Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	
Prime Care Home Health Agency, Inc., (CCN: 05-8225),	
Petitioner,	Date: October 24, 2007
- v. -	Docket No. C-07-119
Centers for Medicare & Medicaid Services.	Decision No. CR1678

DECISION

This matter is before me on the Motion for Summary Judgment filed on April 4, 2007, by the Centers for Medicare & Medicaid Services (CMS). By its Motion, CMS seeks the summary affirmation of its October 25, 2006 determination to terminate the Medicare provider agreement of Petitioner Prime Care Home Health Agency, Inc. (Prime Care).

In support of their positions on CMS's Motion for Summary Judgment, the parties have proffered exhibits: CMS has proffered CMS Exhibits 1-5 (CMS Exs. 1-5) and CMS Attachments 1 and 2 (CMS Att. 1-2), and they are all admitted as designated. Prime Care has proffered two un-numbered Petitioner's Exhibits, which I designate Petitioner's Exhibits 1 and 2 (P. Exs. 1-2) and admit with that designation.

Because there are no material facts in dispute, and because the undisputed facts clearly show that CMS is entitled to judgment in its favor as a matter of law, I grant CMS's Motion for Summary Judgment.

The Material Facts:

Prime Care is a home health agency (HHA) and maintains its only office in Rancho Cucamonga, California. Until the events that form the basis of this litigation, it provided services as a HHA under the Medicare program, pursuant to the general plan established at section 1861(o) of the Social Security Act (Act), 42 U.S.C. § 1395x(o), and the implementing regulations at 42 C.F.R. Part 484. During all times at issue, Prime Care's Administrator and Director of Patient Care Services (DPCS) was E. Obasi; its Assistant Administrator was K. Obasi, the husband of E. Obasi. Prime Care's office manager was C. Kendrick, and its receptionist was J. Motuliki.

At approximately 9:35 a.m. on the morning of Monday, September 25, 2006, Prime Care's office was visited by two Health Facilities Evaluator Nurses (HFENs) employed by the California Department of Health Services. K. Neumann, R.N., and H. Williams, R.N., were there to conduct a standard unannounced re-certification survey of Prime Care. When the two HFENs arrived, the only person present at Prime Care's office was Ms. Motuliki, the receptionist. Ms. Motuliki "was barely a week into the job when the state surveyors came to the office for a survey." Declaration of J. Motuliki.

The two HFENs explained the purpose of their visit to Ms. Motuliki. Ms. Motuliki, in turn, told the HFENs that Administrator-DPCS E. Obasi and Assistant Administrator K. Obasi were on vacation; she attempted to reach the Obasis by telephone but was unable to do so.

The HFENs asked Ms. Motuliki for a list of Prime Care's active patients and for a list of its patients scheduled for home visits. Ms. Motuliki provided two lists. The first list was dated July 11, 2006, and showed seven "Active Patients." The second list was dated September 15, 2006, and named 23 patients described as "Active, On Hold." Of the total 30 names on both lists, only one name appeared on both.

Once they had received the two patient lists from Ms. Motuliki, the two HFENs then asked Ms. Motuliki to provide Prime Care's clinical records for the listed patients. Ms. Motuliki did not comply with their request: after she left the room and entered another room briefly, she returned and told the HFENs that the requested records were in a locked filing cabinet. Ms. Motuliki told the HFENs that she did not have a key to the filing cabinet. According to Ms. Motuliki's statement to the HFENs, office manager C. Kendrick had a key, but had forgotten to leave it in the office.

HFEN K. Neumann talked with Ms. Kendrick by telephone at approximately 10:00 a.m. Ms. Kendrick told HFEN Neumann that she herself was out of town and that the Administrator-DPCS had given her the day off. Ms. Kendrick specifically admitted that "there was no one in charge of Prime Care that day." CMS Ex. 1, at 3, CMS Ex. 4, at 2. Ms. Kendrick asked that the survey be rescheduled, and told the HFENs that she had no idea where the Obasis might be and did not know how to reach them.

Although she had told the HFENs that she was out of town, Ms. Kendrick arrived at Prime Care's office at approximately 10:45 a.m. She was, however, unable to produce a key to the locked filing cabinet containing the patient clinical records, and was unable to produce those records herself.

The HFENs then asked Ms. Kendrick for a list of Prime Care's active patients and patients scheduled for home visits, and Ms. Kendrick responded by producing a third list, this one dated that day, September 25, 2006. It listed 13 "Active Patients." CMS Ex. 3, CMS Ex. 4, at 2. All 13 names on the September 25, 2006 list appeared on the list dated September 15, 2006, but 10 names on the September 15, 2006 list did not appear on the September 25, 2006 list, and none of the names on the July 11, 2006 list appeared on the September 25, 2006 list. The list dated September 25, 2006 contained no information identifying a treating physician for any of the 13 patients, and provided no diagnostic information whatsoever for any of them.

At approximately 10:55 a.m., HFEN Neumann was able to talk by telephone with Administrator-DPCS Obasi and ask her whether anyone was in charge of Prime Care in Ms. Obasi's absence. Ms. Obasi identified one D. Kraku as being in charge. At some point during the past hour and a half, Ms. Kendrick and Ms. Motuliki had made similar statements. When HFEN Neumann talked with Ms. Kraku by telephone, Ms. Kraku described her position at Prime Care. HFEN Neumann believed that Ms. Kraku said that she was simply the "RN (on call)" and had been telephoned by Ms. Kendrick "just a little bit ago." CMS EX. 1, at 4. Ms. Kraku later asserted that she identified herself to HFEN Neumann as Prime Care's Assistant Director of Nursing (ADON). In any case, Ms. Kraku declined to come to the Prime Care office because of what she described as a pending medical appointment. Ms. Kraku later asserted that she had been ill on September 25, 2006.

The HFENs remained at Prime Care's office reviewing other documents until the late afternoon, except for an hour-long lunch break. At approximately 4:20 p.m., Assistant Administrator K. Obasi telephoned and told the HFENs that he and Ms. Obasi were held up in traffic and would be unable to reach Prime Care's office that day. Seven weeks later, on November 12, 2006, Prime Care's Assistant Administrator admitted that "On

September 22, 2006, my wife and I went out of town and we were scheduled to return on September 25, 2006. When we traveled, we forgot to leave the key to the locked filing cabinet at the office or with someone at the office." Declaration of K.Obasi. Mr. Obasi did not state precisely where "out of town" he and the Administrator-DPSC had been, but HFEN Neumann's notes suggest that it had been San Luis Obispo, California, at least two hundred miles away from Prime Care's office.

The HFENs ended their survey of Prime Care just after 4:20 p.m. on Monday, September 25, 2006.

CMS notified Prime Care on October 25, 2006 that its Medicare provider agreement was to be terminated effective November 17, 2006. On November 12, 2006, Prime Care filed its Request for Hearing and thereby perfected this appeal of that determination.

Controlling Statutes and Regulations:

Under the Medicare program, a HHA is a public agency or private organization that provides skilled nursing and other therapeutic services to individuals primarily on the basis of visits to their homes. Section 1861(m) of the Act, 42 U.S.C. § 1395x(m), describes the covered services that HHAs provide under the Medicare program. Section 1861(o) of the Act, 42 U.S.C. § 1395x(o), establishes the statutory definitions that govern HHA participation in the Medicare program. Finally, section 1891(a) of the Act, 42 U.S.C. § 1395bbb(a), creates a framework of conditions with which HHAs must comply in order to participate in the Medicare program.

The Secretary of Health and Human Services (Secretary) has issued regulations at 42 C.F.R. Part 484 which further govern the participation of HHAs in the Medicare program. Specifically, the provisions contained in 42 C.F.R. §§ 484.10 - 484.55 set out the Secretary's refinement of the statutory requirements for HHAs' participation in Medicare by establishing fourteen general Conditions of Participation (COPs). The regulations express these COPs as broadly-stated criteria for HHAs' performance in various fields, such as patient rights, compliance with local, state and federal laws, skilled nursing and therapy services, and patient assessments. The regulations also establish Standards of Participation (SOPs) as subsidiary components of the COPs. Two COPs are relevant here. The COP established at 42 C.F.R. § 484.14 requires that the HHA be organized and administered in an efficient, rational, and transparent fashion, and that its personnel and the services they render be adequately supervised. The COP set out at 42 C.F.R. § 484.48 addresses the manner in which the HHA must collect, maintain, and protect its patient records.

To determine whether an individual HHA is complying with all COPs, a state survey agency evaluates the provider's satisfaction of the various SOPs within the fourteen COPs. 42 C.F.R. § 488.26(b). The state survey agency documents and records its findings on a standardized Statement of Deficiencies form (SOD), often referred to as a Form 2567 (2567). Failure to comply with a COP occurs where deficiencies, either individually or in combination, are "of such character as to substantially limit the provider's or supplier's capacity to furnish adequate care or which adversely affect the health and safety of patients . . ." 42 C.F.R. § 488.24(b). After weighing any documented deficiencies, CMS may terminate the HHA's participation in Medicare when it determines, either based on the state survey agency's SOD or on its own initiative, that the HHA is not complying with one or more COPs. Section 1866(b)(2)(A) of the Act, 42 U.S.C. § 1395cc(b)(2)(A); 42 C.F.R. §§ 488.20, 488.24, and 488.26.

Another substantial body of regulatory authority applies to virtually all providers of services that participate in the Medicare program. Two provisions of that body of authority are relevant here. All Medicare providers, including HHAs, are required to comply substantially with the terms of 42 C.F.R. § 489.53(a)(5), which authorizes CMS to terminate a provider's participation if the provider "refuses to permit examination of its fiscal or other records by, or on behalf of CMS, as necessary . . ." and with the similar provisions of 42 C.F.R. § 489.53(a)(13), which authorizes termination of a provider's participation if the provider "refuses to permit photocopying of any records by, or on behalf of CMS, as necessary . . . ."

A decision by CMS to terminate the HHA's participation agreement is an "initial determination" that the HHA may appeal by requesting a hearing before an Administrative Law Judge (ALJ) of this forum. 42 C.F.R. §§ 489.53(d), 498.3(b)(8), 498.5(b). The terms of 42 C.F.R. Part 498 govern the litigation of any such appeal.

Discussion:

The most striking thing about the recitation of material facts above is not the alarming state of disarray they depict at Prime Care's office on September 25, 2006. It is rather that each of those material facts is established without contradiction in CMS Exs. 1, 3, 4 and 5, P. Ex. 2, and in the Declarations of K. Obasi, C. Kendrick, and J. Motuliki attached to Prime Care's Request for Hearing. Although provided a full and fair opportunity to contradict the facts thus established *prima facie* by competent evidence, Prime Care simply has failed to do so. In substance, Prime Care's position has never varied from that expressed in the first sentence of its Request for Hearing: "The essential facts of this matter are not in dispute."

That is not to say, however, that Prime Care does not adamantly deny that it is liable to termination. It has raised multiple defenses to that action and to the CMS Motion. Unfortunately for Prime Care, many of those defenses are of dubious worth. A few of them are presented in terms regrettably close to those condemned by the last six words of FED. R. CIV. P. 12(f).

Some of Prime Care's efforts are entirely unencumbered by any burden of evidence, such as its assertion that "This type of arbitrariness and capriciousness is the kind that lends itself to rumors that improper conduct like racism, bribery and corruption are at play." Pet. Resp. Br., at 3. Were I required to address that argument in a finding of fact, I would find that there is no evidence whatsoever to support Prime Care's gratuitous innuendo.

Some of Prime Care's efforts betray an embarrassing ignorance of the procedural rules of this forum, such as this argument, which is directly contrary to the clear terms of Civil Remedies Division Procedures (CRDP), paragraph 3, and the filing-acknowledgment letter of December 15, 2006:

> According to the Briefing Schedule dated March 6, 2007 . . . CMS' Reply Brief was due on or before May 25, 2007. However, CMS failed to comply with the order and instead mailed out its Reply Brief on May 25, 2007. As a preliminary matter, Petitioner respectfully requests that the Honorable Judge treats the Reply Brief as untimely and discountenance it.

Pet. Resp. Br., at 1-2.

The CRDP and the filing-acknowledgment letter are plain: pleadings are "filed" when they are mailed. CMS's May 25, 2007 Reply Brief was timely and properly filed.

Another of Prime Care's arguments is simply misinformed and misdirected. Prime Care insists that there is no evidence that its patients were placed in immediate jeopardy. Pet. Opp. Br., at 2-4, 11-13, 27-35. Neither the state agency nor CMS has ever asserted that they were. CMS Rep. Br., at 4-5. Although the basis for Prime Care's insistence that immediate-jeopardy deficiencies are at issue is ultimately known best to its counsel (Pet. Resp. Br., at 2), it seems quite likely that its concern is the result of misreading the G-Tag references on the 2567, which references the letter "G." Here, however, the reference to the letter "G" has no significance in describing the scope or severity of the cited violations.

Yet another of Prime Care's defenses appears to have been raised without adequate consideration of the settled authority of this forum and the Article III courts. Prime Care complains that CMS failed to observe certain procedures set out in the State Operations Manual (SOM) by which the state surveyors are to be guided. Without exploring in detail the provisions of the SOM upon which Prime Care relies, and without accepting Prime Care's assertion that those procedures were not observed, it does not require an extended discussion to put Prime Care's argument to rest. Whatever the SOM may suggest, its suggestions to the state agency are precisely that and nothing more. They are suggestions without the force or effect of law, and they may not be relied on to extend, enlarge, or otherwise alter the plain meaning of applicable regulations. *Beverly Health & Rehabilitation Services, Inc. v. Thompson*, 223 F. Supp. 2d 73, at 99-106 (D.D.C. 2002); *Cal Turner Extended Care Pavilion*, DAB No. 2030 (2006); *Aase Haugen Homes, Inc.*, DAB No. 2013, at 15 (2006). Prime Care can find no shelter in the SOM.

Having thus marshaled an army of such meretricious forces, Prime Care raises at its head the *oriflamme* of estoppel. Pet. Opp. Br, at 20-21; Pet. Resp. Br., at 3. Prime Care points to a promptly-corrected error in September 29, 2006 correspondence from the state agency, four days after the September 25, 2006 survey and four weeks before CMS's letter of October 25, 2006, and asserts that the state agency's error estops CMS from imposing the termination sanction based on the survey results. But this argument can hope for little favor in this forum. First, because it is beyond my authority as an ALJ to consider; next, because estoppel generally will not run against the federal government or one of its agencies; and third, because the factual predicates for invoking that equitable remedy are not present here. My summary of the reasons why the defense of estoppel is not available to Prime Care is admittedly terse, but there is no better discussion of the matter than that set out by ALJ S.T. Kessel in *Oak Lawn Endoscopy*, DAB CR1187 (2004), and I adopt it here. *See also Office of Personnel Management v. Richmond*, 496 U.S. 414 (1990); *Heckler v. Community Health Services*, 467 U.S. 51 (1984); *Schweiker v. Hansen*, 450 U.S. 785 (1981); *Rosewood Living Center*, DAB No. 2019 (2006); *Everett Rehabilitation and Medical Center*, DAB No. 1628 (1997).

These failed arguments aside, Prime Care's principal reliance is on its defense of "inadvertence" in connection with the locked records cabinet and the deficiencies cited based on 42 C.F.R. §§ 489.53(a)(5) and (a)(13), and on its assertion that the disarray, confusion, and unresponsiveness encountered by the surveyors on September 25, 2006 did not rise to levels of substantial noncompliance with the COPs found at 42 C.F.R. §§ 484.14 and 484.48. Prime Care offers that notion as the core of its resistance to CMS's Motion for Summary Judgment.

Dispositions by summary judgment are authorized in this forum, and this forum looks to FED. R. CIV. P. 56 for guidance in addressing motions for summary judgment. Summary judgment may be entered when the record shows that there is no genuine dispute as to any material fact, and that the moving party is entitled to judgment as a matter of law. *White Lake Family Medicine, P.C.*, DAB No. 1951 (2004); *Lebanon Nursing and Rehabilitation Center*, DAB No. 1918 (2004). The party moving for summary judgment bears the initial burden of showing the basis for its motion and identifying the portions of the record that it believes demonstrate the absence of a genuine factual dispute. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). CMS has made a *prima facie* showing that there are no material facts in dispute as to Prime Care's citation for non-compliance with the two COPs set out at 42 C.F.R. §§ 484.14 and 484.48, and for its non-compliance with the two requirements established by 42 C.F.R. §§ 489.53(a)(5) and 489.53(a)(13). As I note above, Prime Care does not dispute or deny the material facts. Thus, Prime Care's termination for noncompliance with 42 C.F.R. §§ 484.14, 484.48, 489.53(a)(5), and 489.53(a)(13) is subject to summary affirmation if CMS has shown itself entitled to judgment as a matter of law. As the following discussion will explain, I believe that the undisputed facts do support CMS's position, and that CMS is entitled to prevail as a matter of law on its Motion for Summary Judgment.

The material facts set out in detail above offer a comprehensive view of the situation at Prime Care on September 25, 2006. I repeat that I have set them out only insofar as they are uncontested, and I explicitly note that I can find in those facts no suggestion that anyone connected with Prime Care took any steps that could fairly be called a deliberate effort to bar the surveyors from opening the file cabinet that contained Prime Care's patient records. Nevertheless, those facts leave Prime Care incontrovertibly liable to termination.

As I wrote in *Professional Home Health Care, Inc*., DAB CR1128 (2004), the decisions of the Departmental Appeals Board (Board) and the ALJs of this forum have made clear that termination of an HHA's participation in the Medicare program is a remedy intended to protect the health and safety of program beneficiaries. Termination is neither intended nor is to be understood as a punishment for infractions by the HHA. Termination should be invoked only in circumstances where the HHA's deficiencies establish that it is substantially incapable of providing care consistent with Medicare participation requirements; the termination remedy is stern, and should not be invoked unless the evidence proving the HHA's failure to comply establishes that the provider cannot provide care consistent with levels required by the Act and the regulations. *CSM Home Health Services, Inc.,* DAB CR440, at 3 (1996). Accordingly, when CMS determines that an SOP deficiency exists, but believes that the deficiency is not serious enough to constitute a COP deficiency, CMS may not terminate the HHA's participation without

first offering it the opportunity to correct the deficiency. 42 C.F.R. § 488.28. But there is a corollary: CMS may terminate the HHA without offering it an opportunity to correct its deficiencies if CMS concludes that the documented deficiencies are of such character as to render the HHA either substantially incapable of providing adequate care to patients, or if CMS determines that the deficiencies may adversely affect patient health and safety. 42 C.F.R. §§ 488.24(b), 488.24(c). CMS is not required to demonstrate actual patient harm. *See National Hospital for Kids in Crisis*, DAB No. 1600 (1996).

The obvious implication of this understanding of the termination remedy is that Prime Care's "inadvertence" defense is irrelevant. The goal of the COPs and the requirements of 42 C.F.R. §§ 489.53(a)(5) and 489(a)(13) is to protect Medicare patients from the HHA's lapses in certain critical areas, and to assure that surveyors are able to investigate and document whether lapses in those areas have occurred, are occurring, or are likely to occur. Whether a patient is placed at risk through the HHA's knowing and willful act, its well-meant act of incompetence, or its act of monumental indifference matters precious little to the patient and the course of that patient's treatment. That continuum of culpability may be of interest in other forms of litigation, but in this case it simply does not matter: Prime Care's patient records were made unavailable to the surveyors by lock and key on September 25, 2006, and the surveyors' access to those patient records was "refused" as surely and effectively as if the front door to Prime Care's office had been locked and barred against their entry. The situation at Prime Care on September 25, 2006 demonstrated that the HHA had constructively refused the surveyors access to the patient records, and thereby had refused to permit them to examine and copy those records. The failings specified at 42 C.F.R. §§ 489.53(a)(5) and 489.53(a)(13) were at that time attributable to Prime Care. Prime Care was liable to termination as a result.

Prime Care's effort to minimize the seriousness of the disarray, confusion, and unresponsiveness that ruled its office all day on September 25, 2006 collapses in the face of the stubborn facts. Prime Care's Administrator-DPCS and Assistant Administrator were both absent. A non-professional employee "barely a week or so into the job" was alone in the office, locked out of the patient records and able to locate only two out-of-date patient lists. She had no idea where Prime Care's Administrator-DPCS and Assistant Administrator might be, but believed that the office manager had the key to the patient-records cabinet. The office manager was absent, out of town on a day off granted to her by the absent Administrator-DPCS, whose precise whereabouts she did not know. When the office manager finally arrived, she did not have and could not find the key to the patient-records cabinet, which remained locked against the surveyors' request for access to it. The office manager was somehow able to produce a list of Prime Care's active patients, but that list was inconsistent with two other lists provided earlier by the receptionist, and it omitted identifying information about the primary diagnosis and

treating physician for every one of the patients listed on it. When the Administrator-DPCS was eventually contacted by telephone, she identified D. Kraku as the person in charge of Prime Care in the Administrator-DPCS's absence, but Ms. Kraku was not at Prime Care. Whether Ms. Kraku did so in her capacity as the ADON or as the on-call RN, she declined to make herself available at Prime Care's office.

From the moment the surveyors entered Prime Care's office at approximately 9:35 a.m. until they left at approximately 4:20 p.m., the only face-to-face contact the surveyors had with Prime Care's management and staff amounted to their interactions with the receptionist and the office manager. Three other Prime Care personnel were absent and unable — or unwilling — to provide useful assistance and reliable information. Of those three, two were obviously executives, and one now claims that she was. Notwithstanding what those five were able to contribute to the re-certification survey, no key was produced, no patient records produced, and no rational organization or delegation of authority was evinced. The situation at Prime Care on September 25, 2006 demonstrated that the HHA had no observable plan for the delegation of authority and responsibility, and for the supervision of its operations, in the absence of the Administrator-DPCS and Assistant Administrator. The situation at Prime Care on September 25, 2006 demonstrated that the HHA had no observable procedures for the use, maintenance, and retention of its patients' clinical records. The COPs set out at 42 C.F.R. §§ 484.14 and 484.48 were at that time not satisfied by Prime Care. Prime Care's capacity to furnish adequate care to its patients was substantially limited by those failures, which were uniquely capable of affecting adversely its patients' health and safety. Prime Care was liable to termination as a result.

Findings and Conclusions:

I find and conclude as follows:

1. Petitioner Prime Care Home Health Agency, Inc. failed to comply substantially with the Condition of Participation in the Medicare program as a HHA set out at 42 C.F.R. § 484.14 when surveyed on September 25, 2006. CMS Exs. 1, 3, 4 and 5; P. Ex. 2; Declarations of K. Obasi, C. Kendrick, and J. Motuliki.

2. Petitioner Prime Care Home Health Agency, Inc. failed to comply substantially with the Condition of Participation in the Medicare program as a HHA set out at 42 C.F.R. § 484.48 when surveyed on September 25, 2006. CMS Exs. 1, 3, 4 and 5; P. Ex. 2; Declarations of K. Obasi, C. Kendrick, and J. Motuliki.

3. Petitioner Prime Care Home Health Agency, Inc. failed to comply substantially with the requirement for participation in the Medicare program as a provider of services set out at 42 C.F.R. § 489.53(a)(5) when surveyed on September 25, 2006. CMS Exs. 1, 3, 4 and 5; P. Ex. 2; Declarations of K. Obasi, C. Kendrick, and J. Motuliki.

4. Petitioner Prime Care Home Health Agency, Inc. failed to comply substantially with the requirement for participation in the Medicare program as a provider of services set out at 42 C.F.R. § 489.53(a)(13) when surveyed on September 25, 2006. CMS Exs. 1, 3, 4 and 5; P. Ex. 2; Declarations of K. Obasi, C. Kendrick, and J. Motuliki.

5. CMS was authorized to terminate Petitioner Prime Care Home Health Agency, Inc.'s participation in the Medicare program effective November 17, 2006. Section 1866(b)(2)(A) of the Act, 42 U.S.C. § 1395cc(b)(2)(A); 42 C.F.R. §§ 488.20, 488.24, 488.26, and 489.53(a).

Conclusion:

For all of the reasons set forth above, the Motion for Summary Judgment filed by CMS in this case should be, and it is, GRANTED. The determination by CMS to terminate the participation of Petitioner Prime Care Home Health Agency, Inc. in the Medicare program as a HHA effective November 17, 2006 is in all respects

AFFIRMED.

/s/
Richard J. Smith
Administrative Law Judge