

**Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division**

Shiloh First Health Care, Inc.
Docket No. A-18-69
Decision No. 2974
October 24, 2019

**REMAND OF
ADMINISTRATIVE LAW JUDGE DECISION**

Shiloh First Health Care, Inc. (Shiloh) appeals the March 20, 2018 Administrative Law Judge (ALJ) decision granting summary judgment in favor of the Centers for Medicare & Medicaid Services (CMS) and sustaining its imposition of a \$10,000 per-instance civil money penalty (CMP). *Shiloh First Health Care, Inc.*, DAB CR5052 (2018) (ALJ Decision). The central issue was whether Shiloh's supervising nurse improperly employed a single lancing device to take blood for glucose testing from more than one patient.

For the reasons explained below, we conclude that Shiloh did present evidence which, construed in its favor as it must be on summary judgment, raised a genuine issue as to a fact material to the result. We therefore vacate the ALJ Decision and remand to the ALJ for further proceedings consistent with this decision.

Applicable Legal Authorities

Section 1891 of the Social Security Act (Act)¹ and regulations at 42 C.F.R. Part 484² provide the conditions for home health agencies (HHAs) to participate in the Medicare program. CMS determines HHA compliance with these requirements through unannounced surveys performed by state agencies under agreements with CMS. 42

¹ The Act can be found at http://www.socialsecurity.gov/OP_Home/ssact/ssact-toc.htm, including cross-references to the United States Code (USC). See also http://uscode.house.gov/table3/1935_531.htm and https://www.ssa.gov/OP_Home/comp2/G-APP-H.html.

² Effective July 13, 2017, CMS revised the conditions of participation in Part 484 that home health agencies must meet to participate in the Medicare and Medicaid programs. Final Rule, *Medicare and Medicaid Program: Conditions of Participation for Home Health Agencies*, 82 Fed. Reg. 4504, 4578 (Jan. 13, 2017). We rely on the regulations in effect when the state agency performed the surveys in 2016, which are the regulations that formed the bases for CMS's determination of noncompliance and the ALJ Decision. *Carmel Convalescent Hosp.*, DAB No. 1584, at 2 n.2 (1996) (Board applies the regulations in effect on the date of the survey and resurvey).

C.F.R. §§ 488.10-488.12; 488.18-488.26; 488.700-488.745. If a survey finds that an HHA is out of compliance with one or more conditions of participation, CMS may terminate the HHA's Medicare participation. Act §§ 1866(b)(2)), 1891(e)); 42 C.F.R. §§ 489.53(a)(3), 488.825(a), 488.830(a).

CMS is also authorized to impose alternative sanctions including CMPs. 42 C.F.R. §§ 488.820, 488.825(a)(3) (permitting alternative sanctions in addition to termination in immediate jeopardy cases), 488.830(a)(2) (permitting alternative sanctions in lieu of termination for up to 6 months in non-immediate jeopardy cases). A CMP may be imposed either for the number of days the HHA is not in compliance with conditions of participation or for each instance of such noncompliance. 42 C.F.R. § 488.845. Compliance with the conditions of participation "depends upon the manner and degree to which the [HHA] satisfies the various standards within each condition." 42 C.F.R. § 488.26(b). Condition-level noncompliance exists "where the deficiencies are of such character as to substantially limit the [HHA's] capacity to furnish adequate care or . . . adversely affect the health and safety of patients." 42 C.F.R. § 488.24(b).

The condition of participation at issue here required, at the relevant time, that an HHA "furnish[] skilled nursing services by or under the supervision of a registered nurse and in accordance with the plan of care." 42 C.F.R. § 484.30. This condition included the following relevant standard:

Duties of the registered nurse. The registered nurse makes the initial evaluation visit, regularly reevaluates the patient's nursing needs, initiates the plan of care and necessary revisions, furnishes those services requiring substantial and specialized nursing skill, initiates appropriate preventive and rehabilitative nursing procedures, prepares clinical and progress notes, coordinates services, informs the physician and other personnel of changes in the patient's condition and needs, counsels the patient and family in meeting nursing and related needs, participates in in-service programs, and supervises and teaches other nursing personnel.

An HHA may request a hearing before an ALJ on a noncompliance determination that is the basis for CMS's imposition of a CMP. 42 C.F.R. § 488.845(c)(2)(i).

Case Background

Shiloh is an HHA located in Sugar Land, Texas. Beginning August 8, 2016, the state survey agency conducted a recertification survey of Shiloh and determined it was noncompliant with the condition of participation at issue here.³ CMS Ex. 3 (August 2016 Statement of Deficiencies (SOD)). Shiloh, at that time, had three registered nurses (RNs), supporting staff/aides, and a patient census of 24. Shiloh Pre-hearing Br. at 3. The surveyor accompanied Shiloh's owner and nurse supervisor (referred to here as RN M) on home health visits to patients. CMS Ex. 3; Shiloh Pre-hearing Br. at 4-6.

The noncompliance allegations arose initially from the surveyor's uncontested observation that RN M used a lancet device which she brought with her to obtain blood for glucose testing from a patient she visited. The surveyor further reported –

Based on observation, interview and record review, the agency failed to ensure that the skilled nurse initiated appropriate preventative nursing procedures in compliance with accepted professional standards and principles for 2 of 4 (#2 and #4) clients requiring finger stick blood glucose sampling in that: [RN M] **utilized a lancing device meant for use with a single client on more than one client.**

CMS Ex. 3, at 2 (emphasis added). The SOD stated that these and two prior patients who had received blood glucose testing could thereby be placed at risk of infections affecting their health, and concluded that Shiloh's practices presented an immediate jeopardy to its patients. *Id.* at 2-3

Based on this survey finding, CMS imposed a per-instance CMP of \$10,000. CMS Ex. 2, at 1.

Shiloh timely sought a hearing before an ALJ. *See* Request for Hearing. The ALJ⁴ instructed both parties that they must file written direct testimony for any witness they sought to present along with their pre-hearing exchange. ALJ Pre-hearing Order at 3, 5-6. The ALJ further instructed that a hearing would only be held if either party sought to cross-examine an opposing party's witness. *Id.*

³ CMS cited, and Shiloh, challenged other deficiency findings, but before the ALJ, CMS sought summary judgment only as to the condition of participation discussed in this decision, so we limit our consideration to this issue, as did the ALJ. ALJ Decision at 2, n.2.

⁴ The case was assigned to one ALJ and later transferred to another. ALJ Decision at 1. Neither party identified any issue relating to this change, and we refer throughout our decision to the actions of the "ALJ" without distinguishing which ALJ was acting.

Standard of Review

Our standard of review on a disputed issue of law is whether the ALJ decision is erroneous. *Guidelines - Appellate Review of Decisions of Administrative Law Judges Affecting a Provider's or Supplier's Enrollment in the Medicare Program*, <https://www.hhs.gov/about/agencies/dab/different-appeals-at-dab/appeals-to-board/guidelines/enrollment/index.html>. Whether summary judgment is appropriate is a legal issue that we therefore address de novo. *Arriva Medical, LLC*, DAB No. 2934, at 9 (2019), *appeal docketed*, *Arriva Medical, LLC v. Sec'y of the United States Dep't of Health & Human Servs.*, No. 9:19-CV-80685 (S.D. Fla. May 24, 2019), and cases cited therein.

In our de novo review of a grant of summary judgment, we apply the same standard appropriate to the ALJ's determination. Summary judgment is appropriate when there is no genuine dispute about a fact or facts material to the outcome of the case and the moving party is entitled to judgment as a matter of law. *Sunsites Pearce Fire Dist.*, DAB No. 2926, at 4 (2019), *appeal docketed*, *Sunsites Pearce Fire Dist. v. Azar*, No. 4:19-CV-00203 (D. Ariz. Apr. 5, 2019), and cases cited therein.

We view the record in the light most favorable to the non-moving party and give that party the benefit of all reasonable inferences that may be drawn from the evidence. *See, e.g., Ramarao Kaza, M.D. and Ramarao Kaza, M.D., P.C.*, DAB No. 2924, at 8 (2019); *Golden Living Ctr. – Trussville*, DAB No. 2937, at 8 (2019), and cases cited therein. “Drawing factual inferences in the light most favorable to the non-moving party does not require that a reviewer draw unreasonable inferences or accept the non-moving party’s legal conclusions.” *Trussville* at 8.

“To defeat an adequately supported summary judgment motion, the nonmoving party may not rely on the denials in its pleadings or briefs, but must furnish evidence of a dispute concerning a material fact.” *Arriva* at 8 (citing *Senior Rehab. & Skilled Nursing Ctr.*, DAB No. 2300, at 3 (2010), *aff'd*, *Senior Rehab. & Skilled Nursing Ctr. v. Health & Human Servs.*, 405 F. App'x 820 (5th Cir. 2010)).

Analysis

1. For purposes of summary judgment, the record shows a genuine dispute of material fact.

It is undisputed that the lancet devices involved here are not designed for use on multiple patients, and that even reuse by one patient requires cleaning beyond external wiping with disinfectant. ALJ Decision at 2-3, and record citations therein. The single question

on which this appeal turns is whether Shiloh produced evidence in support of its denial that RN M improperly used the same lancet devices on more than one patient and failed to clean them appropriately.

The surveyor does not report having seen the same device used on more than one patient,⁵ but does report observing RN M using a monitor and lancet which she had brought to the site with her to test a patient and then only cleaned the lancet's external surface with a disinfectant wipe. CMS Ex. 22, at 2.

She also states that, when interviewed, RN M explained she bought and kept "the glucometer equipment . . . for the use of patients who needed to have blood glucose checks." *Id.* at 3. The surveyor further declares that RN M "stated that she cleaned the lancing device with a disinfectant wipe in between patients" and specifically denied that any cleaning measures were needed or taken beyond that step. *Id.* RN M reportedly told the surveyor that this device and these steps comprised her typical procedure used for checking patients' blood glucose. *Id.* The surveyor also interviewed several patients who indicated that RN M sometimes or regularly used her own equipment to test their blood glucose. *Id.* at 3-4.

This evidence sufficed to set out a prima facie case that Shiloh's nurse failed to employ infection prevention meeting professional standards set out in section 484.30. Shiloh does not deny this and, in fact, states as much in its appellate filing. Shiloh Request to Reconsider ALJ Decision (RR) at 2. The question before the ALJ, therefore, was whether Shiloh came forward with evidence which, taken as true, would, with all reasonable inferences drawn in Shiloh's favor, raise one or more genuine disputes as to any material fact(s).

Shiloh asserted directly that RN M "did not, at any time, use the same lancing device on multiple patients." Shiloh Pre-hearing Br. at 1. Shiloh further averred that, while the surveyor observed RN M using a lancet device on Patient 2, the surveyor did *not* observe RN M use the same lancet device on any other patient. *Id.* Instead, Shiloh said, RN M used her own "new equipment" on Patient 2, because the patient was out of supplies for his own device (which was shown to the surveyor). *Id.* at 5. RN M "does not deny using the instruments, including lancing devi[c]e, that she carries with her on field trips on patient[s] who do not have one, or run out of supplies to make theirs unusable, but emphatically denies that the only cleaning she does is wiping it with disinfecting wipe." *Id.* at 6. Shiloh also contends that the surveyor was biased, "made something up" when she was unable to find actual faults, *id.* at 4, and issued the immediate jeopardy citation as "a malicious cry 'wolf,['] when there was no 'wolf,'" *id.* at 6.

⁵ Indeed, as Shiloh points out, it appears that only one of the patients visited during the survey required blood glucose testing so the surveyor could not have observed a second use of the glucometer equipment the nurse brought with her. Shiloh Request to Reconsider ALJ Decision (RR) at 3.

These assertions, accepted as true and supported by reasonable inferences, would suffice to defeat summary judgment and to require the ALJ to evaluate the competing evidence as to this core factual dispute. Indeed, the ALJ states as much: “Petitioner asserts as a fact that none of its nurses ‘at any time, use the same lancing device on multiple patients.’ That is an assertion of fact, which, if supported by evidence, would be reason for me to deny CMS’s motion for summary judgment.” ALJ Decision at 4 (quoting Shiloh Pre-hearing br. at 1).

However, the ALJ points out that the statements directly denying CMS’s allegations appear only in Shiloh’s brief. *Id.* As such, the ALJ finds “counsel’s characterization” in its brief of RN M’s “purported testimony” not sufficient to raise a dispute of fact and characterizes such statements in brief as “bald denial without support.” *Id.* The ALJ notes that, in her declaration, RN M “does not deny re-using lancets nor does she ‘emphatically deny’ cleaning used lancets by wiping them with an alcohol saturated swab” and “does not address the allegations concerning re-use of lancets.” *Id.* (citing P. Ex. 2).

For a party to defeat summary judgment, as explained above, a denial in a brief must be supported by evidence in the record that, taken as true for purposes of summary judgment, along with any supportive inferences that may reasonably be drawn from it, raises a genuine dispute about a material fact. Argument is, of course, not itself evidence. Thus, the ALJ would be correct in rejecting counsel’s arguments absent evidence, and we would be able to affirm, except that RN M’s declaration (which is evidence) contains more than the ALJ acknowledges. We therefore next consider that declaration.

Much of the declaration sets out complaints and concerns about the surveyor and her conduct. P. Ex. 2. But the declaration states up front that the declarant “adopt[s] the contents of my Pre-hearing brief submitted by my Attorney in my defenses,” and then continues that the declarant has “a few other statements to make regarding the conduct of the survey by [the surveyor], and its outcome.” *Id.* at 1. This statement is not without ambiguity but may reasonably be read as intended to incorporate the factual assertions in the brief as those of the declarant, along with supplemental statements included in the declaration itself.

A witness declaration is evidence. To the extent that this witness’s declaration is read as including the assertion set out in the brief that RN M never reused a lancet device on a different patient, therefore, the record does contain evidence favorable to Shiloh directly bearing on the central fact in dispute. Moreover, on summary judgment, it is not appropriate to consider the credibility of the witnesses or the weight to be accorded to competing evidence.

Therefore, the matter must be remanded to the ALJ to consider the content, credibility and weight to be attributed to RN M's statement along with the evidence put forward by CMS.

2. On remand, the ALJ shall determine what witness testimony is admissible and provide an opportunity for cross-examination.

The ALJ ordered both parties to file the written direct testimony of any witness they sought to present along with their pre-hearing exchange. ALJ Pre-hearing Order at 3, 5-6. As the ALJ noted in his decision, Shiloh identified as an exhibit RN M's declaration but failed to submit it with the exchange. ALJ Decision at 1, n.1. The ALJ provided Shiloh with an opportunity to submit the missing exhibit, which it did. *Id.* at 1 n.1, and 2. On March 20, 2018, CMS then requested to cross-examine Shiloh's sole witness, RN M, assuming summary judgment was not granted. Therefore, on remand, the ALJ should hold a hearing to permit cross-examination.

In its own witness and exhibit list, CMS stated before the ALJ that it "has not determined which persons with relevant knowledge will be called as witnesses, but anticipates that the testimony of the [surveyor] may be used at the hearing," and provided as CMS Exhibit 22 a declaration by the surveyor as a "prior statement" of a witness. CMS Prehearing Exchange (Ex. and Witness List) at 3. It is not clear whether the ALJ treated CMS Exhibit 22 as the written direct testimony of the surveyor or considered it on some other basis because the ALJ did not rule on admission of any of the exhibits. ALJ Decision at 2.⁶

If CMS failed to proffer written direct testimony for any witness, then prior statements of such witness generally would not be admissible absent providing the opposing party with an opportunity to cross-examine. On remand, the ALJ may determine whether to strike the prior statement or to permit CMS to use it as written direct testimony. If the ALJ permits CMS to use the surveyor's prior statement in lieu of written direct testimony, the ALJ should make that clear and should inquire whether Shiloh wishes to cross-examine the surveyor.

⁶ The ALJ states that he merely cites "to some of the exhibits in order to illustrate undisputed facts or to explain why there are no disputes as to material facts." ALJ Decision at 2. Despite this statement, the ALJ also affirms that he "reviewed the parties' contentions **and their supporting exhibits**," specifically including RN M's affidavit. *Id.* (emphasis added). Neither party asserted that any of the proffered exhibits were inadmissible. We therefore presume that he did consider all of the evidence in the record before him for purposes of resolving the summary judgment motion despite not ruling on ultimate admissibility. On remand, the ALJ should determine the admissibility of all exhibits, including the patient letters Shiloh sought to add on appeal which we do not and need not consider for the present decision.

The ALJ's orders do not appear to contemplate any further opportunities for identifying additional witnesses as CMS implied by its assertion that it had not yet determined which witnesses to call. If, on remand, the ALJ permits either party to identify further witnesses, for rebuttal or other purposes, the opposing party must be given an opportunity to cross-examine.

We also note that the ALJ Decision was limited to the single noncompliance allegation as to which CMS sought summary judgment. On remand, the ALJ may determine whether other issues are properly before him.

3. The ALJ correctly concluded that Shiloh may not challenge the immediate jeopardy determination.

The ALJ noted that both parties presented argument about whether the alleged noncompliance, if present, constituted an immediate jeopardy for Shiloh's patients, but explained that he did not need to resolve this question. ALJ Decision at 4-5. On appeal, Shiloh objects that the ALJ did not address whether immediate jeopardy justified the "severe penalty" imposed. RR at 2.

An HHA may challenge CMS's determination of the HHA's level of noncompliance "only if a successful challenge on this issue would affect . . . [t]he **range** of civil money penalty amounts that CMS could collect[.]" 42 C.F.R. § 498.3(b)(14)(i) (emphasis added). The regulations provide for a single range of CMP amounts that may be imposed on a per-instance basis. 42 C.F.R. § 488.845(b)(6).

Because the level of noncompliance (i.e., immediate jeopardy) does not affect the applicable range of per-instance CMP, Shiloh may not challenge, and the ALJ may not decide, whether CMS's determination of immediate jeopardy is correct.

4. On remand, the ALJ may determine whether, if Shiloh was noncompliant as alleged, the amount of the per-instance CMP is reasonable.

When an ALJ or the Board "finds that the basis for imposing a civil monetary penalty exists," the ALJ or the Board "may not— (1) Set a penalty of zero or reduce a penalty to zero; (2) Review the exercise of discretion by CMS to impose a [CMP]"; or "(3) Consider any factors in reviewing the amount of the penalty other than those specified" in the regulations. *Id.* at §§ 488.845(h); *see also* 498.3(b)(13). The sum of these regulations is that the ALJ's review of the CMP, should noncompliance be established, is limited to determining whether the regulatory factors support the reasonableness of the amount.

The relevant regulatory factors specified for reviewing the amount of the penalty include: an HHA's size and resources; evidence that it has a built-in, self-regulating quality assessment and performance improvement system; the extent to which deficiencies pose immediate jeopardy; the nature, incidence, manner, degree, and duration of deficiencies or noncompliance; the agency's overall compliance history and the presence of repeat deficiencies; the extent to which deficiencies are directly related to the failure to provide quality patient care; the extent to which an agency is part of a larger organization with performance problems; and, an indication of any system-wide failure to provide quality care. 42 C.F.R. §§ 488.845(b)(1), 488.815(a)-(f).

While \$10,000 is the top of the range of per-instance CMP amounts, per-day CMPs in the immediate jeopardy range may reach much higher total amounts. To demonstrate that the amount imposed is not reasonable, Shiloh has to proffer or point to evidence relevant to the regulatory factors supporting that position. In reviewing the reasonableness of the amount of the CMP on remand, the ALJ shall consider at the close of proceedings whether, if noncompliance was present, Shiloh demonstrated that, based on the regulatory factors, the CMP amount should be reduced.

Conclusion

We vacate the ALJ decision on summary judgment and remand for further proceedings consistent with this decision.

/s/

Christopher S. Randolph

/s/

Constance B. Tobias

/s/

Leslie A. Sussan
Presiding Board Member