Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Community Home Health,	)	Date: March 30, 2007
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-07-123
	)	Decision No. CR1582
Centers for Medicare & Medicaid Services.	)	
	)	

DECISION

Petitioner, Community Home Health (Petitioner or Community), is a home health agency (HHA) that, until its termination on September 27, 2006, was certified to participate in the Medicare program as a provider of services. Following surveys completed June 29, 2006, August 17, 2006, and September 20, 2006, the Centers for Medicare & Medicaid Services (CMS) terminated Community's Medicare participation because, according to CMS, it failed to maintain substantial compliance with conditions of participation. Petitioner here challenges its termination.

The parties have filed cross motions for summary judgment.

I agree that this case presents no material facts in dispute, and is appropriate for summary judgment. For the reasons set forth below, I find that Community was not in substantial compliance with Medicare conditions of participation in June 2006. The State Agency afforded it a reasonable opportunity to achieve compliance, but, because it failed to achieve and/or maintain substantial compliance, CMS was authorized to terminate its provider agreement. I therefore deny Petitioner's Motion and grant CMS's Motion for Summary Judgment.

I. Background

An HHA is a public agency or private organization that provides skilled nursing and other health care services to patients in their homes. Social Security Act (Act), section 1861(o). It may participate in the Medicare program if it meets the statutory definition and complies with certain requirements, called conditions of participation. Act, sections 1861(o), 1891; 42 C.F.R. Part 484; 42 C.F.R. § 488.3. A "condition of participation" represents a broad category of home health services. Each condition is contained in a single regulation, which is divided into subparts called standards.

CMS, on behalf of the Secretary, must determine whether a Medicare provider (including an HHA) complies substantially with Medicare's statutory and regulatory requirements. Act, section 1866(b)(2). To monitor compliance, CMS contracts with state agencies that conduct periodic surveys. Act, section 1864(a); 42 C.F.R. § 488.20. The regulations require that each provider be surveyed once every twelve months, and more often, if necessary, to ensure that identified deficiencies are corrected. 42 C.F.R. § 488.20.

Here, based on a survey completed June 29, 2006, the Alabama Department of Health (State Agency) determined that Community was not in substantial compliance with two conditions: 42 C.F.R. § 484.30 (Skilled Nursing Services) and 42 C.F.R. § 484.52 (Evaluation of the Agency's Program). The surveyors also noted several standard-level deficiencies: 42 C.F.R. §§ 484.18(a) (Plan of Care); 484.36(b)(3)(iii) (Competency Evaluation & In-Service Training); and 484.36(c)(1) (Assignment & Duties of Home Health Aide). P. Ex. 1; CMS Ex. 2. In a letter dated July 7, 2006, the State Agency notified Petitioner that it was not in compliance with the two conditions, and that "regulations preclude the recertification" of a provider not in compliance with conditions. The letter further advised Community that the State Agency would therefore recommend that CMS terminate Community's Medicare participation within 90 days (September 27, 2006). However, Community could avoid termination if it achieved substantial compliance prior to its termination date. CMS Ex. 1.

Petitioner submitted a plan of correction (POC), promising to correct its deficiencies no later than August 10, 2006. P. Ex. 2; CMS Ex. 3.

State Agency surveyors revisited Community on August 17, 2006, and determined that it had not brought itself into substantial compliance, citing one condition-level deficiency, 42 C.F.R. § 484.36 (Home Health Aide Services),[1] and four standard-level deficiencies: 42 C.F.R. §§ 484.14(b) (Governing Body); 484.18(a) (Plan of Care); 484.30 (Skilled Nursing Services); and 484.30(a) (Duties of the Registered Nurse). P. Ex. 2; CMS Ex. 4.

In a notice letter dated August 23, 2006, CMS advised Community that the follow-up survey showed that it was out of compliance with the Home Health Aide Services Condition. CMS included with the letter a copy of the survey report form (CMS-2567). That document contains a list of all the deficiencies cited. CMS warned Community that its provider agreement would terminate on September 27, 2006, if the deficiencies were not corrected. The letter advised Petitioner of its appeal rights.

Petitioner did not immediately appeal, but submitted another plan of correction, promising complete correction no later than August 29, 2006.[2] P. Exs. 3, 5; CMS Ex. 6. The State Agency conducted another survey on September 20, 2006, but again found that Community was not in substantial compliance, citing three conditions: 42 C.F.R. §§ 484.14 (Organization, Services & Administration); 484.30 (Skilled Nursing Services); and 484.48 (Clinical Records); and two standards: 42 C.F.R. § 484.18(a) (Plan of Care) and 484.55(c) (Drug Regimen Review). P. Ex. 8; CMS Ex. 7. CMS sent Petitioner a notice letter dated September 28, 2006, advising that it was out of compliance with the three conditions, and that its Medicare agreement terminated effective September 27, 2006. The letter reminded Petitioner that its appeal rights had been explained in the August 23, 2006 letter. CMS Ex. 8.

By letter dated November 22, 2006, Petitioner appealed its termination, and the matter has been assigned to me. The parties have filed cross-motions for summary judgment with accompanying briefs (P. Br., CMS Br.). With its motion, CMS submited ten exhibits (CMS Exs. 1-10). With its motion, Petitioner submitted fifteen exhibits (P. Exs. 1-15). Petitioner also filed a brief in opposition to CMS's motion for summary judgment (P. Reply), attaching ten additional exhibits (P. Exs. 16-25).

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[1] Within the cited condition, the surveyors cited three deficient standards: §§ 484.36(b)(3)(ii), 484.36(b)(3)(iii), 484.36(c)(1). CMS Ex. 4, at 11-17.

[2] I discuss below Petitioner's apparent failure to request timely review of the August survey.

II. Issues

- I consider first whether summary judgment is appropriate.

- On the merits, the issue is whether, based on all of the survey findings, CMS was authorized to terminate Petitioner's Medicare provider agreement.

III. Discussion

A. Summary Judgment is appropriate because no material facts are in dispute and CMS is entitled to judgment as a matter of law.[3]

Summary judgment is appropriate if a case presents no genuine issue of material fact, and one party is entitled to judgment as a matter of law. The moving party may show the absence of a genuine factual dispute by presenting evidence so one-sided that it must prevail as a matter of law, or by showing that the non-moving party has presented no evidence "sufficient to establish the existence of an element essential to [that party's] case, and on which [that party] will bear the burden of proof at trial." *Livingston Care Center v. U.S. Dept. of Health and Human Services,* 388 F.3d 168, 173 (6th Cir. 2004) (quoting *Celotex Corp. v. Catrett,* 477 U.S. 317, 322 (1986)). To avoid summary judgment, the non-moving party must then act affirmatively by tendering evidence of specific facts showing that a dispute exists. *Matsushita Elec. Indus. Co., Ltd., v. Zenith Radio Corp.,* 475 U.S. 574, 586 n.11 (1986); *see also Vandalia Park,* DAB No. 1939 (2004); *Lebanon Nursing and Rehabilitation Center,* DAB No. 1918 (2004). In examining the evidence for purposes of determining the appropriateness of summary judgment, I must draw all reasonable inferences in the light most favorable to the non-moving party. *Livingston Care Center,* 388 F.3d at 172; *Guardian Health Care Center,* DAB No. 1943, at 8 (2004). However, drawing factual inferences in the light most favorable to the non-moving party does not require that I accept the non-moving party's legal conclusions. *Cf. Guardian Health Care Center*, DAB No. 1942, at 11 ("A dispute over the conclusion to be drawn from applying relevant legal criteria to undisputed facts does not preclude summary judgment if the record is sufficiently developed and there is only one reasonable conclusion that can be drawn from those facts.")

As discussed below, no material facts are in dispute here. Petitioner has explicitly not challenged the June 2006 survey findings (P. Motion at 2), and CMS does not suggest that Community's Medicare participation be terminated based on the June deficiencies. Instead, the State Agency (with CMS's apparent concurrence) afforded Community the

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[3] I make Findings of Fact and Conclusions of Law (Findings) to support my decision in this case. I set forth each Finding, in italics and bold, as a separate heading.

opportunity to correct, and the parties focus on whether, during the August and September surveys, Community demonstrated that it had achieved substantial compliance. As a matter of law, CMS was authorized to terminate if, during either of these surveys, Community was not in substantial compliance with even one single condition of participation. And, even drawing every possible inference in Community's favor, the undisputed facts establish that, at the time of the September survey, it was not in substantial compliance with the clinical records condition, 42 C.F.R. § 484.48.[4]

B. Because Community failed to maintain substantial compliance with all Medicare Conditions of Participation, CMS may terminate its program participation.

1. Community's request for review of the August survey was untimely, but, even if reviewable, the August survey findings are not material if Community did not thereafter maintain substantial compliance.

I note first that Petitioner is probably not entitled to review of the August survey, because it failed to request review timely. The August 23 notice letter unambiguously states that "[a] written request for hearing *must* be filed no later than sixty days after the date of this letter. . . ." CMS Ex. 5, at 1. The regulations that govern these proceedings state that the affected party "must file the request in writing within 60 days from receipt of the notice . . . ." 42 C.F.R. § 498.40; *see also* Act, sections 1866(h), 205(b) (hearing request *must* be

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[4] Petitioner's appeal seeks review of the August and September condition-level deficiencies only, and not any of the separate standards. CMS argues, correctly, that uncorrected deficiencies, even at the standard level, justify termination. 42 C.F.R. § 488.28. In CMS's view, I should grant summary judgment because Community had a standard-level deficiency (§ 484.18(a) – Plan of Care) in August that went uncorrected in September. (In fact, the same standard was also cited as a deficiency in June). Because Petitioner did not include this standard-level deficiency in its appeal, CMS argues that it is entitled to summary judgment on the termination. I would find this argument compelling but for the ambiguity of the August and September notice letters. Petitioner complains – with some justification – that the language of these letters misled it into believing that CMS based its termination solely on condition-level deficiencies. Had it understood that CMS was considering uncorrected standard-level deficiencies as an independent basis for termination, it might have appealed them as well. Petitioner's argument is somewhat weakened, however, because CMS accompanied the August letter with a copy of the survey report form and warned that Community's Medicare participation would end "if the deficiencies are not corrected." In any event, because I decide the case on other issues, I need not and do not resolve the matter here.

filed within sixty days after receipt of the notice of CMS's determination). Act, section 205(b); *Cary Health and Rehabilitation Center,* DAB No. 1771, at 8-9 (2001). Petitioner's hearing request is dated November 22, 2006, well beyond the 60-day limit. Although CMS has not moved for dismissal, the regulations authorize me, on my own motion, to dismiss an untimely hearing request if the time for filing has not been extended. 42 C.F.R. § 498.70(c). Upon receipt of a written request, I may extend the period for filing based on a finding of good cause, but I have received no request for an extension, and there has been no showing of good cause. 42 C.F.R. § 498.40(c). Given the tardiness of its hearing request, and the absence of any showing of good cause for the tardiness, I doubt very much that I have the authority to review the August survey.

Moreover, the August survey findings are not material to my ultimate conclusion here. I reject Petitioner's suggestion that the August survey results are in fact dispositive because "if the erroneous finding of the August . . . survey. . . is reversed . . . then the September survey should never have taken place." P. Motion at 3. CMS (and the State Agency) have the discretion to order surveys "as frequently as necessary to ascertain compliance and confirm correction of deficiencies." 42 C.F.R. § 488.20(b)(1). Their exercise of that discretion is not reviewable. Even if Community were found in substantial compliance in August, CMS was free to follow-up with an additional survey (or surveys) to insure that the HHA maintained its substantial compliance. And unless Community demonstrated that it had maintained compliance, CMS was authorized to terminate. Act, section 1866(b)(2)(A); 42 C.F.R. § 489.53(a)(3); *Comprehensive Professional Home Visits*, DAB No. 1934, at 3, 13 (2004); *see also Family Home Health Services*, DAB No. 1716 (2000) (CMS may terminate a provider agreement if the provider is not complying with the Act, regulations, or the terms of its provider agreement).

I now consider whether Community was in compliance with all conditions at the time of the September survey.

2. Community was not in substantial compliance with the clinical records condition of participation, 42 C.F.R. § 484.48, because it failed to safeguard patient medical records against loss and unauthorized use.

Among other requirements, the clinical records regulation requires the HHA to safeguard clinical record information against loss or unauthorized use. Written procedures must govern the use and removal of records, and the conditions for release of information. The patient's written consent is required for release of information not authorized by law. 42 C.F.R. § 484.48(b).

By its own admission, Petitioner failed to safeguard its patients' medical records against loss and unauthorized use. CMS alleges that one of Community's employees removed and photocopied confidential medical records, keeping them in her home. And an undisclosed number of the original records were simply lost. P. Ex. 11. Community does not dispute these allegations, and fills in a few (but very few) additional details.[5] Originals of patient records were in an employee's car when she was involved in an automobile accident. According to an employee counseling notice, dated August 25, 2006, following the accident, the records "were given to spouse to maintain at home" but, inexplicably, the records were lost. So instead of returning the original records, the employee submitted copies that she had been maintaining in her home; hence the HHA discovered that she had impermissibly copied and kept confidential medical records in her home. P. Ex. 11. The employee maintained that she did not know that she was breaking the law. *Id.*

Petitioner minimizes these record irregularities as an "isolated incident" (P. Br. at 12) that was rapidly discovered and corrected. I disagree. That Community even discovered the breach was pure serendipity. Unknown to Community, one of its employees – by all accounts acting purely out of ignorance – was able to appropriate and hold original medical documents for an indefinite period of time, to photocopy those documents, and, eventually, to lose them. This breach seriously compromised patient privacy and suggests serious problems with the HHA's procedures for safeguarding its patients' records. I consider this a serious violation of the regulation, sufficient to render the condition out of compliance.[6] *See* 42 C.F.R. §§ 488.24(b), 488.26(b) (The manner and degree of a provider's satisfaction of the component standards determines whether an HHA complies with a particular condition. Deficiencies in some standards may not sufficiently affect the overall condition so as to put the condition out. On the other hand, one standard may be so crucial that a deficiency in that area alone may put the condition out. Failure to

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[5] For purposes of summary judgement, I have accepted Petitioner's version of these events. I note that, aside from an employee counseling note and a receipt for locks, Petitioner submits virtually no evidence addressing the issue. Petitioner has not submitted a declaration from the employee herself nor from anyone else familiar with these events. Pursuant to my prehearing order, the parties were required to submit "all proposed exhibits" and "the complete written direct testimony of any proposed witness." It thus appears that Petitioner has no additional evidence regarding this issue.

[6] Although the issue is not specifically before me, both the employee and Community may also be subject to sanction under the Health Insurance Portability and Accountability Act of 1996, P.L. 104-191, which requires a "covered entity" to maintain reasonable and appropriate safeguards to prevent disclosure of protected health information.

comply with a condition occurs where the deficiencies, individually or in combination, 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 . . . .")

Petitioner also asserts that, when it discovered the problem, it immediately obtained all outstanding patient records, counseled the employee involved, further secured patient records, and provided additional in-service training to all Community employees. P. Br. at 12-13. Petitioner provides little specific evidence as to when it accomplished these tasks, suggesting, without support, that it did so prior to the September survey. But, as CMS points out, Petitioner did not even install locks to protect its records until September 25, 2006, after the time of the survey. P. Ex. 13. Moreover, the problems here were systemic. Whatever procedures Community had in place to protect its records were not working. To achieve substantial compliance, Community had to correct its problems, demonstrate that no other instances had occurred, and implement a plan of correction designed to assure that no incidents would occur in the future. Under Medicare rules, Community has the burden of proving that it has done so, and its unsupported assertions do not satisfy that burden. *Hermina Traeye Memorial Nursing Home*, DAB No. 1810, at 13 (2002). Further, to avoid summary judgment, Petitioner was required to act affirmatively by tendering evidence of specific facts establishing a dispute on this issue. Aside from the receipt for locks, which shows correction *following* the survey, Petitioner has come forward with no such evidence. *Matsushita Elec.*, 474 U.S. at 586 n.11.[7]

Finally, Petitioner points out that surveyors only discovered the violation because it "was so thorough and chose to document the event in the employee's personnel file," and argues that "Community should not be punished for being responsible and making notations to the employee's record." P. Br. at 13. Of course, covering up the employee's illegal actions would itself have been illegal. That Petitioner did not violate the law in this regard does not preclude CMS's acting on the underlying deficiency.

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[7] A provider whose deficiency has the potential for more than minimal harm is presumed out of compliance "from the date of completion of the survey in which [it was] cited until the date of the resurvey in which substantial compliance was established." *Lake City Extended Care Center*, DAB No. 1658, at 14 (1998).

IV. Conclusion

Community was not in substantial compliance with program requirements in June 2006. CMS afforded it an opportunity to correct its deficiencies, but the uncontroverted evidence establishes that, at the time of the September 2006 survey, it was not in compliance with at least one Medicare condition of participation. CMS is therefore authorized to terminate its provider agreement.

/s/

Carolyn Cozad Hughes
Administrative Law Judge