

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

Profound Health Care
Docket No. A-10-107
Decision No. 2371
March 29, 2011

**REMAND OF
ADMINISTRATIVE LAW JUDGE DECISION**

Profound Health Care (Profound), a home health agency (HHA) located in Los Angeles, California, appeals the August 18, 2010 decision of Administrative Law Judge (ALJ) Richard J. Smith, upholding the termination of Profound's Medicare provider agreement. *Profound Health Care*, DAB CR2223 (2010) (ALJ Decision). The ALJ granted the motion for summary disposition filed by the Centers for Medicare & Medicaid Services (CMS). The ALJ determined that Profound violated the condition of participation at 42 C.F.R. § 484.20 and that the violation was a sufficient basis for CMS to terminate Profound's Medicare provider agreement effective November 23, 2009.

For the reasons explained below, we affirm the ALJ's determination on summary judgment that Profound has not raised a genuine dispute of fact material to the issue of whether Profound failed to transmit Outcome and Assessment Information Set (OASIS) data within the time limits established under 42 C.F.R. § 484.20. Viewing the record evidence in the light most favorable to Profound, however, we conclude that there is a material dispute of fact as to whether Profound's noncompliance with section 484.20 constituted a condition-level violation warranting termination of Profound's provider agreement. Accordingly, we remand this matter to the ALJ to conduct further proceedings consistent with this decision.

Legal Background

Title XVIII of the Social Security Act (Act) establishes the Medicare program, which reimburses health care providers and suppliers for the medical care and services they furnish to Medicare beneficiaries.¹ Act §§ 1811, 1812, 1831, 1832 (42 U.S.C. §§ 1395(c), (d), (j), (k)). The program is administered by CMS and its contractors on

¹ The current version of the Social Security Act can be found at http://www.socialsecurity.gov/OP_Home/ssact/ssact.htm. Each section of the Act on that website contains a reference to the corresponding United States Code chapter and section. Also, a cross-reference table for the Act and the United States Code can be found at 42 U.S.C.A. Ch. 7, Disp Table.

behalf of the Secretary of Health and Human Services (Secretary). An HHA is a Medicare “provider of services.” Act § 1861(u). To participate in Medicare, an HHA must, among other things, meet the requirements of sections 1861(o), 1861(z), and 1891(a) of the Act and the regulations at 42 C.F.R. Part 484.²

HHA compliance with Medicare participation requirements is determined through surveys performed by state agencies under agreements with CMS. 42 C.F.R. § 488.10. The state survey agencies make and document findings with respect to an HHA’s compliance with each of the conditions governing Medicare participation. 42 C.F.R. §§ 488.11, 488.12, 488.18 to 488.28.

The regulatory conditions of participation for HHAs are set forth at 42 C.F.R. Part 484, subparts B and C. Each condition of participation is contained in a single regulation, which is divided into subparts called standards of participation. *Id.* Compliance with a condition of participation is determined by the manner and degree to which the provider satisfies the standards within the condition. 42 C.F.R. § 488.26(b); *CSM Home Health Services*, DAB No. 1622, at 6-7 (1997). If “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,” the provider is not in compliance with the condition of participation. 42 C.F.R. § 488.24(b).

The condition of participation set forth at 42 C.F.R. § 484.55 requires each HHA to perform comprehensive patient assessments and assessment updates that incorporate the OASIS data. OASIS is an “assessment instrument developed to measure patient health care outcomes in HHAs” 70 Fed. Reg. 76,199 (2005). The comprehensive assessment must be completed “no later than 5 calendar days after the start of care,” and must be updated and revised “not less frequently” than (with limited exceptions) the last five days of every 60 days beginning with the start-of-care date, and at discharge. 42 C.F.R. §§ 484.55(b), 484.55(d).

The condition of participation at section 484.20 requires each HHA to “electronically report all OASIS data collected in accordance with § 484.55.” Section 484.20(a) further provides:

Standard: Encoding and transmitting OASIS data. An HHA must encode and electronically transmit each completed OASIS assessment to the State agency or the CMS OASIS contractor, regarding each beneficiary with respect to which such information is required to be transmitted (as

² Unless indicated otherwise, the regulations cited in this decision were in effect during the relevant period, March 2009 through November 2009.

determined by the Secretary), within 30 days of completing the assessment of the beneficiary.

CMS may terminate an HHA that is not in substantial compliance with program requirements, and failure to meet one or more conditions of participation is considered a lack of substantial compliance. Act, §§ 1866(b)(2)(B), 1861(o)(6); 42 C.F.R. § 489.53(a)(3). If CMS decides to terminate an HHA's Medicare provider agreement because the HHA does not meet a condition of participation, the HHA has the right to appeal that determination pursuant to section 1866(h) of the Act and 42 C.F.R. Part 498. See 42 C.F.R. §§ 498.1, 498.3(b)(8). The right of appeal includes a hearing before an ALJ (subpart D of Part 498), and, if the HHA seeks it, review of the ALJ decision by the Departmental Appeals Board (subpart E of Part 498).

Background and ALJ Decision³

Based on a survey completed on June 1, 2009, the California Department of Public Health (State agency) determined that Profound failed to comply with the participation requirements at 42 C.F.R. §§ 484.14, 484.18, 484.48, and 484.55. CMS Ex. 1. Profound thereafter submitted a corrective action plan addressing the cited deficiencies. *Id.*

On August 18, 2009, the State agency completed a follow-up survey of Profound. The State agency determined that Profound continued to be noncompliant with the conditions of participation cited in the June 1, 2009 survey. CMS Exs. 1, 2. The State agency further determined that Profound failed to comply with four additional conditions of participation, including the condition of participation governing the reporting of OASIS information at section 484.20. *Id.*

By letter dated October 22, 2009, CMS notified Profound that CMS was terminating Profound's Medicare provider agreement effective November 23, 2009. CMS Ex. 1. CMS cited two independent grounds to support the action. First, CMS stated, the deficiencies cited in the August 2009 follow-up survey, either individually or in combination, substantially limited Profound's capacity to render adequate care or adversely affected patient health and safety within the meaning of section 488.24(b) of the regulations. *Id.* Second, CMS stated that termination was warranted based on the findings in the August follow-up survey that Profound had failed to correct deficiencies identified in the June 2009 survey. *Id.*

³ The following background information is drawn from the ALJ Decision and the record before the ALJ and summarized here for the convenience of the reader, but should not be treated as new findings.

On December 17, 2009, Profound filed a request for hearing to contest the termination. On February 5, 2010, CMS filed a motion for summary judgment, arguing that there were no material factual disputes with respect to Profound's noncompliance with multiple conditions of participation, including the condition at 484.20. CMS contended that each of these condition-level violations was sufficient to justify the termination of Profound's provider agreement. Profound filed its objections to CMS's motion on February 19, 2010. By ruling dated April 13, 2010, the ALJ solicited additional briefing from the parties.

Following the parties' submission of additional arguments and evidence, the ALJ granted CMS's motion. The ALJ found that in May, June, and July 2009, Profound failed to transmit required OASIS reports to CMS or the State agency in violation of section 484.20. The ALJ stated that Profound had conceded that it "was not able to timely transmit OASIS data." ALJ Decision at 5-6, quoting Request for Hearing at 25. The ALJ addressed Profound's assertion that its failure to transmit the data timely was due to a burglary of its offices and theft of its computer systems on July 21, 2009. While the ALJ "accept[ed] Profound's assertion that its offices were burglarized and its computers [were] stolen on that date," he concluded that the theft did "not explain or excuse [Profound's] failure to file the required reports for May and June." *Id.* at 6. Furthermore, the ALJ found, the only OASIS reports provided to the surveyors for the relevant time period were transmitted June 1, 2009. *Id.*, citing CMS Ex. 2, at 79-81. Those reports, however, showed that the data transmitted on June 1, 2009 had been collected in March and April 2009, rendering the transmission untimely. *Id.* Moreover, the ALJ found that "[n]o OASIS report for July was transmitted even after the stolen computers had been replaced and the network restored." *Id.*

The ALJ next addressed whether Profound's noncompliance with section 484.20 constituted a condition-level violation supporting termination of Profound's provider agreement. The ALJ concluded that --

Profound's lapse was serious and prolonged, and carried with it the obvious potential of limiting substantially its capacity to furnish adequate care to, and to protect the health and safety of, its patients. The [condition of participation] set out at 42 C.F.R. § 484.20 was breached by Profound's failure to transmit the reports for three months, and that breach warrants CMS's termination of Profound's Medicare provider agreement.

Id. at 6. Accordingly, the ALJ sustained CMS's termination of Profound's provider agreement effective November 23, 2009.

Standard of Review

Whether summary judgment is appropriate is a legal issue that we address de novo. *Lebanon Nursing and Rehabilitation Center*, DAB No. 1918 (2004). The party moving for summary judgment bears the initial burden of demonstrating that there are no genuine issues of material fact for trial and that it is entitled to judgment as a matter of law. See *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-25 (1986); *Everett Rehabilitation and Medical Center*, DAB No. 1628, at 3 (1997). If a moving party carries its initial burden, the non-moving party must “come forward with ‘specific facts showing that there is a genuine issue for trial.’” *Matsushita Elec. Industrial Co. v. Zenith Radio*, 474 U.S. 574, 587 (1986) (quoting Fed. R. Civ. Pro. 56(e)). In evaluating a summary judgment motion, a tribunal must view the entire record in the light most favorable to the nonmoving party, drawing all reasonable inferences from the evidence in that party’s favor. *Madison Health Care, Inc.*, DAB No. 1927 (2004). The standard of review on a disputed conclusion of law is whether the ALJ decision is erroneous. See *Departmental Appeals Board, Guidelines--Appellate Review of Decisions of Administrative Law Judges Affecting a Provider's Participation in the Medicare and Medicaid Programs* at <http://www.hhs.gov/dab/divisions/appellate/guidelines/prov.html>.

Analysis

Below, we first address the ALJ’s conclusion that there were no facts in dispute material to whether Profound failed to timely transmit OASIS data due in May, June and July 2009, as required under section 484.20. We explain that the plain language of the regulation required Profound to transmit OASIS data no later than 30 days after the completion of each required patient assessment, and we reject Profound’s argument on appeal that HHAs may transmit OASIS data up to 60 days after the completion of an assessment. Applying the correct legal standard to the uncontested record evidence, we conclude that there is no material factual dispute that Profound failed to timely transmit OASIS data under section 484.20.

We next discuss Profound’s argument that the ALJ erred in determining that there was no disputed material fact regarding whether Profound’s noncompliance with section 484.20 constituted a condition-level violation warranting termination. We explain that the record does not evidence a nexus between Profound’s noncompliance with the OASIS data transmission time limits and Profound’s capacity to furnish adequate care or to protect the health and safety of its patients. Accordingly, we reverse the ALJ’s conclusion that Profound’s noncompliance with section 484.20 alone was a sufficient basis to sustain CMS’s termination of Profound’s provider agreement on summary judgment, and we remand the case for further proceedings.

A. The ALJ correctly determined that there is no material factual dispute that Profound failed to transmit OASIS data within the time limits established at 42 C.F.R. § 484.20.

Profound argues that the ALJ’s “determination that Profound failed to transmit required OASIS data during May, June and July, 2009 . . . is incorrect.” P. Br. at 11. Profound contends that it transmitted OASIS data on May 26, 2009 and June 1, 2009, and that “[a]ll required OASIS documentation due during the calendar months of May, June and July, 2009 was transmitted prior to the July 21, 2009 burglary.” P. Br. at 12. Profound argues that it complied with the OASIS data transmission time limits established under 42 C.F.R § 484.20 and CMS’s 2004 interpretive guidelines.⁴ Under the guidelines, Profound avers, it “had up to 60 days from the receipt of the start of care or recertification data to submit the required OASIS data – by the last day of the current month for OASIS data collected during the previous month.” P. Reply at 10. Accordingly, Profound argues, OASIS data for three patients with “start of care” dates ranging from May 8, 2009, through June 30, 2009, and four patients with “recertification” dates ranging from May 19, 2009 through June 6, 2009, was not due until August 2009. P. Reply at 8-11; P. Ex. 6, at 1, 2, 7; P. Ex. 7, at 2, 8, 12, 18. Although this data was not transmitted until October 13, 2009, Profound continues, the delay was due to the July 21, 2009 burglary and theft of its computers. The theft, Profound further argues, should be considered an event out of Profound’s control, analogous to the 2008 hurricanes – Gustav and Ike – that prompted CMS to suspend HHA OASIS data submission requirements until the damage from those hurricanes was repaired. P. Br. at 14.⁵

Profound’s contentions are based on an erroneous understanding of the time limits for transmitting OASIS data under the applicable regulations. Most notably, Profound’s reliance on 2004 CMS interpretive guidelines to support its argument that HHAs may transmit OASIS data up to 60 days after completing each assessment required under section 484.55 is misplaced. The guidelines cited by Profound specifically refer to, and

⁴ Profound submits with its reply brief a document titled, “Home Health Care Regulations and CMS Interpretive Guidelines,” which includes the May 21, 2004 revision to the CMS State Operations Manual (SOM), appendix B, Guidance to Surveyors of HHAs. P. Ex. D, at 5. The SOM is available at <http://www.cms.gov/Manuals/IOM/list.asp>.

⁵ To support its arguments, Profound proffers new evidence on appeal including a declaration by its Chief Financial Officer (CFO) dated September 22, 2010; OASIS reports; and an October 3, 2008 document titled, “CMS Response to the Hurricane Emergency – Gustav/Ike.” Profound also submits copies of 30-day progress notes and plans of treatment that are included in the ALJ record at P. Ex. 6. Because we conclude, based on undisputed material facts and Profound’s own characterization of the evidence, that the ALJ did not err in determining on summary judgment that Profound violated section 484.20, we need not rule on whether the proffered evidence is admissible. On remand, the ALJ may determine whether to admit the evidence into the record.

track the language of, a version of section 484.20 that was in effect prior to June 21, 2006. 64 Fed. Reg. 3748 (1999); 70 Fed. Reg. 76,199. Under that interim final rule, issued in January 1999, section 484.20(a) required HHAs to encode OASIS data within seven days of completing an OASIS data set. *Id.* Section 484.20(c)(1) of the interim final rule required HHAs to transmit OASIS data “at least monthly,” and section 484.20(c)(2) stated that “[f]or all assessments completed in the previous month, transmit OASIS data in a format that meets the requirements of paragraph (d) of this section.” Referencing subsection 483.20(c)(1) of the earlier version of the regulation, the CMS guidelines cited by Profound stated, “[b]y the last day of the current month, HHAs must electronically transmit all OASIS data collected, encoded, and locked in the previous month for each patient . . . to the State agency or CMS OASIS contractor. At a minimum, HHAs must transmit OASIS data at least monthly.”⁶ P. Reply at 10; SOM App. B, G323. Thus, the interim final regulation and CMS’s interpretive guidelines arguably provided HHAs more than 30 days, and in some cases up to 60 days, from the date of each required assessment to transmit OASIS data.

On December 23, 2005, however, the Secretary issued a final revised rule, effective June 21, 2006, which changed the OASIS data transmission requirements. 64 Fed. Reg. at 76,199 - 76,208. Among other things, the Secretary revised section 484.20(a) to require HHAs to both electronically encode and transmit to the State agency or CMS Oasis contractor complete OASIS data “regarding each beneficiary with respect to which such information is required to be transmitted (as determined by the Secretary), within 30 days of completing the assessment of the beneficiary.” *Id.* at 76,208. Section 484.55, which sets forth the guidelines for the collection of assessment data, requires HHAs to complete each beneficiary’s comprehensive assessment no later than five calendar days after the beneficiary’s start of care; to complete updated and revised assessments for each beneficiary not less frequently than (with limited exceptions) “the last five days of every 60 days beginning with the start-of-care date,” and to complete assessments upon discharge. Accordingly, the regulation in effect in 2009 superseded the 2004 guidelines and required Profound to transmit OASIS data for each patient no later than 30 days from the date the HHA completed each assessment required under section 484.55.

Applying this standard to the uncontested evidence, and accepting Profound’s own characterization of the evidence, we conclude that there is no genuine issue of disputed material fact that Profound failed to comply with the OASIS data transmission requirements of section 484.20. Specifically, Profound’s own evidence shows that there were patients with 60-day recertification periods ending May 19, 2009, May 30, 2009,

⁶ The statement of deficiencies from the survey ending August 18, 2009 indicates that the surveyors, too, relied in part on the superseded CMS guidelines. CMS Ex. 2, at 79-80 (stating that “Based on interview and record review, the [HHA] failed to electronically transmit report all [OASIS] data for each patient . . . at least monthly.”).

and May 31, 2009, and June 6, 2009. P. Ex. 7, at 2, 8, 12, 18. Profound does not deny that it failed to transmit OASIS data for those patients within 30 days from the dates on which Profound was required to complete updated and revised assessments of these patients (within the last five days of the recertification periods). Indeed, Profound states that the updated assessment data was not transmitted until October 13, 2009. P. Reply at 8-11. Moreover, the uncontested evidence shows that there were three patients with start-of-care dates ranging from May 8, 2009 to June 30, 2009. P. Ex. 6, at 1, 2, 7. Profound does not deny that it failed to transmit the OASIS data within 30 days from the dates on which it was required to complete comprehensive assessments on those patients (no later than five days after each patient's start-of-care date). Indeed, Profound states that the required data for these patients was not transmitted until October 13, 2009. P. Reply at 8-9. Moreover, Profound does not deny that the OASIS data it transmitted on June 1, 2009 was from assessments completed in March and April 2009, as the ALJ found and the uncontested evidence shows. ALJ Decision at 6; CMS Ex. 2, at 79-81. Consequently, that data transmission also failed to meet the 30-day time limit established under the applicable regulation.

Furthermore, while there is no dispute that Profound's computer systems were stolen on July 21, 2009, the theft does not explain or justify Profound's failure to timely transmit OASIS data due before that date, which includes the assessment data for the patients with recertification periods ending between May 19, 2009 and June 6, 2009, the patient with the May 8, 2009 start-of-care date, and the data from March and April 2009 that was not transmitted until June 1, 2009. Thus, although in the past CMS may have temporarily suspended the OASIS data transmission requirements where extraordinary events have prevented HHAs from meeting those requirements, Profound points to no event to explain its failure to timely file OASIS data prior to the date its computers were stolen.

Accordingly, we sustain the ALJ's determination that Profound failed to timely transmit OASIS data pursuant to section 484.20 of the regulations.

B. The record evidence creates a dispute of material fact as to whether Profound's failure to transmit OASIS on a timely basis constituted a condition-level violation.

Profound also argues that even if the ALJ did not err in concluding that Profound failed to submit required OASIS data during May, June and July 2009, its noncompliance "should not be considered a conditional [sic] violation." P. Br. at 11, 16-17. The "alleged failure to submit OASIS information," Profound contends, "did not render Profound 'substantially incapable of providing adequate care to patients,' the standard for 'involuntary' termination." P. Br. at 28. Accordingly, Profound argues, the alleged deficiency did not justify the termination of its Medicare provider agreement. Profound

also avers that because its “temporary failure to submit OASIS data was rectified before Profound was terminated by CMS,” its noncompliance with the OASIS data transmission time limits was not a proper basis for termination of its provider agreement. P. Reply at 13; P. Br. at 21-24.

As described above, an HHA’s noncompliance with regulatory requirements is considered a condition-level violation “where 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). 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. *Aspen Grove Home Health*, DAB No. 2275, at 23 (2009). Thus, a provider’s contention that it took corrective action prior to the date its Medicare agreement was terminated “is irrelevant.” *Id.*, citing *Community Home Health*, DAB No. 2134 (2007).

Here, the ALJ determined that Profound’s failure to timely transmit OASIS data in May, June, and July 2009 constituted a condition-level violation because it “carried with it the obvious potential of limiting substantially its capacity to furnish adequate care to, and to protect the health and safety of, its patients.” ALJ Decision at 6. The ALJ did not, however, explain what “obvious potential” harm flowed from Profound’s failure to transmit the data within the time limits established under section 484.20. Furthermore, we find no evidence in the record establishing a nexus between Profound’s failure to timely transmit OASIS data and its capacity to furnish adequate care; nor is there evidence that Profound’s untimely data transmissions had an adverse impact on the health and safety of its patients. According to the survey statement of deficiencies (SOD), the surveyors concluded that the “cumulative effect” of Profound’s failure to timely transmit OASIS data “resulted in the agency’s failure to deliver statutorily mandated compliance with organization and administrative functions and providing services to their patients.” CMS Ex. 2, at 79. Yet, the SOD does not include any explanation of how Profound’s delayed transmission of OASIS data resulted in the HHA’s failure to provide services to its patients. CMS argues that “[i]f an HHA does not timely submit the data it cannot be reviewed to assess the HHA’s care and thus adversely affects the health and safety of patients.” CMS Br. at 8, citing 72 Fed. Reg. 25,319-20 (2007). This argument suggests that a provider’s failure to timely transmit OASIS data has the *potential* to adversely impact CMS’s or the State Agency’s *oversight* of an HHA. Under the governing standard for determining whether a provider’s noncompliance constituted a condition-level violation, however, the evidence must show that the deficiency in fact substantially limited the provider’s capacity to furnish adequate care or adversely affected the health and safety of the provider’s patients. 42 C.F.R. § 488.24(b).

Accordingly, viewing the entire record in the light most favorable to Profound, we conclude that the ALJ erred in determining on CMS's motion for summary judgment that Profound's noncompliance with section 484.20 alone was a sufficient basis to terminate Profound's provider agreement. We therefore remand this case for further proceedings. On remand, the ALJ may order further development of the record as he deems necessary to determine whether Profound's noncompliance with section 484.20 demonstrably affected its ability to provide patient care or adversely impacted the health and safety of its patients. In doing so, the ALJ may also consider other alleged deficiencies identified during the June and August 2009 surveys, which may shed light on the nature and impact of Profound's noncompliance with section 484.20.

Conclusion

Based on the foregoing analysis, we sustain the ALJ's determination on summary judgment that Profound failed to timely transmit OASIS data pursuant to 42 C.F.R. § 484.20. We reverse the ALJ's determination on summary judgment that Profound's noncompliance with section 484.20 constituted a condition-level violation warranting termination of Profound's provider agreement. Accordingly, we remand this matter for further proceedings consistent with this decision.

/s/

Judith A. Ballard

/s/

Leslie A. Sussan

/s/

Stephen M. Godek
Presiding Board Member