and implement the accepted plan within a reasonable period. *CSM Home Health Services*, DAB No. 1622 at 19; *Aspen Grove Home Health*, DAB No. 2275 at 21.

Termination of a provider agreement is governed by the procedures set forth in 42 C.F.R. § 489.53. CMS may terminate a provider such as Petitioner, when the provider no longer meets the appropriate conditions for participation under the Act and 42 C.F.R. pt. 484.

42 C.F.R. § 489.53(a)(3). Pursuant to 42 C.F.R. § 489.53(d)(1), CMS must give the provider notice of termination at least 15 days before the effective date of termination. In this case, there is no dispute that CMS notified Petitioner on November 14, 2012, that Petitioner's provider agreement would be terminated December 21, 2012, subject to the findings of a revisit survey. CMS Ex. 3. There is also no dispute that CMS gave public notice by publication on December 2, 2012, as required by 42 C.F.R. § 489.53(d)(5). P. Ex. 20.

The provider's right to review includes rights to notice and a de novo hearing by an ALJ and judicial review. Act § 1866(h)(1); 42 C.F.R. §§ 498.3(b)(8), 498.5(b). The hearing before an ALJ pursuant to 42 C.F.R. pt. 498, is a de novo proceeding. *The Residence at Salem Woods*, DAB No. 2052 (2006); *Cal Turner Extended Care*, DAB No. 2030 (2006); *Beechwood Sanitarium*, DAB No. 1906 (2004); *Emerald Oaks*, DAB No. 1800 at 11 (2001); *Anesthesiologists Affiliated*, DAB CR65 (1990), *aff'd*, 941 F.2d 678 (8th Cir. 1991). The standard of proof, or quantum of evidence required, is a preponderance of the evidence. CMS has the burden of coming forward with the evidence and making a prima facie showing of a basis for termination. The Departmental Appeals Board (Board) has stated that CMS must come 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." *Evergreene Nursing Care Ctr.*, DAB No. 2069 at 7 (2007); *Batavia Nursing & Convalescent Ctr.*, DAB No 1904 (2004). "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). CMS makes a prima facie showing if the credible evidence CMS relies on is sufficient to support a decision in its favor absent an effective rebuttal.

The Board has long held that Petitioner bears the ultimate burden of persuasion to show by a preponderance of the evidence that it was in compliance with the condition of participation or any affirmative defense. *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. App'x 181 (6th Cir. 2005); *Emerald Oaks*, DAB No. 1800; *Cross Creek Health Care Ctr.*, DAB No. 1665 (1998); *Hillman Rehab. Ctr.*, DAB No. 1611, DAB CR500 (1997), *rev'd* DAB No. 1663 (1998), *aff'd*, *Hillman Rehab. Ctr. v. United States*, No. 98-3789 (GEB), 1999 WL 34813783 (D.N.J. May 13, 1999). However, only when CMS makes a prima facie showing of noncompliance, is the facility burdened to show, by a preponderance of the evidence on the record as a whole, that it was in substantial compliance or had an affirmative defense. *Evergreene Nursing Care Ctr.*, DAB No. 2069 at 4. 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 compliance. "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 7-8 (citations omitted).

B. Issue

Whether there was a basis to terminate Petitioner's provider agreement as a HHA in the Medicare program.

C. Findings of Fact, Conclusions of Law, and Analysis

My conclusions of law are set forth in bold text followed by my findings of fact and analysis. I have carefully considered all the evidence and the arguments of both parties, though not all may be specifically discussed in this decision. I discuss in this decision the credible evidence given the greatest weight in my decision-making.[2] I also discuss any evidence that I find is not credible or worthy of weight. The fact that evidence is not specifically discussed should not be considered sufficient to rebut the presumption that I considered all the evidence and assigned such weight or probative value to the credible evidence that I determined appropriate within my discretion as an ALJ. There is no requirement for me to discuss the weight given every piece of evidence considered in this case, nor would it be consistent with notions of judicial economy to do so. Charles H. Koch, Jr., *Admin. L. & Prac.* § 5:64 (3d ed. 2013).

1. Petitioner violated the condition of participation for a HHA established by 42 C.F.R. § 484.18.

2. Petitioner's violation of 42 C.F.R. § 484.18 adversely affected the health and safety of patients.

3. Petitioner's violation of 42 C.F.R. § 484.18 shows that Petitioner's capacity to furnish adequate care was substantially limited.

4. There was a basis to terminate Petitioner's provider agreement and participation in Medicare as a HHA on December 21, 2012.

a. Facts Related to the Survey Cycle, Survey Findings and Conclusions, and Notices

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[2] "Credible evidence" is evidence that is worthy of belief. *Black's Law Dictionary* 596 (8th ed. 2004). The "weight of evidence" is the persuasiveness of some evidence compared to other evidence. *Id*. at 1625.

Petitioner was subject to a recertification survey on August 23, 2012, followed by revisit surveys on October 3, 2012 and December 3, 2012. An overview of the survey findings and conclusions is helpful.

The surveyors who conducted the August 23, 2012 recertification survey found that Petitioner was not in compliance with four conditions of participation. The surveyors found Petitioner noncompliant with the condition of participation established by 42 C.F.R. § 484.16 (Tag[3] G151) based on standard-level violations of 42 C.F.R. § 484.16 and 484.16(a) (Tags G152, G153 and G154). The surveyors found Petitioner was not in compliance with the condition of participation established by 42 C.F.R. § 484.32 (Tag G184) based on standard-level violations of 42 C.F.R. § 484.32 and 484.32(a) (Tags G186 and G190). The surveyors found Petitioner not in compliance with the condition of participation established by 42 C.F.R. § 484.36 (Tag G202) based on standard-level violations of 42 C.F.R. § 484.36(b)(2)(ii)-(iii), 484.36(c)(1)-(2), and 484.36(d)(2) (Tags G214, G215, G224, G225, and G229). The surveyors found condition-level noncompliance with 42 C.F.R. § 484.52 (Tag G242) based on standard-level violations of 42 C.F.R. § 484.52 and 484.52(b) (Tags G243, G244, G245, G246, and G250). The surveyors found standard-level violations of 42 C.F.R. §§ 484.12(c) (Tag G121), 484.14(c) (Tag G133), 484.30(a) (Tag G178), and 484.48 (Tag G236). The surveyors also found standard-level noncompliance with 42 C.F.R. § 484.18 and 484.18(a) (Tags G158 and G159). CMS Ex. 6.

The October 3, 2012 survey found continuing condition-level noncompliance with 42 C.F.R. § 484.36 (Tag G202) based on standard-level violations of 42 C.F.R. § 484.36(c)(1)-(2) and (d)(2) (Tags G224, G225 and G229). The surveyors also found continuing condition-level noncompliance with 42 C.F.R. § 484.52 (Tag G242) based on standard-level noncompliance with 42 C.F.R. § 484.52 and 484.52(b) (Tags G243, G244,

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[3] This is a "Tag" designation used in CMS Pub. 100-07, State Operations Manual (SOM), app. B – Guidance to Surveyors: Home Health Agencies (rev. Aug. 12, 2005) (http://www.cms.hhs.gov/Manuals/IOM/list.asp). The "Tag" refers to the specific regulatory provision allegedly violated and CMS's policy guidance to surveyors. Although the SOM does not have the force and effect of law, the provisions of the Act and regulations interpreted clearly do have such force and effect. *Ind. Dep't of Pub. Welfare v. Sullivan*, 934 F.2d 853 (7th Cir. 1991); *Northwest Tissue Ctr. v. Shalala*, 1 F.3d 522 (7th Cir. 1993). Thus, while the Secretary may not seek to enforce the provisions of the SOM, she may seek to enforce the provisions of the Act or regulations as interpreted by the SOM.

G245, and G250). The surveyors found standard-level noncompliance with 42 C.F.R. § 484.14(g) (Tag G143) and continuing standard-level noncompliance with 42 C.F.R. § 484.48 (Tag G236). The surveyors also found continuing standard-level noncompliance with 42 C.F.R. § 484.18 (Tag G158). CMS Ex. 19.

A second revisit survey was conducted on December 3, 2012. The survey found that Petitioner was not compliant with the requirement of 42 C.F.R. § 484.18 (Tag G156) at the condition-level. The condition-level noncompliance was based on standard-level noncompliance with 42 C.F.R. § 484.18(a), (b), and (c) (Tags G160, G163 and G166, respectively). CMS Ex. 24. The state agency determined that all citations of condition-level and standard-level violations of other conditions of participation cited by the August and October surveys were corrected by Petitioner not later than December 3, 2012. CMS Exs. 20, 25.

The state agency notified Petitioner on September 4, 2012, of the findings of the August 2012 survey. The state agency advised Petitioner that if the noncompliance found by the survey was not corrected within 45 days, the state agency would recommend to CMS that Petitioner's provider agreement and Medicare participation be terminated. CMS Ex. 1. On October 22, 2012, CMS notified Petitioner of the findings of the October 2012 revisit. CMS advised Petitioner that its Medicare provider agreement would be terminated November 21, 2012, unless Petitioner filed a credible allegation that it had returned to compliance. CMS Ex. 2. On November 4, 2012, CMS notified Petitioner that it had received Petitioner's plan of correction and found it acceptable. CMS advised Petitioner that it was extending the termination date to December 21, 2012, to permit the state agency to conduct a revisit survey. CMS Ex. 3. The December 3, 2012 revisit found that Petitioner had not returned to compliance with program participation requirements but remained noncompliant with 42 C.F.R. § 484.18 at the condition-level. Accordingly, Petitioner's participation in Medicare as a HHA was terminated by CMS effective December 21, 2012. CMS Ex. 5.

I conclude that the only alleged noncompliance that is at issue before me is the alleged violations of 42 C.F.R. § 484.18, as that noncompliance was the basis for termination of Petitioner's enrollment on December 21, 2012.

b. The Condition of Participation Established by 42 C.F.R. § 484.18

The regulations at 42 C.F.R. pt. 484 establish the conditions of participation and standards by which HHA compliance with the Medicare program is determined. The standards set forth in the regulations are essentially the yardsticks by which surveyors measure the level of compliance of the HHA. If HHA performance does not measure-up to the regulatory requirements, a deficiency exists. If a deficiency is found the question is whether that deficiency alone or considered in combination with another deficiency is

"of such character as to substantially limit the provider's . . . capacity to furnish adequate care or which adversely affect the health and safety of patients. . . ." 42 C.F.R. § 488.24(b). If the provider's capacity to furnish adequate care is substantially limited or if the health and safety of patients is adversely affected then a condition-level deficiency exists and termination must occur. If no condition-level deficiency exists, CMS may still consider whether one or more standard-level deficiencies are repeated on survey and resurvey and, if no correction has occurred, CMS may declare the provider agreement terminated on that basis.

CMS argues in this case that continuing standard-level noncompliance with 42 C.F.R. § 484.18 as found by all three surveys in this case is a basis for termination. CMS also argues that the finding of condition-level noncompliance by the last survey completed on December 3, 2012, is also an adequate basis for termination of Petitioner's participation in Medicare as a HHA. CMS Br. at 12-15; CMS Reply at 3. If I determine that Petitioner failed to meet even one condition of participation, I may conclude that there is a basis for termination of Petitioner's provider agreement. I conclude that Petitioner was not in compliance with the condition of participation established by 42 C.F.R. § 484.18 at the condition-level as determined by the survey completed on December 3, 2012. Therefore, it is not necessary for me to consider the repeated standard-level deficiencies cited by CMS as a basis for termination.

The condition of participation established by 42 C.F.R. § 484.18 provides:

> Patients are accepted for treatment on the basis of a reasonable expectation that the patient's medical, nursing, and social needs can be met adequately by the agency in the patient's place of residence. Care follows a written plan of care established and periodically reviewed by a doctor of medicine, osteopathy, or podiatric medicine.
>
> (a) Standard: Plan of care. The plan of care developed in consultation with the agency staff covers all pertinent diagnoses, including mental status, types of services and equipment required, frequency of visits, prognosis, rehabilitation potential, functional limitations, activities permitted, nutritional requirements, medications and treatments, any safety measures to protect against injury, instructions for timely discharge or referral, and any other appropriate items. If a physician refers a patient under a plan of care that cannot be completed until after an evaluation visit, the physician is consulted to approve additions or modifications to the original plan. Orders for therapy services include the specific procedures and modalities to be

> used and the amount, frequency, and duration. The therapist and other agency personnel participate in developing the plan of care.
>
> (b) Standard: Periodic review of plan of care. The total plan of care is reviewed by the attending physician and HHA personnel as often as the severity of the patient's condition requires, but at least once every 60 days or more frequently when there is a beneficiary elected transfer; a significant change in condition resulting in a change in the case-mix assignment; or a discharge and return to the same HHA during the 60–day episode. Agency professional staff promptly alert the physician to any changes that suggest a need to alter the plan of care.
>
> (c) Standard: Conformance with physician orders. Drugs and treatments are administered by agency staff only as ordered by the physician with the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per agency policy developed in consultation with a physician, and after an assessment for contraindications. Verbal orders are put in writing and signed and dated with the date of receipt by the registered nurse or qualified therapist (as defined in § 484.4 of this chapter) responsible for furnishing or supervising the ordered services. Verbal orders are only accepted by personnel authorized to do so by applicable State and Federal laws and regulations as well as by the HHA's internal policies.

42 C.F.R. § 484.18; CMS Ex. 33.

c. Facts Related to Specific Deficiencies and Analysis

The Statement of Deficiency (SOD) for the survey completed December 3, 2012 alleges that Petitioner violated 42 C.F.R. § 484.18 at the condition-level because Petitioner:

> failed to ensure the patient received services as ordered on the plan of care, verbal orders were accurately written, and that the plan of care and verbal orders were reviewed by the Physician as evidenced by the signature [of the physician].

CMS Ex. 24 at 1-2. The SOD alleges that clinical records of four of Petitioner's patients were reviewed. In two cases the surveyors found Petitioner's staff did not provide care

as specified in the plan of care. In two cases, the plan of care was not signed by the physician to show that he or she had reviewed the plan of care. In one case, the physician had not signed the plan of care to show that he or she had reviewed the recertified plan of care. In two cases, a verbal order was not countersigned by the physician and the date on a verbal order did not reflect the date of receipt of the order. CMS Ex. 24 at 2. The allegations are more fully described in the SOD under Tags G158, G160, G163, and G166, which allege the specific standard-level deficiencies that caused the condition-level violation. CMS Ex. 24.

(i) Tag G158 – Patient 2

Under Tag G158, the surveyors cited Petitioner because the plan of care for Patient 2 dated October 26, 2012, required that the nurse assess the patient's weight at each visit but there was no weight recorded for the October 31, 2012 visit. The surveyors also cited Petitioner because Patient 2's plan of care required two visits the week of October 26, 2012, but only one visit was documented. CMS Ex. 24 at 3.

Patient 2's plan of care for the period October 26 through December 24, 2012 shows that Petitioner's care of Patient 2 began on October 26, 2012. The plan of care specified that the skilled nurse was to observe and assess the patient, including weight gain and loss. CMS Ex. 28 at 7. The Skilled Nursing Visit Report dated October 31, 2012, does not list Patient 2's weight during that visit, supporting an inference that the patient was not weighed. CMS Exs. 28 at 9; 37 at 3. Patient 2's plan of care also specified that she was to be seen by a skilled nurse two times for one week and one time for eight weeks. CMS Ex. 28 at 7. The CMS evidence includes a Physician's Telephone Order signed by the nurse on November 1, 2012 that requests Patient 2's discharge because she was no longer homebound. CMS Ex. 28 at 12. There is no evidence that Patient 2 had more than the single visit by the skilled nurse on October 31, 2012. However, the plan of care specified that the patient was to be discharged when goals were met. Patient 2's discharge was ordered less than one week after her care began, because she was no longer homebound. CMS Ex. 28 at 7-12. I conclude that the failure to conduct a second skilled nurse visit between October 26 and 31, 2012, a period of less than a week, was not a violation of Patient 2's plan of care.

Petitioner argues that it was determined during the start of care evaluation that Patient 2 was not suitable for home health care as she was not homebound and she was discharged from Petitioner's care on November 6, 2012. P. Prehearing Brief (P. PHB) at 9; P. Br. at 13. However, the Skilled Nursing Visit Report dated October 31, 2012, is marked to indicate under "Homebound" that the patient was limited and unable to leave the home without assistance and that it was a taxing effort to leave home. The Skilled Nursing Visit Report does not state that Patient 2 was not homebound on October 31, 2012. CMS Ex. 28 at 9-11. Petitioner produced a physical therapy evaluation for Patient 2 dated November 6, 2012, which states that Patient 2 was not homebound as of

November 6, 2012. The physical therapy report does not address whether or not Patient 2 was homebound upon admission to Petitioner's care on October 26 or on October 31, 2012, when she was evaluated by the skilled nurse. P. Ex. 17. The evidence does not show why Petitioner had a physical therapy evaluation done on November 6, 2012, five days after the verbal order of the physician on November 1, 2012 to discharge the patient because she was not homebound. CMS Ex. 28 at 12. Petitioner also produced a second Physician's Telephone Order which directed Patient 2's discharge because she was not homebound. P. Ex. 18. The telephone order Petitioner submitted (P. Ex. 18) is dated November 6, 2012 but the telephone order CMS submitted (CMS Ex. 28 at 12) is dated November 1, 2012 . Comparing the copy of the Physician's Telephone Order admitted as CMS Ex. 28 at 12 with the copy of the Physician's Telephone Order admitted as P. Ex. 18, I conclude that they are copies of the same document. However, the copy of the document offered as P. Ex. 18 was altered so that the date near the nurse's signature was changed from "11/1/2012" to "11/6/2012" by adding a loop at the bottom of the numeral 1. Although the printed text on CMS Ex. 28 at 12 is slightly smaller and lighter than that on P. Ex. 18, it is common knowledge among office workers who use copy machines that the size of text and the darkness of the print may be affected by copier settings or the quality of the copier. More accurate indications that the two exhibits are copies of the same document with an alteration of the numeral "1" are the shape of the capital letters used for the physician name; the similar spacing of all the hand printed information except of course the physician signature which appears on P. Ex. 18 but not CMS Ex. 28 at 12; the shape of the parenthesis used in the physician phone and fax numbers; the cursive writing slant, shape and spacing is identical in both; and the "2012" appears to be identical in both documents. I conclude that P. Ex. 18 was intentionally altered for an undetermined purpose by an unknown individual, and the dates "11/6/2012" near the nurse's signature is not credible or entitled to weight.

Petitioner also argues that Patient 2 refused to be weighed on October 31, 2012. P. PHB at 10; P. Br. at 13. Contrary to Petitioner's assertion there is no evidence in the Skilled Nursing Visit Report dated October 31, 2012, that Patient 2 refused to be weighed. CMS Ex. 28 at 9-11. There is no other evidence in the record that Patient 2 refused to be weighed. The evidence shows that Petitioner failed to comply with Patient 2's plan of care on October 31, 2012, because there is no weight reflected in the Skilled Nursing Visit Report completed on that date. CMS Ex. 28 at 9.

(ii) Tag G158 – Patient 3

The surveyors also cited Petitioner under Tag G158 because Patient 3's plan of care required monitoring blood glucose every visit and the skilled nursing notes dated November 23, 2012, did not document that blood glucose was checked during that visit. The surveyors cited Petitioner because Patient 3's plan of care required one visit per week for nine weeks and there was no record of a visit the week of October 28 to November 3, 2012. The surveyors cited Petitioner because Patient 3's plan of care

required a physical therapy evaluation but no evaluation was documented in the record. CMS Ex. 24 at 3-4; CMS Ex. 37 at 3.

Patient 3's plan of care for the period October 26 through December 24, 2012, required that she be seen by a skilled nurse one time per week for nine weeks; that she be evaluated by physical therapy; and that a blood sugar level be determined by a finger stick and glucose monitor every skilled nurse visit and that the physician be notified if the blood sugar was not within specified parameters. CMS Ex. 29 at 7. A Skilled Nursing Visit Reports contain entries dated November 9, 16, and 30, 2012 reflecting that Patient 3's blood glucose level was checked. CMS Ex. 29 at 10, 12, 16. The Skilled Nursing Visit Report dated November 23, 2012, does not indicate that blood glucose was checked, triggering an inference that it was not. CMS Ex. 29 at 14. Surveyor Avelina Abella stated in her declaration dated January 9, 2014, that as of the date of the survey there was no documentation that the physical therapy evaluation had been done. She also stated that no record was found for a skilled nurse visit for one of the required weeks, but she did not state which week. CMS Ex 37 at 3. I note that there is no record in the CMS evidence of a visit between October 26, 2012 and November 9, 2012, a period of more than a week. Petitioner has failed to submit evidence that a nursing visit was done between October 26 and November 9, 2012. There is also no record that Patient 3 ever received the ordered physical therapy evaluation.

Petitioner argues the blood glucose reading for November 23, 2012, was in the original Skilled Nursing Visit Report but the skilled nurse, Diane Washington, RN, accidentally omitted the information when she rewrote the note to make it neater. P. Br. at 12; P. PHB at 8-9; P. Ex. 25 at 3 ¶ 10. Petitioner does not discuss P. Ex. 6 in its argument. However, the document is listed on Petitioner's exhibit list as "Blood Glucose Note for Pt. #3." P. Ex. 6 is a two-page photocopy of a Skilled Nursing Visit Report dated November 23, 2012. I have compared P. Ex. 6 with CMS Ex. 29 at 14-15. I conclude based on comparison of the cursive writing, the spacing of the letters, the shape of the numerals, and the shape of the other characters, that both exhibits are copies of the same document despite the fact that some of the entries on P. Ex. 6 have been obscured or redacted and the size and contrast of the two documents are slightly different due to the effects of copying. P. Ex. 6 at 1 contains the entry of "95" mg/gl for blood sugar glucose by Accucheck while on CMS Ex. 29 at 14 there is no numeral entered in the blank for mg/gl for blood sugar. I conclude that the numeral "95" was added to the document by an unknown person for an unknown reason after the Skilled Nursing Visit Report was copied and provided to the surveyors. Therefore, I conclude that P. Ex. 6 does not establish that RN Washington included a blood glucose reading originally on her Skilled Nursing Visit Report which she simply omitted when she recopied the document to make it neater. I have no affidavit or declaration from RN Washington to evaluate. Accordingly, I conclude that P. Ex. 6 is not reliable evidence and entitled to no weight.

Petitioner characterizes the missing blood sugar test result as a documentation error that is not serious and of no impact. P. Br. at 12. Petitioner's evidence does not show that the absence of the blood sugar test result was only a documentation error. The inference that no blood sugar check was done on November 23, 2012, is not affected by Petitioner's arguments or evidence. The plan of care shows that Patient 3's physician ordered blood sugar testing establishing the medical need for the test, and Petitioner has presented no competent medical or other evidence to show that the testing was unnecessary. Even if the absence of the entry was a clerical or documentation error, Petitioner has not presented competent evidence to support a finding that the absence of the entry had no potential adverse effect upon Patient 3 or her care and treatment.

(iii) Tag G160 – Patient 1

The surveyors cited Petitioner under Tag G160 related to Patient 1 because on December 3, 2012, the patient's October 6, 2012 plan of care did not contain the physician's signature to show that the physician had reviewed the plan of care. CMS Ex. 24 at 4-5; CMS Ex. 36 at 5 ¶ 19; CMS Ex. 37 at 3 ¶ 12. CMS produced addenda to the October plan of care of Patient 1 for the period October 6 through December 4, 2102 that are not signed by a physician. CMS Ex. 27 at 7-8. CMS submitted a copy of Petitioner's Plan of Care Policy which required that the original plan of care be mailed or faxed to the physician for signature and returned to Petitioner for retention. CMS Ex. 32 at 2 ¶¶ 3, 5. The absence of the physician signature on the plan of care supports an inference that the physician did not review the plan of care.

Petitioner argues that Patient 1's physician repeatedly ignored Petitioner's requests to sign the plan of care, even though he signed the order to start care on October 2, 2012. P. Br. at 13; P. PHB at 9; P. Ex. 7; P. Ex. 26 at 2 ¶ 7. Petitioner states that after November 21, 2012, its skilled nurse could no longer gain access to Patient 1's residence and the patient was discharged on December 4, 2012. Petitioner cites no evidence in support of its arguments and they are insufficient to support an inference that the physician did review Patient 1's plan of care.

(iv) Tag G160 – Patient 2

The surveyors also cited Petitioner under Tag G160 related to Patient 2, (the same patient previously discussed as cited under Tag G158). The surveyors allege that on December 3, 2012, Patient 2's plan of care dated October 26, 2012, was not signed by her physician and there was no evidence that the physician reviewed the plan of care. CMS Ex. 24 at 5. The copy of Patient 2's plan of care for the period October 26 through December 24, 2012, placed in evidence by CMS, is not signed by a physician. CMS Ex. 28 at 8; CMS Ex. 37 at 3 ¶ 12. The absence of the physician's signature triggers an inference that the physician did not review the plan of care.

Petitioner argues that Patient 2's physician faxed a copy of the signed plan of care to Petitioner on December 3, 2012, when the surveyor asked about the missing signature. P. Br. at 13; P. PHB at 9-10; P. Ex. 8. The plan of care submitted by Petitioner bears a signature in the block for the attending physician signature but the physician did not date his signature as required by the form. Therefore, Petitioner's evidence is insufficient to show that the physician actually reviewed the plan of care prior to December 3, 2012 when the surveyors brought the issue to Petitioner's attention.

(v) Tag G163 – Patient 4

The surveyors cited Petitioner under Tag G163 because on December 3, 2012, Patient 4's recertification plan of care dated October 12, 2012, did not contain a physician's signature to show that a physician had reviewed the plan of care. CMS Ex. 24 at 6; CMS Ex. 36 at 5 ¶ 20; CMS Ex. 37 at 4 ¶ 13. Patient 4's start of care was August 13, 2012. Patient 4's plan of care for the period October 12, 2012 to December 10, 2012, admitted as CMS Ex. 30 at 7-10, is not signed by a physician.

Petitioner does not deny that the plan of care was not signed by the physician. P. Br. at 13-14; P. PHB at 10.

The absence of the physician's signature supports the inference that the physician did not review the recertification plan of care.

(vi) Tag G166 –Patient 4

The surveyors cited Petitioner under Tag G166 because a nurse incorrectly dated a record of a verbal order for Patient 4. The nurse dated the order October 8, 2012, but Petitioner's Administrator informed the surveyor that the order should have been dated October 18, 2012. CMS Ex. 24 at 7-8; CMS Ex. 30 at 11; CMS Ex. 36 at 5 ¶ 21; CMS Ex. 37 at 4 ¶ 14.

Petitioner agrees that the record of the verbal order was dated incorrectly by the nurse. P. Br. at 13-14; P. PHB at 10.

(vii) Tag G166 – Patient 2

The surveyors also cited Petitioner under Tag G166 because Patient 2's November 1, 2012 discharge order was not signed by a physician before the date of the survey. CMS Ex. 24 at 8. The physician's telephone order to discharge Patient 2 is signed by the nurse and dated November 1, 2012. The telephone order obtained by the surveyors on about December 3, 2012 does not bear a physician's signature. CMS Ex. 28 at 12. Petitioner asserts that Patient 2 was discharged on November 6, 2012, citing to P. Exs. 17 and 18. P. Br. at 13; P. PHB at 9. For reasons discussed above related to Tag G158

and Patient 2, I do not find that P. Ex. 18 is credible or entitled to weight because the document was intentionally altered. However, I have no reason to doubt that the physician did not sign the recording of his verbal order until December 6, 2012, consistent with the allegations of the surveyors. P. Ex. 17 is a Physical Therapy Evaluation for Patient 2, dated November 6, 2012, five days after the nurse dated the record of the verbal order to discharge Patient 2. The Physical Therapy Evaluation bears a signature in the box for the physicians' signature, but it is not dated. P. Ex. 17 at 2. Furthermore, Petitioner offers no explanation for how a physician signature on the Physical Therapy Evaluation addresses the missing physician signature on the record of verbal order to discharge Patient 2 that was dated by the nurse November 1, 2012.

(viii) Tag G166 – Petitioner's Policies

There is no dispute that Petitioner had policies regarding physician orders and clinical documentation.

Petitioner's policy related to physician orders required that all medications, treatments and services provided must be ordered by a physician. The policy provided that physician orders may be received by telephone or in writing, but orders must be countersigned by the physician in a timely manner. Verbal orders may only be received by licensed personal designated by Petitioner consistent with applicable state and federal law and organization policy. The policy required that verbal orders be read back to the physician to verify accuracy. The recording of the verbal order had to be dated, include the specific order, be signed by the person who received the order and be sent to the physician for signature. CMS Ex. 32 at 3.

Petitioner's policy regarding clinical documentation specifies that the purpose of clinical documentation is to ensure that there is an accurate record of services provided, patient response, the need for ongoing care, compliance with the plan of care, modifications to the plan of care, and interdisciplinary involvement. CMS Ex. 32 at 5.

Petitioner does not dispute that it was a practice of the agency for all plans of care and verbal orders to be signed by the physician and added to the clinical record within 30 days. CMS Ex. 24 at 8; P. Ex. 26 at 1.

(ix) Analysis

Based on the forgoing discussion of the facts which are established by a preponderance of the evidence, I conclude that at the time of the survey on December 3, 2012, Petitioner was not in compliance with four standard-level requirements established by 42 C.F.R. § 484.18(a), (b), and (c). I further conclude that the four standard-level deficiencies amounted to condition-level noncompliance with 42 C.F.R. § 484.18 because the deficiencies were of such character that the health and safety of the four

patients was adversely impacted and jeopardized because the deficiencies had the potential to harm each patient. The condition-level noncompliance was also of such character to show that Petitioner's capacity to render adequate care in accordance with physician orders was seriously limited. 42 C.F.R. §§ 488.24(b), 488.28(b).

I conclude that there is a basis for termination of Petitioner's provider agreement and participation in Medicare and that termination is appropriate. CMS is authorized to terminate a HHA's provider agreement if the HHA has a condition-level deficiency. Act §§ 1861 (o)(6), 1866(b)(2)(B), 1891(e) (42 U.S.C. §§ 1395x(o)(6), 1395cc(b)(2)(B), 1395bbb(e)); 42 C.F.R. § 489.53(a)(3). CMS's decision to terminate a provider agreement is discretionary. 42 C.F.R. § 489.53(a); *United Medical Home Care*, DAB No. 2194 at 13. If I find a basis exists for the termination by CMS, then I will uphold the termination of Petitioner's provider agreement and participation in Medicare. *Comprehensive Professional Home Visits*, DAB No. 1934 (2004). Accordingly, if I find that Petitioner was out of compliance at the condition-level of participation of 42 C.F.R. § 484.18 during the December 3, 2012 survey, then I will uphold the termination of Petitioner's provider agreement and participation in the Medicare program. I do not review whether the selection of termination is the appropriate remedy. I conclude based on my review of the facts in this case that there was no abuse of discretion by CMS in selecting termination given the number and nature of the deficiencies established by the record. *United Medical Home Care*, DAB No. 2194 at 13.

Whether or not there is compliance with a condition of participation depends upon "the manner and degree to which the provider . . . satisfies the various standards within each condition." 42 C.F.R. § 488.26(b); *CSM Home Health Services*, DAB No. 1622 at 6-7. The state agency certifies that a HHA is not in compliance with a condition of participation when Petitioner's deficiencies are "of such character as to substantially limit the providers . . . capacity to furnish adequate care or which adversely affect the health and safety of patients." 42 C.F.R. § 488.24(b). An appellate panel of the Board has stated:

> Under the governing standard for determining whether a provider's noncompliance constituted a condition-level violation, . . . the evidence must show that the deficiency substantially limited the provider's capacity to furnish adequate care or adversely affected the health and safety of the provider's patients.

Profound Health Care, DAB No. 2371 at 9 (2011) (citing 42 C.F.R. § 488.24(b)).

When a provider's Medicare participation is terminated because of noncompliance, "the critical date for establishing compliance is the survey date, not the subsequent effective date of the termination." *Carmel Convalescent Hospital*, DAB No. 1584 at 12 (1996);

Rosewood Living Ctr., DAB No. 2019 at 11 (2006). A provider's efforts to bring itself into compliance after the date of the resurvey are "completely irrelevant to the facility's appeal of [CMS's] determination to terminate." *Carmel*, DAB No. 1584 at 13. CMS is not required to afford a provider the opportunity to correct its failure to comply with a condition of participation before terminating the provider. 42 C.F.R. § 489.53; *Aspen Grove Home Health*, DAB No. 2275 at 23. Thus, a provider's contention that it took corrective action prior to the date its Medicare agreement was terminated "is irrelevant." *Profound Health Care* DAB No. 2371 at 8; *Aspen Grove Home Health*, DAB No. 2275 at 23; *Community Home Health*, DAB No. 2134 (2007).

The condition and standards at issue in this case are established by 42 C.F.R. § 484.18. Home health services provided by a home health agency are authorized for Medicare payment under a plan for furnishing home health items and services to a Medicare eligible individual who is under the care of a physician. The plan of care must be "established and periodically reviewed by a physician." Act § 1861(m); 42 C.F.R. § 484.18. The physician's signature on a plan of care is evidence that the physician established or reviewed the plan of care as required by the Act.

Petitioner's policies required physician signatures on plans of care and orders. Petitioner also required that signed orders and plans of care be added to the clinical record. Petitioner's policy shows that Petitioner recognized that the purpose of clinical documentation is to ensure that there is an accurate record of services provided, patient response, the need for ongoing care, compliance with the plan of care, modifications to the plan of care, and interdisciplinary involvement. CMS Ex. 32 at 3-5. Petitioner's policy is consistent with the requirements of the Act and regulations. CMS policy set forth in SOM app. B Tag G166 (CMS Ex. 33) instructs surveyors that all plans of care must be signed and dated by the physician and all verbal orders must be countersigned by the physician as soon as possible. Both the SOM and Petitioner's policies are good evidence of the standard of practice and the standard of care for home health agencies.

I have found as follows for each deficiency cited by the surveyors:

Tag G158

Resident 2 – Petitioner failed to follow the plan of care by failing to weigh the patient on October 31, 2012.

Resident 3 – Petitioner failed to follow the plan of care by:

- Failing to check the patient's blood glucose on November 23, 2012;
- Failing to conduct a skilled nursing visit between October 28 and November 3, 2012;
- Failing to order a physical therapy evaluation of the patient.

Tag G160

Resident 1 – Petitioner failed to produce evidence that the physician established and reviewed the plan of care.
Resident 2 – Petitioner failed to produce evidence that the physician established and reviewed the plan of care.

Tag G163

Resident 4 – Petitioner failed to produce evidence that the physician established and reviewed the recertification plan of care.

Tag G166

Resident 4 – A record of a verbal order was not dated with the date on which it was received from the physician.
Resident 2 – Petitioner failed to produce evidence that the physician ordered the patient's discharge.

Petitioner's failure to follow the plans of care for Patients 2 and 3 violates 42 C.F.R. § 484.18 (Tag G158), which requires that home health services be delivered according to a written plan of care established and reviewed by a physician.

Petitioner's failure to produce evidence that a physician established the plan of care for Patients 1 and 2 constitutes a violation of 42 C.F.R. § 484.18. The surveyors alleged that the absence of a physician signature constituted a violation of 42 C.F.R. § 484.18(a) (Tag G160), in the case of Patients 1 and 2. However in the SOD the surveyors alleged that the physician failed to review the initial plan of care which is required by 42 C.F.R. § 484.18, rather than that the physician failed to approve additions or modifications to the original plan as required by 42 C.F.R. § 484.18(a). CMS Ex. 24 at 4-5. The surveyors' allegations under Tag G160 are more appropriately alleged under Tag G158. Petitioner made no objection or alleged any prejudice due to the surveyors' error. I conclude that Petitioner suffered no prejudice because the SOD provided sufficiently specific allegations to place Petitioner on notice of the basis for the deficiency citation and what Petitioner needed to defend.

Petitioner's failure to produce evidence that a physician reviewed the recertification plan of care for Patient 4 violated 42 C.F.R. § 484.18(b) (Tag G163).

The incorrectly dated record of a verbal order in the case of Patient 4 and the failure of Petitioner to obtain a countersignature of the physician on the record of the verbal order to discharge Patient 2, violated 42 C.F.R. § 484.18(c) (Tag G166), Petitioner's policy, CMS policy, and standards of practice and care.

I conclude that the seven standard-level deficiencies discussed, collectively amount to a condition-level violation 42 C.F.R. § 484.18 (Tag G156). The deficiencies jeopardized the health and safety of Petitioner's patients, who were denied care and services directed by their plans of care, and who were subject to care and services that Petitioner has not shown were established and reviewed by a physician. Although no actual harm to any patient is alleged by the surveyors, I find no authority to support an argument that a patient must be injured before Petitioner is subject to termination for condition-level noncompliance. The deficiencies also show that Petitioner's ability to deliver adequate care and services in accordance with a physician orders was seriously limited.

Petitioner argues that Patients 1, 2, and 4 were either discharged are due to be discharged at the time of the December 2012 survey and should not have been considered under 42 C.F.R. § 484.18. P. PHB at 8, 10-11. Petitioner cites no legal authority to support its argument. I find no provision of the regulations or the Act that prevents surveyors from considering the records of discharged patients or those due to be discharged. 42 C.F.R. § 488.18-488.28. I further note that all the records considered by the surveyors related to the period after completion of the October 3, 2012 survey. CMS Ex. 19.

Petitioner argues that it had implemented its plan of correction that was accepted by CMS on November 14, 2012. P. PHB at 10. I infer that the plan of correction to which Petitioner refers was the plan of correction dated October 31, 2012, for the deficiencies cited by the revisit survey completed on October 3, 2012. CMS Ex. 19. Petitioner recognizes that even if CMS accepts a plan of correction, a provider is not considered in compliance until CMS determines that noncompliance no longer exists, usually through a revisit survey. P. Br. at 10. A revisit survey is performed in the case of a provider or supplier that was cited to be deficient on an initial certification, recertification, or a substantiated complaint survey. The revisit survey is intended to evaluate whether previously cited deficiencies have been corrected and to determine whether or not the provider or supplier has returned to substantial compliance with conditions of participation, requirements, or conditions for coverage. Revisit surveys include both offsite and onsite reviews. 42 C.F.R. § 488.30(a). Petitioner argues that when CMS accepted Petitioner's plan of correction, that plan of correction became part of the provider's obligations and duties under the contract between CMS and Petitioner. The gist of Petitioner's argument is that CMS is bound to the terms of the accepted plan of correction at least as to any noncompliance by Petitioner that predated the date of acceptance of the plan. Petitioner asserts that CMS is limited on revisit to examine only those deficiencies cited during the prior survey or surveys. Petitioner asserts that CMS may only terminate after accepting a plan of correction based on Petitioner's failure to implement its plan of correction. Petitioner's arguments are in error for several reasons. Petitioner cites in support of its argument *Nazareno Medical Hospice Farjardo, Conguas, Cayey*, DAB CR386 (1995) and *Guanynabo Hospice Care, Inc.*, DAB CR374 (1995). Both decisions were issued by ALJs and have no binding precedential effect

upon me or the Board. The analysis of the decisions is also not persuasive in large part because the cases were decided prior to the Board's *Hillman* opinion in 1997 and incorrectly imposed the ultimate burden of persuasion upon the Health Care Finance Administration (now CMS) rather than the petitioners in those cases. Petitioner cites to no other cases in the last 20 years that apply the *Nazareno* and *Guanynabo* decisions in the manner argued by Petitioner. Furthermore, the regulations applicable in this case are clear that a revisit survey is intended to evaluate whether previously cited deficiencies have been corrected and to determine whether or not the provider or supplier has returned to substantial compliance with conditions of participation. 42 C.F.R. § 488.30(a). The regulation does not suggest that the revisit survey is limited to determining whether a provider corrected and was in substantial compliance with the regulations previously cited as being violated. Rather the regulation is clear that the revisit considers whether previously cited deficiencies were corrected and whether Petitioner was in substantial compliance at the time of the revisit. Furthermore, even if Petitioner's argument had some merit, the condition-level noncompliance cited by the December 2012 survey was for violation of 42 C.F.R. § 484.18, which was one of the regulations with which Petitioner was cited by both the August and the October 2012 surveys. The December 2012 survey concluded that Petitioner was noncompliant with 42 C.F.R. § 484.18 at the condition-level based on different examples than the single example cited by the October 2012 survey. CMS Ex. 19 at 3-4; CMS Ex. 24. The examples cited by the December 2012 survey also post-date the October 2012 survey. I conclude that Petitioner's argument that the findings and conclusions of the December 2012 revisit survey cannot be a basis for termination is meritless.[4]

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[4] Petitioner makes various allegations regarding the conduct of the surveyors during the December 2012 revisit and the actions of the state agency. P. Exs. 24, 25; Request for Hearing at 14-15. Petitioner does not request in its final brief any relief based on the allegations. Based on my de novo review of the evidence, specifically Petitioner's clinical records, I have found condition-level noncompliance with 42 C.F.R. § 484.18. I find no impact of any alleged conduct by the surveyors that Petitioner characterizes as inappropriate, even if I assume that the allegations have merit. My findings in this case do not rely upon the credibility of the surveyors or their observations. Failure of surveyors to follow regulatory survey procedures should not invalidate otherwise supported deficiency findings or relieve a provider of its obligation to comply with the conditions of participation. *Cf.* 42 C.F.R. §§ 488.305(b), 488.318(b)(1).

III. Conclusion

For the foregoing reasons, I conclude that Petitioner was not in compliance with the condition of participation at 42 C.F.R. § 484.18 as of the December 3, 2012 revisit survey. There was a basis for termination of Petitioner's participation as a HHA in the Medicare program effective December 21, 2012.

/s/
Keith W. Sickendick
Administrative Law Judge