Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Director of the Office for Civil Rights,

Petitioner,

v.

Lincare, Inc., d/b/a United Medical,

Respondent.

Docket No. C-14-1056

Decision No. CR4505

Date: January 13, 2016

DECISION

Respondent, Lincare, Inc., d/b/a United Medical, supplies respiratory care, infusion therapy, and medical equipment to patients in their homes. The estranged husband of one of its managers complained that his wife allowed him access to the "protected health information" of Lincare patients, even though he was not authorized to see it. Following a lengthy investigation, the Director of the Office for Civil Rights (OCR) determined that Respondent Lincare violated the Health Insurance Portability and Accountability Act of 1996 (HIPAA) because it did not implement policies and procedures to safeguard records containing its patients' protected health information (PHI), and it failed to protect against disclosure to unauthorized persons the PHI of 278 of its patients. OCR proposes a civil money penalty (CMP) of $239,800.

OCR moves for summary judgment, which Respondent Lincare opposes.

I agree that the undisputed evidence establishes that Lincare violated HIPAA. I therefore grant OCR's motion and sustain the $239,800 CMP.

Background

HIPAA, sections 1171 through 1180 of the Social Security Act (Act) (collectively referred to as the Administrative Simplification Provisions), creates privacy rights and protections for consumers of health services. Pursuant to its provisions, the Secretary of Health and Human Services has implemented a "Privacy Rule," which sets standards for protecting PHI. 45 C.F.R. Part 160 and Part 164, Subpart E; *see* Act § 1172(d). Except as permitted by the regulations, a "covered entity," such as Respondent Lincare (see discussion below for definition), may not disclose PHI, a type of individually identifiable health information (see below). 45 C.F.R. § 164.502(a). It "must reasonably safeguard" PHI from "any intentional or unintentional use or disclosure that is in violation of the standards, implementation specifications or other requirements" of Subpart E of the Privacy Rule. 45 C.F.R. § 164.530(c)(2).

Here, Richard Shaw was married to Lincare Manager Faith Shaw, although their marriage went through a rough patch. She left him and, in late 2008, Richard Shaw complained to OCR that she left behind documents containing the PHI of Lincare patients. The documents were in his possession even though he was not authorized to see them. OCR Exhibit (Ex.) 1; OCR Ex. 2 at 1-2 (Montoya Decl. ¶ 3). OCR investigated and determined that Respondent Lincare had violated HIPAA's Privacy Rule. In a letter dated January 28, 2014, OCR advised Respondent Lincare that it proposed imposing a $239,800 CMP. OCR Ex. 1.

Respondent Lincare appeals and OCR now moves for summary judgment. *See* 45 C.F.R. § 160.508(b)(13). With its motion and brief (OCR Br.), OCR submits 41 exhibits (OCR Exs. 1 – 41). Respondent Lincare filed a brief opposing summary judgment (R. Br.), along with one exhibit (R. Ex. 1). OCR filed a reply (OCR Reply) and Respondent filed a sur-reply (R. Sur-reply).

Issues

As a threshold matter, I consider whether summary judgment is appropriate.

On the merits, the issue is whether Respondent Lincare violated HIPAA standards. Because Respondent did not properly challenge the amount of the CMP, that issue is not before me.

Discussion

Summary Judgment. Summary judgment is appropriate if a case presents no genuine issue of material fact, and the moving party is entitled to judgment as a matter of law. *Bartley Healthcare Nursing & Rehab.*, DAB No. 2539 at 3 (2013) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-25 (1986)); *Ill. Knights Templar Home*, DAB No. 2274 at 3-4 (2009), and cases cited therein.

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 Ctr. v. Dep't of Health & Human Servs.*, 388 F.3d 168, 173 (6th Cir. 2004) (quoting *Celotex Corp.*, 477 U.S. at 323-24). 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. v. Zenith Radio Corp.*, 475 U.S. 574, 586 n.11 (1986); *see also Vandalia Park*, DAB No. 1939 (2004); *Lebanon Nursing & Rehab. Ctr.*, DAB No. 1918 (2004). The non-moving party may not simply rely on denials, but must furnish admissible evidence of a dispute concerning a material fact. *Ill. Knights Templar*, DAB No. 2274 at 4; *Livingston Care Ctr.*, DAB No. 1871 at 5 (2003).

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. *Brightview Care Ctr.*, DAB No. 2132 at 2, 9 (2007); *Livingston Care Ctr.*, 388 F.3d at 172; *Guardian Health Care Ctr.*, DAB No. 1943 at 8 (2004); *but see Brightview*, DAB No. 2132 at 10 (entry of summary judgment upheld where inferences and views of non-moving party are not reasonable). 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 Ctr.*, DAB No. 1943 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.").

Admissible evidence. Respondent Lincare argues that OCR has not demonstrated that it must prevail as a matter of law because its evidence is unreliable and inadmissible. According to Respondent, OCR's affidavits are unreliable because they include legal conclusions and "simple, unsworn hearsay." Without specifically challenging any one of the non-testimonial exhibits, Respondent characterizes them all as "un-verified pieces of paper." R. Br. at 6.[1]

As a threshold matter, the Federal Rules of Civil Procedure do not even require a movant to support its motion with affidavits. Rules 56(a) and (b) say that either party may move for summary judgment "with or without supporting affidavits." *See Celotex Corp.*,477 U.S. at 323 (finding "no express or implied requirement in Rule 56 that the moving party support its motion with affidavits or other similar materials negating the opponent's claim. On the contrary, Rule 56(c), which refers to 'the affidavits, *if any*' (emphasis added), suggests the absence of such a requirement."); *Hartnagel v. Norman*, 953 F.2d 394, 395 (8th Cir. 1992) ("The movant is not required by the rules to support its motion with affidavits or other similar materials *negating* the opponent's claim.").

Moreover, although I may apply the Federal Rules of Evidence "where appropriate," I am not bound by them, and I have broad discretion to admit evidence. I *must* exclude evidence that is irrelevant or immaterial; I *may* exclude relevant evidence "if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or by considerations of undue delay or needless presentation of cumulative evidence." 45 C.F.R. § 160.540. Applying these criteria, OCR's exhibits are unquestionably admissible:

- Affidavits. The affidavits include the testimony of Valerie Montoya, the OCR investigator assigned to Mr. Shaw's complaint. OCR Ex. 3 (Montoya Decl.). She describes Complainant Shaw's accusations, the admissions and other statements made to her by Lincare Center Manager (and estranged wife) Faith Shaw, and the admissions and other statements made to her by Lincare Area Manager Darrell Layton. Under the Federal Rules of Evidence, all of these statements would be admissible for the fact that the individuals made them.[2] Fed. R. Evid. 801(c).

[1] Respondent's criticism could more easily apply to its own exhibit – the written declaration of Lincare Corporate Compliance Officer Jenna Pederson. Without additional foundation or explanation, she declares as true selected quotations from statements that she and two other Lincare employees made, which Respondent cited in its brief opposing summary judgment. R. Ex. 1.

[2] Unless offered for the truth of the matter asserted, the statements would not even qualify as hearsay. Fed. R. Evid. 801(c)(2).

Moreover, because Lincare employees made these statements about "a matter within the scope of [their employment] relationship . . . while it existed," they are admissible as exceptions to the hearsay rule. Rule 801(d)(2).

Respondent Lincare claims that Center Manager Shaw made her statements to Investigator Montoya after her employment at Lincare had ended. R. Sur-reply at 6. But Respondent offers no evidence of – in fact, does not even mention – when the employment relationship ended. In correspondence dated July 28, 2009, Lincare told Investigator Montoya that Ms. Shaw was the Center Manager until July 2009 and then became a patient account coordinator in Lincare's Regional Billing and Collections office. OCR Ex. 30 at 2; *see also* OCR Ex. 12 at 1; OCR Ex. 32 at 4.[3]

More remarkably, Respondent also claims – again without providing any support – that the statements made by Center Manager Shaw and Area Manager Layton are outside the scope of their jobs. R. Sur-reply at 6. This cannot possibly be true. The statements in question refer to the Lincare policies and instructions for protecting PHI and to Manager Shaw's handling of the PHI she removed from the office she managed. Both Manager Shaw and Area Manager Layton, who was Manager Shaw's immediate supervisor, explained the company's policies for maintaining PHI taken out of the office. Their jobs required them to handle, or supervise those who handled, PHI. If protecting PHI were "outside the scope" of their jobs, the company was guilty of even more serious HIPAA violations than those alleged here. But the actual uncontroverted evidence establishes that these PHI matters were within the scope of their employment.

Investigator Montoya also authenticates some of OCR's exhibits, specifically, the compromised documents containing PHI that Mr. Shaw turned over to OCR (see below). OCR Ex. 3 at 2 (Montoya Decl. ¶ 8); OCR Ex. 5; OCR Ex. 7.

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[3] Some evidence suggests that, by late August 2010, Manager Shaw no longer worked at Lincare. OCR Ex. 19. In the absence of any evidence to the contrary, I could reasonably infer that she was still an employee when she spoke to Investigator Montoya in August 2009 and even as late as June 2010. Of course, her departure from the company does not make her subsequent statements inadmissible in these proceedings, particularly considering that they are supported by other evidence and not specifically challenged by Lincare. 45 C.F.R. § 160.540; *see Florence Park Care Ctr.*, DAB No. 1931 (2004) (holding that the moving party must submit evidence only with respect to facts that are in dispute).

The second affidavit was prepared by Laurie A. Rinehart-Thomas, the director of Health Information Management and Systems at Ohio State University. Ms. Rinehart-Thomas is certified by the American Health Information Management Association as a registered health information administrator. OCR Ex. 4 (Rinehart-Thomas Decl.). She offers her expert opinion on Respondent Lincare's HIPAA compliance and also describes standards in the industry against which to measure the reasonableness of Respondent's conduct. To the extent that her declaration asserts facts regarding industry standards and practices, those facts would be relevant and material. While I agree that I have the ultimate authority to decide legal questions, I do not agree that a witness's declaration is inadmissible simply because it includes legal conclusions. Indeed, the rules say the opposite. Rule 704 says that an opinion "is not objectionable just because it embraces the ultimate issue." Fed. R. Evid. 704(a).[4]

- Other exhibits. Nor are OCR's other exhibits "unverified pieces of paper" that would not be admissible. Not only are OCR's exhibits relevant and material and thus admissible under 45 C.F.R. § 160.540, they would be admissible under the Federal Rules. They include:

    1. OCR's notice letter and other correspondence between OCR and Respondent Lincare (OCR Exs. 1, 29, 30, 31, 32);

    2. Complainant Shaw's written complaint (OCR Ex. 2) and other documents from OCR's investigation (OCR Exs. 6, 10, 17, 18, 19, 20);

    3. The Lincare patient documents containing the PHI that is the subject of this appeal (OCR Exs. 5, 7, 10);

    4. Respondent Lincare's written policies and procedures regarding patient PHI (OCR Exs. 8, 9);

    5. Email correspondence among Lincare employees regarding the missing documents (OCR Exs. 11, 12, 13);

    6. Handwritten notes of a Lincare employee, which describe employee conversations regarding the missing documents (OCR Exs. 20-28);

    7. The criminal court docket sheet for a criminal complaint the company brought against Complainant Richard Shaw (OCR Ex. 14);

[4] Ms. Rinehart-Thomas offers interesting insights into the types of practices companies use to protect PHI. These might have been useful in a closer case. But, here, I need not rely on her opinions in order to conclude that Lincare violated HIPAA.

8. Correspondence between Respondent Lincare and Complainant Shaw regarding the missing documents (OCR Exs. 15, 16);

9. Transcripts of Investigator Montoya's interviews with Lincare employees (OCR Exs. 33, 34);

10. Research materials regarding the importance of protecting PHI (OCR Exs. 35-38); and

11. OCR materials with instructions about protecting PHI (OCR Exs. 39-41).

Respondent Lincare has not come forward with any evidence suggesting that this evidence is unreliable and does not even allege that it disputes the underlying facts established by these documents. In fact, it has explicitly admitted most of them. R. Br. at 2-5.

OCR has thus come forward with admissible evidence, which, as the following discussion shows, establishes that it must prevail at trial. To avoid summary judgment, Respondent Lincare had to come forward with evidence showing a dispute of material fact. But it has not done so, and OCR is therefore entitled to summary judgment. *See Guardian Health Care Ctr.*, DAB No. 1943 (finding summary judgment appropriate where the moving party identified certain facts as undisputed, and the nonmoving party failed to identify which of those facts were in dispute, relying instead on unsubstantiated assertions and generalizations to oppose the motion); *Florence Park Care Ctr.*, DAB No. 1931.

1. OCR is entitled to summary judgment because the undisputed evidence establishes that Respondent Lincare did not reasonably safeguard the PHI of its patients, as required by 45 C.F.R. § 164.530(c), which allowed an unauthorized individual access to that information.[5]

Privacy Rule. As noted above, HIPAA creates privacy rights and protections for consumers of health services, and, pursuant to its provisions, the Secretary has implemented the Privacy Rule, which mandates that a covered entity reasonably safeguard PHI from any use or disclosure that violates the rule's requirements. 45 C.F.R. § 164.530(c)(2).

"Disclosure" includes "the release, transfer, provision of access to, or divulging of information outside the entity holding the information." 45 C.F.R. § 160.103.

[5] My findings of fact/conclusions of law are set forth, in italics and bold, in the discussion captions of this decision.

The regulations define "covered entity," as 1) a health plan; 2) health care clearing house; or 3) health care provider who transmits any health information in electronic form in connection with a transaction covered by HIPAA. Act § 1172(a); *see* Act § 1173(a)(1); 45 C.F.R.§§ 160.102, 160.103, 160.104. Employees, volunteers, trainees, and other persons whose conduct, in performing work for a covered entity, is "under the direct control of such covered entity" are considered the entity's "workforce." 45 C.F.R. § 160.103.

"Health information" means any information, whether oral or recorded in any form, that 1) is created or received by, among other entities, a health care provider; and 2) relates to an individual's physical or mental health or condition, the provision of care to an individual, or payment for providing health care to an individual. 45 C.F.R. § 160.103. The regulations then define particular types of health information:

- "Individually identifiable health information" is a subset of health information, *including demographic information*, that is collected from an individual. It is created or received by a health care provider or other specified entity, and relates to an individual's physical or mental health or condition (past, present, or future); the provision of health care to an individual; or payment for providing health care to an individual. The information identifies an individual or could be used to identify an individual. 45 C.F.R. § 160.103.

- "Protected health information" (PHI) is a type of individually identifiable health information. With limited exceptions not applicable here, it means identifiable health information that is transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium. 45 C.F.R. § 160.103.

HIPAA authorizes the Secretary to impose CMPs on those who violate its standards. It incorporates most of the existing CMP provisions of the Act, which are found at section 1128A. Act § 1176(a)(2); 45 C.F.R. § 160.402(a). Section 1128A of the Act makes a principal liable for the actions of its agent acting within the scope of that agency. Act § 1128A(*l*); 45 C.F.R. § 160.402(c)(1).

Lincare's HIPAA violations: disclosure of PHI to an unauthorized individual. The material facts of this case are not in dispute. Respondent Lincare supplies oxygen and other respiratory therapy equipment and services to patients in their homes or at alternative sites. It operates more than 850 branch locations in 48 states. R. Br. at 1. The parties agree that Lincare is a "covered entity." OCR Br. at 4; R. Br. at 2.

This case centers around the Lincare branch located in Wynne, Arkansas, which was doing business as United Medical. Faith Shaw was the Wynne Center's manager from October 2005 until July 2009 and, as such, was responsible for maintaining the PHI of its patients. The parties agree that she was a workforce member. OCR Br. at 4; R. Br. at 2; OCR Ex. 19; OCR Ex. 32 at 3 (referring to Ms. Shaw as "Ms. Williams").

Among other materials, Ms. Shaw was responsible for:

- An "Emergency Procedures Manual," dated February 2005, which contained PHI of 270 Lincare patients, specifically their names, addresses, telephone numbers, and emergency contacts (OCR Br. at 4; R. Br. at 4; OCR Ex. 5); and

- Patient-specific documents dated between June 2007 and July 2008 for eight Lincare patients. These included patient assessments and care plans, physician prescriptions, certificates of necessity, and confirmations of orders. These documents also contained patient names, addresses, telephone numbers, dates of birth, medical symptoms, diagnoses, medical test results, prescriptions, names of physicians, and names of pharmacies. OCR Br. at 4-5; R. Br. at 4; OCR Ex. 7.

The parties agree that all of these materials included PHI. OCR Br. at 4; R. Br. at 2-3.

The parties also agree that, because Lincare employees provided services away from the company's offices, they had to remove from those offices records containing PHI. In addition, prior to November 2008, the company instructed its center managers to maintain copies of the procedures manual "secured" in their vehicles so that company employees would have access to patient contact information if a center office were destroyed or otherwise made inaccessible. OCR Ex. 18 at 1-2; OCR Ex. 33 at 30; OCR Ex. 34 at 20-22, 26, 30, 33; R. Br. at 9.

Accordingly, Center Manager Shaw took from the office the manual and other documents containing PHI. She told the OCR investigator that she kept the documents in her car even though she knew that her husband had keys to the car. When she moved out of the marital home in August 2008, she left the documents behind. She also admitted to the OCR investigator that, when she left, she didn't even know where the car was parked. OCR Ex. 18.

Neither Center Manager Shaw nor anyone else from Lincare realized that the documents were missing until about November 2008, when Richard Shaw – who, everyone agrees, was not authorized to see the PHI – reported to Lincare and then to OCR that he had them. OCR Br. at 5; R. Br. at 3-4; OCR Ex. 3 at 2-6 (Montoya Decl. ¶¶ 7, 10, 11, 17); OCR Ex. 17, OCR Ex. 18; OCR Ex. 30 at 1, OCR Ex. 33 at 13.

Affirmative Defenses. HIPAA limits the affirmative defenses available to Respondent Lincare. Act § 1176(a)(1). For violations occurring on or after February 18, 2009, OCR may not impose a CMP if: 1) the covered entity establishes that it did not know about the violation (determined in accordance with federal common law of agency) and, by exercising reasonable diligence, would not have known about the violation; or 2) despite the exercise of ordinary business care and prudence, circumstances made it unreasonable for the covered entity to comply with the violated provision; the violation was not caused by "willful neglect"; and it was corrected within 30 days of the date the covered entity knew or should have known about it. OCR may extend the 30-day period as it deems appropriate, "based on the nature and extent of the failure to comply." 45 C.F.R. § 160.410(b).

Respondent Lincare claims that it was the victim of a theft, for which it should not be held accountable. Without providing evidence to support its accusations, it maintains that Complainant Shaw "stole" the manual and attempted to use it as leverage to induce his estranged wife to return to him. R. Br. at 16. For purposes of summary judgment, I need not accept such unsupported allegations as true. But even if I accepted the allegations, Lincare's "defense" is just as damaging – perhaps even more damaging – than the OCR version of events. Under HIPAA, Respondent was obliged to take reasonable steps to protect its PHI from theft.[6] It violated that obligation when Manager Shaw took documents out of the office, left them in places (car or home) accessible to this purportedly untrustworthy and possibly unbalanced individual, and then, apparently without giving a thought to the security of those documents, abandoned them entirely.[7]

Further, as OCR correctly points out, even after it learned of the breach, Lincare took no steps to prevent further disclosure of PHI. Indeed, managers did not seem to recognize that they had a significant problem protecting PHI that was removed from the office. When asked whether Lincare considered revising its policies to include specific guidelines for safeguarding PHI taken out of its offices, Corporate Compliance Officer

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[6] The drafters of the regulations noted that theft "may or may not signal a violation of [the Privacy Rule], depending on the circumstances and whether the covered entity had reasonable policies to protect against theft." 65 Fed. Reg. 82462, 82562 (December 28, 2000).

[7] Lincare has not come forward with a shred of evidence to substantiate its defamatory allegations against Complainant Shaw, and, in fact, all the evidence before me suggests that he found the documents in the house or car that he shared with his wife. *See, e.g.*, OCR Exs. 17, 18. The company filed a criminal complaint against him and had him arrested, but the charges were dropped. OCR Ex. 14 at 2; R. Br. at 3. In any event, there is no question that Mr. Shaw called OCR to report the unauthorized disclosure and that he turned the documents over to that office. He may have wanted to punish his wife or to compel her return, but his is hardly the behavior of someone intent on stealing PHI.

Pederson replied that Lincare personnel "considered putting a policy together that said thou shalt not let anybody steal your protected health information." OCR Ex. 33 at 29. I do not consider this a serious response.

Thus, undisputed evidence establishes that Manager Shaw, a Lincare workforce member, removed her patients' PHI from the company office, left it in places to which her husband, an unauthorized person, had access, and then abandoned it altogether. Neither she nor anyone else at Lincare even knew that the information was missing until months later. Lincare thus failed to "reasonably safeguard" its patients' PHI and violated section 164.530(c) of the HIPAA Privacy Rule.

2. OCR is entitled to summary judgment because the undisputed evidence establishes that, in violation of 45 C.F.R. § 164.530(i), Respondent Lincare failed to develop or implement policies and procedures to protect from disclosure the PHI that staff removed from branch offices.

HIPAA requirements. A covered entity must implement policies and procedures that, with respect to PHI, comply with the "standards, implementation specifications, or other requirements" of subparts D and E of the Privacy Rule. The policies and procedures must be reasonably designed, taking into account the size *and the type of activities* undertaken by the covered entity to ensure compliance. 45 C.F.R. § 164.530(i)(1). The covered entity must maintain its policies and procedures "in written or electronic form." 45 C.F.R. §164.530(j)(1)(i).

Lincare's HIPAA violation: inadequate policies and procedures for protecting PHI. As noted above, the parties agree that, in order to perform their duties, Lincare employees had to take out of the office documents containing PHI. OCR Br. at 5; R. Br. at 3-4. The parties also agree that Lincare was required to develop and implement policies and procedures reasonably designed to protect its patients' PHI while those documents were out of the office. OCR Br. at 6; R. Br. at 6-7.

In attempting to identify a material fact in dispute, Respondent Lincare asserts that the question of whether its policies were "reasonably designed" presents a factual dispute requiring a hearing. R. Br. at 7. But deciding whether Lincare's policies met the regulatory requirements that they be reasonably designed is a legal question. And, as the undisputed evidence establishes, Lincare's policies were inadequate. In fact, no written policy even addressed staff's protecting PHI that was removed from the offices.

At the time of the unauthorized disclosures to Complainant Shaw, Respondent Lincare had in place a written privacy policy that addressed maintaining records within the center offices but said nothing about removing them from those offices. Indeed, a strict reading of the policy suggests that such documents should not leave the office, but must be kept in areas inaccessible to all except company employees. The policy explicitly prohibits

outsiders from areas where PHI is stored, limiting their access to the office's "front entrance area or lobby." OCR Ex. 9 at 4 ("Access to areas containing PHI is limited to company employees.").

The company ostensibly revised its policies in 2009, which was after it learned of the unauthorized disclosure. Yet, the new policies and procedures provide no guidance to employees required to remove documents from the office's secured storage space; in that respect, its policies for protecting patient records were virtually unchanged. OCR Ex. 8 at 4. Indeed, as noted above, Lincare management did not seem to recognize any problem and did not seriously consider amending its policies to safeguard PHI removed from the office. OCR Ex. 33 at 29 ("We considered putting a policy together that said thou shalt not let anybody steal your protected health information.").

According to Area Manager Layton, sometime after the breach – he could not remember when – he instructed staff to return all patient-specific information to the center on the same day it was taken out. Area Manager Layton conceded that he had no written record of those instructions. OCR Ex. 34 at 27; *see* R. Br. at 9 (affirming that staff were instructed to return the manual to the offices at night, but not indicating when that policy went into effect).

To establish that it had in place and implemented an adequate policy, Respondent Lincare points to the following bullet point in the written policy:

- Information Storage – filing cabinets and medical charts are to be kept in secured locations where they cannot be accessed by the public.

OCR Ex. 8 at 4; OCR Ex. 9 at 4; R. Br. at 7.

In context, this provision plainly addresses file storage within the office. It and other instructions are explicitly addressed to "each location," not to the individual employees, and it is in a list of instructions for storage of information within the office. But, even if it applied to documents taken out of the office, the policy does not satisfy the regulation because it provides no usable guidance to employees. Given the "type of activities" Lincare employees engage in, i.e., providing care in patient homes and regularly taking PHI out of the office, the bullet point does nothing to ensure compliance with the requirements of the Privacy Rule.

Respondent Lincare suggests that its policies are deliberately broad so that the individual centers could tailor them to meet their differing needs. R. Br. at 7. Developing such individualized policies, which take into account an office's size and type of activities,

would certainly be consistent with the regulations. But those policies must still be maintained "in written or electronic form." Respondent Lincare has come forward with no such policies for its Wynne, Arkansas (or any other) branch and does not claim that they existed in the required format.

Instead, Respondent Lincare suggests that it satisfied HIPAA requirements because its employees were trained in privacy policies, and "understood those policies, practices and procedures[.]" R. Br. at 8. But even if this training were flawless (and no evidence suggests that it was even adequate), staff training does not compensate for missing policies.[8] *In addition* to having policies and procedures in place, the covered entity must train all members of its workforce. 45 C.F.R. § 164.530(b).

Finally, the company had no policies – written or otherwise – in place to monitor documents removed from their offices and to ensure their return. This meant that PHI could be missing for indefinite periods without the company's knowledge, as happened with the documents Manager Shaw removed and later abandoned.

Respondent Lincare presents no evidence to establish that it maintained, in written or electronic form, policies and procedures reasonably designed to address protecting the PHI removed from its offices. Indeed, no evidence suggests that it implemented any coherent policies to keep that information secure. It therefore violated section 164.530(i) of the HIPAA Privacy Rule.

3. Respondent Lincare has waived any challenge to the amount of the proposed penalty.

OCR argues that Respondent Lincare has waived any challenge to the amount of the CMP. I agree. To preserve that issue, a party's hearing request must include "the factual and legal basis for opposing the penalty." 45 C.F.R. § 160.504(c); OCR Ex. 1 at 8; OCR Reply at 18. Here, except to challenge the HIPAA violation itself, neither Lincare's hearing request nor its subsequent submissions challenge the amount of the penalty. It thus waived any challenge to the amount of the penalty.

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[8] Respondent offers no real evidence describing the training curriculum. It relies on selected quotes from company employees describing their training. The employee descriptions are far from comprehensive; they do not specify what the policies were or when they were implemented. For example, Respondent quotes Service Representative Robert Dean Scott describing a Wynne Center policy to return the manual to the office at night. R. Br. at 9. Neither he nor Respondent indicates when this policy went into effect. R. Br. at 9. Based on the undisputed evidence in the record, it probably occurred sometime after the breach. OCR Ex. 34 at 27.

Moreover, even if it had otherwise preserved the issue, the respondent has the burden of going forward and the burden of persuasion with respect to any challenge to the amount of the proposed penalty. 45 C.F.R. § 160.534(b)(ii). Because it proffers no evidence or argument attacking the amount of the penalty, Respondent Lincare has not met its burden, and I must affirm the amount of the proposed penalty.

Conclusion

The undisputed evidence establishes that Lincare violated HIPAA because it failed to safeguard the PHI of its patients; a member of its workforce disclosed patient PHI to an unauthorized person; and it lacked policies and procedures reasonably designed to ensure compliance with the Privacy Rule. I therefore grant OCR's motion for summary judgment and sustain the $239,800 CMP.

/s/
Carolyn Cozad Hughes
Administrative Law Judge