Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Appellate Division

In the Case of:	DATE: November 29, 2007
Community Home Health,	
Petitioner,	Civil Remedies CR1582 App. Div. Docket No. A-07-99
	Decision No. 2134
- v. -	
Centers for Medicare & Medicaid Services.	

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Community Home Health (Community, Petitioner), a home health agency (HHA), appealed the March 30, 2007 decision of Administrative Law Judge (ALJ) Carolyn Cozad Hughes upholding the termination of Community's Medicare provider agreement. Community Home Health, DAB CR1582 (2007) (ALJ Decision). Based on Community's motion for summary judgment and undisputed evidence presented by Community, the ALJ granted summary judgment for the Centers for Medicare & Medicaid Services (CMS). The ALJ found that Community was not in substantial compliance with the condition of Medicare participation at 42 C.F.R. § 484.48 because it failed to safeguard patient medical records (clinical records) against loss and unauthorized use. CMS had filed a cross-motion for summary judgment, but not on this issue. Community denies that it was out of compliance with 42 C.F.R. § 484.48,[1] asserting that the incident on which the ALJ relied was isolated and that Community took swift action to prevent a recurrence. Community contends that by deciding this case for CMS on the basis of Community's motion for summary judgment, the ALJ denied Community

[1] We cite to the 2006 Code of Federal Regulations throughout this decision; all the relevant regulations were unchanged during the times at issue here.

the opportunity to provide additional evidence of substantial compliance.

For the reasons discussed below, we uphold the ALJ's determination on summary judgment that Community was not in substantial compliance with the clinical records condition, and that CMS therefore had a sufficient basis for terminating its Medicare provider agreement. We find it unnecessary to determine whether the ALJ erred procedurally by granting summary judgment for CMS without notifying Community of her intent to do so or offering Community an opportunity to present additional evidence because any such error would be harmless under the circumstances of this case. Community has not shown that it was prejudiced since it has not proffered any specific evidence to show the existence of a material dispute of fact precluding entry of summary judgment for CMS. This decision is based on the record for the ALJ Decision, the parties' briefs on appeal, and the oral argument before the Board on September 19, 2007.

Applicable Legal Authority

Section 1861(m) of the Social Security Act (Act) defines "home health services" as, inter alia, "part-time or intermittent nursing care . . . part-time or intermittent services of a home health aide . . . and medical supplies . . . and durable medical equipment." Section 1861(m) further defines such services as ones "furnished to an individual, who is under the care of a physician, by a home health agency . . . under a plan . . . established and periodically reviewed by a physician . . . provided on a visiting basis in a place of residence used as such individual's home . . . ."[2]

Section 1861(o) of the Act defines an HHA as –

> a public agency or private organization, or a subdivision of such an agency or organization, which –
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> (1) is primarily engaged in providing skilled nursing services and other therapeutic services;

[2] The current version of the Social Security Act can be found at www.ssa.gov/OP Home/ssact/comp-ssa.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.

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> (3) maintains clinical records on all patients; [and]
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> (6) meets the conditions of participation specified in section 1891(a) and such other conditions of participation as the Secretary may find necessary in the interest of the health and safety of individuals who are furnished services by such agency or organization. . . .
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> * * * *

(Emphasis added.) Section 1891(a)(l)(C) of the Act lists several of the conditions of participation that an HHA is required to meet, including that "[t]he agency protects and promotes the rights of each individual under its care, including . . . the right to confidentiality of the clinical records described in section 1861(o)(3)." Section 1861(a)(1)(C).

The federal regulations in subparts B and C of 42 C.F.R. Part 484 (sections 484.10 to 484.55) also set forth conditions of participation in the Medicare program for HHAs. The clinical records condition provides:

> A clinical record containing pertinent past and current findings in accordance with accepted professional standards is maintained for every patient receiving home health services. In addition to the plan of care, the record contains appropriate identifying information; name of physician; drug, dietary, treatment, and activity orders; signed and dated clinical and progress notes; copies of summary reports sent to the attending physician; and a discharge summary.
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> * * * *
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> (b) *Standards: Protection of records.* Clinical record information is safeguarded against loss or unauthorized use. Written procedures govern use and removal of records and the conditions for release of information. Patient's written consent is required for release of information not authorized by law.

42 C.F.R. § 484.48.

For HHAs, 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 the HHAs' (or "providers'") compliance with each of the conditions, and each of the standards in the conditions, governing Medicare participation. 42 C.F.R. §§ 488.11, 488.12, 488.18 to 488.28.

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 it 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).

Case Background

The state survey agency, the Alabama Department of Public Health, completed a survey of Community on June 29, 2006 and determined that the HHA did not meet two conditions of Medicare participation (42 C.F.R. § 484.30 (governing skilled nursing services) and 42 C.F.R. § 484.52 (governing evaluation of the agency's program)); the survey report also noted several standard-level deficiencies. Pet. Ex. 1. On July 7, 2006, the state survey agency notified Community that it would recommend that CMS terminate Community's Medicare participation within 90 days (September 27, 2006) unless it achieved substantial compliance prior to that date. Id. On July 17, 2006, Community submitted a plan of correction (POC), committing to correct its deficiencies no later than August 10, 2006. Id.

The state survey agency resurveyed Community on August 17, 2006, and found that it still had one condition-level deficiency (42 C.F.R. § 484.36 (governing home health aide services)) and four standard-level deficiencies. Pet. Ex. 2. By letter dated August 23, 2006, CMS notified Community that its provider agreement would terminate on September 27, 2006, if the deficiencies were not corrected by that date. Id. On August 28, 2006, Community submitted another POC, promising compliance by August 29, 2006.

Pet. Ex. 3. In response to an oral comment on September 1, 2006 from the state survey agency that the POC was incomplete, Community submitted a revised POC on September 4, 2006; in the revised POC Community did not change its assertion that it would be in compliance by August 29, 2006. Pet. Ex. 5.

The state survey agency conducted another survey on September 20, 2006, and found Community out of compliance with three conditions and two standards. Pet. Ex. 8. The condition-level deficiencies were in organization, services, and administration (42 C.F.R. § 484.14); skilled nursing services (42 C.F.R. § 484.30); and clinical records (42 C.F.R. § 484.48). CMS sent Community a letter dated September 28, 2006, referring to the condition-level deficiencies and notifying Community that its Medicare provider agreement terminated effective September 27, 2006. Id.

By letter dated November 22, 2006, Community appealed the termination. On December 22, 2006, Community moved for summary judgment, relying on documentary evidence it had submitted and making legal arguments contesting each of the condition-level deficiencies cited in the August and September surveys. Petitioner Community Home Health's Motion for Summary Disposition, or in the Alternative, Motion for Expedited Hearing (Pet. Motion for Summary Disposition).[3] CMS opposed Community's motion for summary disposition, contending that there were genuine issues of material fact regarding each condition-level deficiency. CMS's Opposition to Petitioner's Motion for Summary Disposition and Cross Motion for Summary Judgment (CMS's Opposition) at 8-19. CMS also filed a cross motion for summary judgment arguing that repeat standard-level deficiencies cited in the August and September surveys provided a basis for terminating Community's Medicare provider agreement. Id. at 19-20.

On March 30, 2007, the ALJ entered summary judgment for CMS sua sponte, upholding CMS's termination of Community's Medicare provider agreement based on failure to comply with the clinical

[3] The motion relied on several exhibits that Community had submitted to the ALJ on November 22, 2006, as part of its "evidentiary submission in support of [its] appeal of the termination." Pet. Motion for Summary Disposition, citing documents originally submitted with Community's Appeal of Termination of Provider Agreement.

records condition at 42 C.F.R. § 484.48. Community filed this appeal on June 1, 2007.[4]

ALJ Decision

The ALJ made the following findings of fact and conclusions of law (FFCLs):

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

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.

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.

ALJ Decision at 4, 5, 6; footnote omitted.

In support of FFCLs A and B.2, the ALJ relied on the evidence Community had submitted in support of its motion for summary judgment. CMS did not move for summary judgment on the clinical records issue. However, the ALJ found that with "no material facts . . . in dispute here" (ALJ Decision at 4), "accept[ing] Petitioner's version of these events" (id. at 7, n.5), and "drawing every possible inference in Community's favor" (id. at

[4] With its appeal, Community submitted a declaration and exhibit (in the form of a voice recording) relevant to the issue of whether its request for review of the August 17, 2006 survey was timely filed. However, since we do not reach the issue of whether the request for review of the August survey was timely filed, we need not address whether the declaration and exhibit would have been admissible under 42 C.F.R. § 498.86, governing the submission of new evidence on appeal.

5), Community was not in substantial compliance with the clinical records condition at the time of the September 2006 survey. Id. at 6-9.

The ALJ noted that Community had not disputed CMS's allegations that "one of Community's employees removed and photocopied confidential medical records, keeping them in her home" and that "an undisclosed number of the original records were simply lost." ALJ Decision at 7, citing Pet. Ex. 11.[5] The ALJ also found that Community's own evidence showed that this employee had original patient medical records in her car, gave them to her spouse to take them home when she was in a car accident, subsequently lost them, and then, in lieu of returning the original records, submitted copies of records she had been maintaining in her home. Id. The ALJ found that this breach "seriously compromised patient privacy and suggests serious problems with the HHA's procedures for safeguarding its patients' records." Id. She further deemed it "a serious violation of the regulation, sufficient to render the condition out of compliance." Id. (citations and footnote omitted). The ALJ also found that Community had not provided much specific evidence as to its corrective actions, and had not taken thorough corrective actions. She stated that because the problems were "systemic," Community needed to correct them by "demonstrat[ing] that no other instances had occurred, and implement[ing] a plan of correction designed to assure that no incidents would occur in the future." Id.

Having decided the case based on Community's failure to comply with the clinical records condition, the ALJ concluded that she did not need to rule on other issues the parties had raised. These included whether Community was out of compliance with the other conditions cited in the August and September surveys; whether the alleged repeat standard-level deficiencies in the August and September surveys provided an alternative basis for termination; and whether CMS's letters notified Community that

[5] Petitioner's Exhibit 11 is an "Employee Counseling Notice," dated August 25, 2006, that contains Community's record of the facts based on talking with the employee involved. CMS's allegations were contained in the state survey agency report (the Sept. 20, 2006 CMS-2567, submitted as Pet. Ex. 8), which relied substantially on this "Employee Counseling Notice" for the survey findings.

CMS would seek to terminate on the basis of these alleged repeat standard-level deficiencies.[6]

Standard of Review

The Board reviews a disputed finding of fact to determine whether the finding is supported by substantial evidence, and a disputed conclusion of law to determine whether it is erroneous. Guidelines for Appellate Review of Decisions of Administrative Law Judges Affecting a Provider's Participation in the Medicare and Medicaid Programs, http://www.hhs.gov/dab/guidelines/prov.html(Guidelines); Batavia Nursing and Convalescent Inn, DAB No. 1911, at 7 (2004), aff'd, Batavia Nursing & Convalescent Ctr. v. Thompson, 143 F. App'x 664 (6th Cir. 2005). The Board reviews de novo the legal issue of whether the ALJ's grant of summary disposition was appropriate. Lebanon Nursing and Rehabilitation Center, DAB No. 1918, at 4 (2004). The Guidelines provide for an ALJ's decision to be modified, reversed, or remanded "if a prejudicial error of procedure . . . was committed."

Analysis

A. The ALJ decided correctly that Community was not in substantial compliance with HHA requirements.

1. The ALJ did not commit reversible error by deciding the case on summary judgment.

Community argues that the ALJ erred by deciding this case on summary judgment. More specifically, Community argues that since CMS did not move for summary judgment on the clinical records issue, Community "had no notice that the [ALJ] was considering entering a judgment on those grounds," and therefore no opportunity to submit additional evidence. Petitioner Community Home Health's Notice of Appeal and Request for Review by the Departmental Appeals Board (Pet. Notice of Appeal) at 4-6, 9-10, 31; Petitioner Community Home Health's Reply to Centers for Medicare & Medicaid Services' Response Brief (Pet. Reply Br.) at 4-6, 7, 11-12. Community also argues that since CMS did not move for summary judgment on the clinical records issue, the ALJ wrongly expected Community to "act affirmatively by tendering evidence of specific facts establishing a dispute on this

[6] We have considered these other issues, and all of the arguments raised by the parties on appeal. However, in this decision, we discuss only those issues that are material to our disposition of this case.

[clinical-records-condition] issue." Pet. Notice of Appeal at 9, quoting ALJ Decision at 8. This was incorrect, Community asserts, because it "place[d] the burden on Community to have submitted evidence on an issue not raised." Pet. Notice of Appeal at 9. The Board does not need to decide whether the ALJ erred by deciding this case for CMS on summary judgment because even if she did, it is not reversible error.

Community relies on six federal appeals court decisions construing Federal Rule of Civil Procedure 56(c) and finding reversible error where the district courts granted summary judgment sua sponte (on grounds not raised in a motion by the prevailing party) without giving the losing party notice and an opportunity to respond.[7] Pet. Notice of Appeal at 5, n.3; Pet. Reply Br. at 4, n.1. These cases do not control the result here. Unlike the appellants in the cases Community relies upon, Community itself moved for summary judgment on the ground on which the ALJ granted summary judgment. Community also submitted undisputed evidence on the issue and represented that there was no material dispute of fact precluding summary judgment in its favor.

Under procedural facts similar to those in Community's case, courts have declined to find error, or at least reversible error, even while generally discouraging the procedure of entering summary judgment sua sponte. Goldstein v. Fidelity and Guaranty Insurance Underwriters, 86 F.3d 749 (7th Cir. 1996) (procedure not encouraged but no error where losing party itself moved for summary judgment on the issue and claimed that there was no genuine issue of material fact); Bridgeway Corp. v. Citibank, 201 F.3d 134 (2d Cir. 2000) (procedure firmly discouraged but no reversible error where court entered summary judgment on issues raised during the proceedings and addressed by the moving party, and moving party could not plausibly claim that given notice it would have presented additional evidence (below or on appeal) that would have shown a material dispute of fact); Exxon Corp. v. St. Paul Fire and Marine Ins. Co., 129 F.3d 781, 786-87 (5th Cir.

[7] Although the federal rules do not bind ALJs or the Board, it is appropriate to look to them for guidance (see, e.g., White Lake Family Medicine, P.C., DAB No. 1951, at 12-14 (2004)). In the instant case, the ALJ's Acknowledgment and Initial Pre-Hearing Order informed the parties that she would hear any motions for summary disposition according to the principles of Rule 56 of the Federal Rules of Civil Procedure and applicable case law. However, the ALJ decision does not discuss any cases involving entry of summary judgment sua sponte.

1997) (circuit permits entry of sua sponte summary judgment in appropriate cases; entry for insured on insurer's motion was appropriate since policy interpretation involved legal, not factual, dispute and insurer indicated by its litigation choices that it had no further evidence to present or argument to make regarding any material dispute of fact); Cool Fuel, Inc. v. Connett, 685 F.2d 309, 311-12 (9th Cir. 1982) (no error to enter summary judgment sua sponte for IRS when taxpayer moved for summary judgment and had a full and fair opportunity to ventilate the issues).

Even in cases where the appellant itself had not moved for summary judgment (or neither party had moved on the issue on which summary judgment was granted), courts have declined to reverse sua sponte entries of summary judgment where, as here, the appellant cannot show that it could have presented additional evidence material to its claim. See, e.g., Tranzact Technologies, Ltd. v. Evergreen Partners, Ltd., 366 F.3d 542 (7th Cir. 2004) (upholding a sua sponte grant of summary judgment where the complaining party could not show on appeal that it was deprived of a chance to present a viable claim); Oppenheimer v. Morton Hotel Corp., 324 F.2d 766 (6th Cir. 1963) (per curiam) (upholding a sua sponte grant of summary judgment where essential facts in the record were undisputed and there was no claim on appeal that counsel had further evidence to submit). Although the regulations at 42 C.F.R. § 498.86 allow the Board to consider new evidence on appeal, Community did not move to submit evidence that might have shown the existence of a material dispute of fact. Neither did Community point to any such evidence when asked during oral argument why the Board should remand to the ALJ absent the proffer of any such evidence. Tr. at 30-31. We therefore find that Community was not prejudiced by the ALJ's decision to enter summary judgment in CMS's favor sua sponte. Accordingly, we find no basis for reversing the decision on procedural grounds.

2. The undisputed material facts establish a condition-level violation of 42 C.F.R. § 484.48 (clinical records).

The undisputed material facts establish that Community failed to comply with the condition at 42 C.F.R. § 484.48, which requires HHAs to maintain clinical records containing specified information on all patients and protect these records from loss or unauthorized use. Section 484.48 provides:

> A clinical record containing pertinent past and current findings in accordance with accepted professional

> standards is maintained for every patient receiving home health services. In addition to the plan of care, the record contains appropriate identifying information; name of physician; drug, dietary, treatment, and activity orders; signed and dated clinical and progress notes; copies of summary reports sent to the attending physician; and a discharge summary. . . .
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> * * * * * * * * * *
>
> (b)*Standards: Protection of records.* Clinical record information is safeguarded against loss or unauthorized use. Written procedures govern use and removal of records and the conditions for release of information. Patient's written consent is required for release of information not authorized by law.

42 C.F.R. § 484.48(b); see also Act, sections 1861(o)(3) (defining HHA, in part, as an organization or agency that "maintains clinical records on all patients") and 1891(a)(1)(C) (requiring HHAs to protect patients' rights to confidentiality of the clinical records described in section 1861(o)(3)); 42 C.F.R. § 484.10(d) (iterating the patient's right to confidentiality of clinical records maintained by the HHA and requiring the HHA to advise the patient of the agency's policies and procedures regarding disclosure of clinical records).[8]

As indicated, clinical notes and progress notes are part of the information that must be included in the clinical records.[9]

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[8] The Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191, 110 Stat. 1936 (1996)) (HIPAA) and regulations at 45 C.F.R. Parts 160, 162, and 164 ("Privacy Rule") also mandate providers to protect privacy rights in health care records.

[9] A clinical note is defined as "a notation of a contact with a patient that is written and dated by a member of the health team, and that describes signs and symptoms, treatment and drugs administered and the patient's reaction, and any changes in physical or emotional condition." 42 C.F.R. § 484.2. A progress note is defined as "a written notation, dated and signed by a member of the health team, that summarizes facts

(continued...)

When section 484.48 was revised in 1989, the drafters explained the importance of such notes, and why they are required for every patient receiving home health services, not just those covered by Medicare.

> Section 1861(o) of the Act requires that in order to be considered an "HHA," an entity must maintain clinical records on its patients. . . . The clinical note is the most essential element of a patient's clinical records since it describes the services furnished to the patient, the patient's response to treatment and current status. This information is essential to ensure the quality of care being furnished by an HHA.
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> . . . A clinical note must be prepared for each visit to a patient on the date of the visit, and must include a description of signs and symptoms, treatment and or drug given, the patient's reaction and any changes in the patient's physical or emotional condition. * * * *

54 Fed. Reg. 33,354, 33,364 (Aug. 14, 1989) (emphasis added). Home health services include "an array of services such as professional nursing care, physical and occupational therapy, speech pathology, medical social services, home health aide services and medical supplies and equipment." Id. at 33,354; see also Act, §§ 1861(m) (defining "home health services") and 1861(o) (defining HHA). "These services are delivered singly, or in combination, to aid in the recovery from an acute illness or to improve a patient's health status." 54 Fed. Reg. at 33,354. Since CMS has determined that the preparation of clinical notes is essential to ensure the quality of care provided by an HHA to individuals needing such services, it is axiomatic that the inability to access such records due to the type of unauthorized removal and loss of records that occurred here would compromise the HHA's capacity to furnish adequate care. It is equally axiomatic that a loss of records or their mishandling or exposure to persons not authorized to have access to the records would violate the statutory and regulatory mandates to protect these records and the patients' privacy interest in them.

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[9](...continued)
about care furnished and the patient's response during a given period of time." Id.

As noted by the ALJ, the material facts showing Community's failure to comply with this condition are undisputed and, indeed, are evidenced by Community's own exhibits, in particular the employee counseling record in Petitioner's Exhibit 11. This exhibit shows that one of Community's employees removed an unspecified number of original patient medical records from the office, kept them in her car, gave the records to her spouse to maintain at home after she was involved in an auto accident and then lost an unspecified number of the original records. Clearly the records that were lost or stored in the employee's car or home were not available to employees of Community who might need access to them. In this regard, it should be noted that the HHA and its professional staff members must rely on clinical records in reviewing each patient's care, planning for continuing care, and determining the appropriateness of continuing care. These professional activities are mandated by 42 C.F.R. § 484.52(b), which requires 60-day clinical records reviews for each patient for these purposes.

In addition, the employee's actions jeopardized the confidentiality of patient records. The counseling record shows that the employee photocopied an unspecified number of patient records, thus enhancing the potential that confidential information would be seen by unauthorized individuals. These records contain confidential information about each patient's illnesses, daily condition, and care (including intimate hygiene details). Pet. Ex. 9. Furthermore, while the report says that the employee returned copies of patient medical records that were maintained in her home, it does not state that the copies represented all of the documents taken or lost, leaving open the possibility that some records (or copies thereof) were never recovered. Given these undisputed facts, we find no basis for reversing the ALJ's conclusion that Community did not meet the HHA condition of participation at 42 C.F.R. § 484.48.

B. Community did not comply with a Medicare condition of participation; accordingly, termination was authorized.

The regulation at 42 C.F.R. § 489.53(a)(3) provides that CMS may terminate an HHA's provider agreement if it finds that the HHA no longer meets the appropriate conditions of participation, as CMS did based on the September 20, 2006 survey. Community does not dispute that this is the law. Neither does Community dispute the material facts of the August incident (identified on the September survey) underlying the finding of noncompliance: the loss of an unknown number of patient records, failure to properly maintain and protect other patient records and failure to protect the confidentiality of patients' health records. However,

Community argues that its provider agreement should not have been terminated because after it "learned that an employee breached its confidentiality policy[,] [i]t took swift and decisive action to correct the situation, further secure its records, and educate its employees." Pet. Notice of Appeal at 27. Community further states, "All of this action was taken before the September survey and, thus, was not a pre-existing problem for which Community should be penalized." Id. Community also asserts that it "took appropriate steps to ensure that patient records were maintained before the termination of its Medicare Provider Agreement." Pet. Reply Br. at 7.

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. Excelsior Health Care Services, Inc., DAB No. 1529, at 6-7 (1995). Thus, Community's assertion that it had taken corrective action by the termination date is irrelevant. Community also seems to be suggesting, however, that CMS may not find a facility out of substantial compliance without showing that the noncompliance identified during the survey was not corrected by the time of the survey. Community cites no authority for this legal proposition, and we need not reach it because we agree with the ALJ that Community's own undisputed evidence, construed most favorably to Community, shows that it had not corrected its deficiencies and achieved substantial compliance by the time of the September 20, 2006 survey.

The specific corrective actions that Community asserts it took include the following: "immediate action to obtain all outstanding patient records, counsel the employee involved, further secure patient records and provide additional in-service training to all Community employees." Pet. Notice of Appeal at 26. The record does contain evidence of the counseling. Pet. Ex. 11. It also contains a document indicating that certain employees attended an in-service training on "Protecting the Privacy of Patient Records" on August 25, 2006. Pet. Ex. 12. While that document does not describe the contents of the in-service beyond the information contained in the topical summary quoted above, we infer for purposes of summary judgment that the document does, as Community asserts, evidence that Community "provided in-service training for all Community employees on confidentiality of medical records." Pet. Notice of Appeal at 18. However, Community does not assert that the in-service training covered procedures for maintaining and protecting records from loss or unavailability, as well as keeping them confidential. Thus, even viewing the in-service exhibit in the light most favorable to Community, it does not support a finding

that all employees were trained to prevent a recurrence of the noncompliance as a whole.

Community cites no evidence for its assertion that it took steps to obtain all outstanding records. If Community is relying on the statement in the employee counseling report "Employee submitted attached copies of patient medical records that were maintained in the home[,]" that statement is not sufficient, even construing the evidence most favorably to Community, to infer that the copies recovered (which are not attached to the exhibit) duplicate all of the original patient records that, according to the same report, the "employee states are now lost." Pet. Ex. 11. The counseling report itself draws no connection (much less an all encompassing connection) between the lost documents and the copied documents that the employee kept in her home. Neither has Community proffered any specific evidence to show such a connection or to show that it received from the employee copies of all of the documents lost by her.[10]

With respect to its assertion that it took steps to "further secure its records," Community states that it "replaced the locks on the medical records room in completion of a pre-survey effort to further secure its medical records." Pet. Notice of Appeal at 18. In support, Community cites Petitioner's Exhibit 13, a work order for the new locks dated September 25, 2006. Id. However, as the ALJ found, that work order shows that the new locks were not installed until five days after the survey. See ALJ Decision at 8. In its reply brief, Community objects:

> CMS presented no evidence that the any [sic] existing locks were inadequate or required replacements. Furthermore, while the installation or replacements of locks is one way in which to secure records, it is not the only way. Neither HIPAA nor applicable

[10] In addition, retrieval of all copies would not alter the fact that an unspecified number of original patient health records were lost and, thus, exposed to persons not authorized to access those records and the confidential information contained in them. We agree with the ALJ that the subject employee's breach "seriously compromised patient privacy and suggests serious problems with the HHA's procedures for safeguarding its patients' records[,]" and that this, in itself, was "a serious violation of the regulation, sufficient to render the condition out of compliance." ALJ Decision at 7.

> regulations specifically require that medical records must be secured by locks.

Pet. Reply Br. at 8.

As the ALJ indicated, the burden of showing that it has corrected its deficiencies and achieved substantial compliance rests on the provider, not CMS. ALJ Decision at 8, citing Hermina Traeye Memorial Nursing Home, DAB No. 1810, at 13 (2002), aff'd sub nom. Sea Island Comprehensive Healthcare Corp. v. U.S. Dept. of Health & Human Servs., 79 F. App'x 563 (4th Cir. 2003).[11] The fact that the HHA regulations might not specifically require that records be secured by locks is immaterial. The regulations do require each HHA to take whatever steps are necessary to assure the security and privacy of its medical records. Community's choice, as a corrective action, to change the locks on its record storage room doors indicates that Community considered the new locks a necessary step to assure the security and privacy of its patient medical records. It is also clear from language in the work order for the lock replacement that Community deemed its existing locks inadequate to protect the medical records. The work order for the locks, introduced into evidence by Community, states as follows:

> BMC Home Health Medical records room is requiring a [sic] update of door locks corresponding to the same single key for compliance with HIPPA [sic] security. The (2) entrances to BMC Home Health medical records will require new door locks installed as soon as possible."

[11] Hermina Traeye involved a situation where the provider was entitled to submit and had submitted a written POC with dates by which the corrections would be completed. The Board rejected the provider's argument that simply submitting the POC established that any cited deficiencies had been corrected because under the regulations CMS must accept the POC and then verify compliance, usually by a revisit. In this case, Community submitted no POC and had no right to do so; neither did CMS have an opportunity to verify Community's assertions that it corrected its deficiencies and achieved substantial compliance. While the circumstances differ, it is reasonable to consider when assessing Community's assertions of correction the burden of proof that Community would have had to meet had it been entitled to an opportunity to correct.

Pet. Ex. 13.[12]

Furthermore, Community states that its medical records policy requires "that all patient records must be returned to the Community records storage area at the end of each day" and that the employee actions in question "were in direct violation of [that policy]." Pet. Notice of Appeal at 18. Presumably, the "records storage area" is the room where the locks were being replaced. Thus, Community itself drew a direct connection between the noncompliance for which its provider agreement was terminated and its changing of the locks on the record room.

In light of our earlier discussion of the pitfalls of sua sponte summary judgment, we have considered whether Community has proffered any evidence on the correction issue that might make a difference to our decision and have concluded that it has not proffered such evidence. At most, Community makes very general assertions to the effect that it could put on evidence if this matter were to go to trial. "If and when Community is provided an opportunity to fully present its case, appropriate evidence to document these actions will be provided." Pet. Reply Br. at 7-8. This is not a proffer of specific evidence of the type needed to defeat a motion for summary judgment. See e.g., Matsushita Elec. Industrial Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986); Livingston Care Center, DAB No. 1871, at 5, 12 (2003), aff'd, Livingston Care Ctr. v. U.S. Dept. of Health and Human Servs., 388 F.3d 168 (6th Cir. 2004) (quoting Fed. R. Civ. P. 56(e) and holding that when responding to a properly supported motion for summary judgment, the opposing party must "come forward with 'specific facts showing that there is a genuine issue for trial'"). Furthermore, in light of the undisputed evidence currently of record regarding the locks, whatever evidence Community might submit with respect to the other corrective actions it took could not overcome the undisputed fact that it did not complete all of its corrections prior to the September 20, 2006 survey.

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[12] According to the invoice, BMC means Bibb Medical Center. Community Home Health is a department of Bibb Medical Center. Pet. Notice of Appeal at 17.

Conclusion

For the foregoing reasons, we affirm in full the ALJ's findings of fact and conclusions of law, except that we modify FFCL B.1. to read as follows:

> It is not necessary to decide whether Community's request for review of the August survey was timely, since even if reviewable, the August survey findings are not material since Community did not thereafter maintain substantial compliance.

Accordingly, we uphold the ALJ's decision sustaining CMS's termination of Community's Medicare provider agreement.

/s/
Judith A. Ballard

/s/
Leslie A. Sussan

/s/
Sheila Ann Hegy
Presiding Board Member