



Director
Office for Civil Rights
Washington, D.C. 20201

Via Certified Mail
U.S. Postal Service
Return Receipt Requested

January 28, 2014

Mr. Paul Tripp
General Counsel
Lincare, Inc.
19387 U.S. Highway 19 North
Clearwater, FL 33764

Re: OCR Transaction Number: 09-92774

NOTICE OF PROPOSED DETERMINATION

Dear Mr. Tripp:

Pursuant to the authority delegated by the Secretary of the United States Department of Health and Human Services (HHS) to the Director of the Office for Civil Rights (OCR), I am writing to inform you that OCR is proposing the imposition of a civil money penalty (CMP) of \$239,800 against Lincare, Inc. d/b/a United Medical (hereinafter referred to as "Lincare").

This action is being taken under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), § 262(a), Pub.L. 104-191, 110 Stat. 1936, as amended, codified at 42 U.S.C. § 1320d-5, and under the enforcement regulations at 45 C.F.R. Part 160, Subpart D.

I. The Statutory Basis for the Proposed Civil Money Penalty

The Secretary of HHS is authorized to impose CMPs (subject to the limitations at 42 U.S.C. § 1320d-5(b)) against any covered entity, as described at 42 U.S.C. § 1320d-1(a), that violates a provision of Part C (Administrative Simplification) of Title XI of the Social Security Act. See 42 U.S.C. § 1320d-5(a), as amended. This authority extends to violations of the regulations commonly known as the Privacy Rule promulgated at 45 C.F.R. Part 160 and subparts A and E of Part 164, pursuant to Section 264(c) of HIPAA. The Secretary has delegated enforcement responsibility for the Privacy Rule to the Director of OCR. See 65 Fed. Reg. 82381 (Dec. 28, 2000).

For violations of the Privacy Rule occurring prior to February 18, 2009, OCR is authorized to impose CMPs of up to \$100 for each such violation, provided that the total amount imposed on a covered entity for violations of an identical requirement or prohibition during a calendar year may not exceed \$25,000. For violations of the Privacy Rule occurring on or after February 18, 2009, pursuant to section 13410(d) of the Health Information Technology for Economic and Clinical Health (HITECH) Act, which was enacted as part of the American Recovery and Reinvestment Act, Pub.L. 111-5, 123 Stat. 115 and which amended the penalty amounts established under HIPAA, OCR is authorized to impose CMPs of not less than \$100 (violation without actual or constructive knowledge); \$1,000 (violation due to reasonable cause); \$10,000 (violation due to willful neglect corrected in 30 days); or \$50,000 (violation due to willful neglect not timely corrected), provided that the total amount imposed on a covered entity for violations of an identical requirement or prohibition during a calendar year may not exceed \$1,500,000. See 42 U.S.C. § 1320d-5(a); 45 C.F.R. § 160.404(b).

II. Findings of Fact

1. Lincare is a covered entity within the definition of that term set forth at 45 C.F.R. § 160.103 and, as such, is required to comply with the requirements of the Privacy Rule. Lincare is a health care provider of respiratory care, infusion therapy, and medical equipment to patients in their homes.
2. Lincare is headquartered in Clearwater, Florida, and operates over 1,200 centers in the United States, including an operating center located in Wynne, Arkansas, that, at the time of the acts and omissions described herein, was doing business as United Medical.
3. Lincare created and maintained protected health information (PHI) related to 278 certain individuals who received health care services from members of the workforce of Lincare from the operating center in Wynne, Arkansas (patients).
4. Lincare employed Faith Shaw as a manager (Center Manager) of the operating center in Wynne from October, 2005 to July, 2009. The Center Manager used the PHI of the 278 patients in the course of her duties.
5. On December 1, 2008, Richard Shaw (Complainant), filed a complaint with OCR asserting that he found the PHI of the 278 Lincare patients inside the home in Wynne, Arkansas he shared with his wife, the Center Manager. Specifically, the Complainant states that he found the PHI under a bed and in a kitchen drawer in approximately November 2008. According to the Complainant, the Center Manager left the PHI in the home when she moved out in approximately August 2008. Complainant delivered the PHI of the 278 Lincare patients to OCR.
6. OCR notified Lincare in writing of its commencement of an investigation of the complaint and of Lincare's compliance with the Privacy Rule on or about June 23, 2009.

7. The PHI of the 278 Lincare patients consists of the following:
 - (A) the names, addresses, telephone numbers and emergency contacts for 270 Lincare patients in an Emergency Procedures Manual dated February 2005 (the Manual); and
 - (B) Patient Assessment and Care Plans, Physician Prescriptions, Certificates of Necessity and Confirmation of Orders containing names, addresses, telephone numbers, dates of birth, medical symptoms, diagnosis, medical test results, prescriptions, names of physicians and names of pharmacies for an additional eight (8) Lincare patients. These documents are dated between June 2007 and July 2008.
8. The Center Manager kept and maintained the PHI described in #7 above continuously, including overnight, in either a vehicle to which the Complainant had access and/or in the home she shared with the Complainant from at least February 1, 2008, until it was found by the Complainant in November 2008. The Center Manager knew that the Complainant had a key to the vehicle and could access the PHI that was kept in the vehicle. Likewise, the Center Manager knew that any PHI kept in the shared home could be accessed by the Complainant.
9. The Center Manager kept and maintained the PHI described in #7 above without safeguards and in such a manner that the Complainant who had access to the vehicle and the shared home could access the PHI described in #7 above.
10. The Center Manager, a workforce member and agent of Lincare, knew or, by exercising reasonable diligence, would have known that the manner in which she kept and maintained the PHI (left continuously, including overnight, in either a vehicle to which she knew the Complainant had access and/or in the home she shared with the Complainant) was not an appropriate way to reasonably safeguard such PHI as required by the Privacy Rule.
11. In keeping and maintaining the PHI described in #7 above without safeguards and in the manner described in #8 and #9 above, the Center Manager provided access to said PHI to the Complainant in approximately November 2008.
12. Lincare's Center Manager, a workforce member and agent of Lincare, knew or, by exercising reasonable diligence, would have known that the Complainant had access to the PHI and that his access to said PHI was not permitted by the Privacy Rule.
13. The Complainant was not authorized to have access to, receive, or use the PHI of the 278 Lincare patients. He was not employed by Lincare as a workforce member or otherwise entitled in any role or capacity to access, receive or use said PHI.
14. Lincare's policies and procedures permitted the Center Manager to keep the PHI described above in #7 in a vehicle for long periods, including overnight, during the period from at least February 1, 2008, until November 2008. Lincare did not record or track the Center

Manager's movement of the PHI described in #7 above into or out of its operating center in Wynne and did not instruct the Center Manager in how to maintain the PHI described in #7 above in a safe and secure manner other than a verbal instruction to keep PHI on the floor of the vehicle.

15. Lincare's policies and procedures for safeguarding PHI in effect during the period of approximately February 1, 2008, to at least July 29, 2009, was its "Company Privacy Policy Health Insurance and Portability Act" ("Privacy Policy"). The Privacy Policy was developed at the corporate level of Lincare by the Corporate Compliance Officer and was applicable to the Lincare operating center in Wynne, Arkansas. The Privacy Policy generally provides that employees are to "keep confidential [PHI] and other information with respect to the patient" and requires "that health information be safeguarded." The Privacy Policy instructs employees how to limit disclosures at the operating centers (including such topics as keeping nonemployees out of the work areas, workplace layout, computer security, chart security, fax and e-mail security, information storage and rules covering conversations). However, the Privacy Policy does not include any policies, procedures or instructions for safeguarding PHI that is taken off the premises of an operating center by an employee.
16. Lincare's policy was to permit employees to take PHI off the premises of the operating center in Wynne, Arkansas, on a daily, routine basis owing to the nature of its health care services that are delivered in the homes of patients. No record or tracking of the PHI that is taken off the premises of said operating center was implemented by Lincare or was included in its policies and procedures for safeguarding PHI during the period of approximately February 1, 2008, to at least July 29, 2009.
17. Lincare knew or, by exercising reasonable diligence, would have known, that its policies and procedures were not reasonably designed to ensure compliance with the requirements of the Privacy Rule to appropriately and reasonably safeguard PHI from unintentional disclosure to unauthorized persons.
18. In as much as OCR's investigation indicated Privacy Rule noncompliance by Lincare, OCR attempted to reach a resolution of the matter by informal means during the period from approximately March 25, 2013, to November 28, 2013.
19. On July 17, 2013, OCR informed Lincare that its investigation indicated that Lincare failed to comply with the Privacy Rule and that this matter had not been resolved by informal means despite OCR's attempts to do so. The letter stated that pursuant to 45 C.F.R. §160.312(a)(3), OCR was informing Lincare of the preliminary indications of noncompliance and providing Lincare with an opportunity to submit written evidence of mitigating factors under 45 C.F.R. §160.408 or affirmative defenses pursuant to 45 C.F.R. §160.410 for OCR's consideration in making its determination of a CMP pursuant to 45 C.F.R. §160.404. The letter stated that Lincare could also submit written evidence to support a waiver of a CMP for violations that were due to reasonable cause and not due to

willful neglect pursuant to 45 C.F.R. §160.412. Each of Lincare's indicated acts of noncompliance and the potential CMP for them were described in the letter. The letter was delivered to Lincare by United Parcel Service and was received by Lincare's agent on July 18, 2013.

20. Lincare responded to the OCR letter referenced in #19 above on or about August 15, 2009.
 - (A) OCR has determined that the information and arguments submitted by Lincare do not support an affirmative defense pursuant to 45 C.F.R. §160.410. (*See* Section IV below).
 - (B) Lincare's response citing mitigating factors pursuant to 45 C.F.R. §160.408 has been considered in determining the amount of the CMP indicated below. (*See* Section V below).
 - (C) OCR has determined that the information and arguments submitted by Lincare do not support a waiver of the CMP pursuant to 45 C.F.R. §160.412. (*See* Section VI below).
21. OCR obtained the authorization of the Attorney General of the United States prior to issuing this Notice of Proposed Determination to impose a CMP.

III. Basis for Civil Money Penalty

Based on the above findings of fact, OCR has determined that Lincare is liable for the following violations of the Privacy Rule and, therefore, is subject to a CMP.

1. **Impermissible Disclosure of Protected Health Information** 45 C.F.R. § 164.502(a). The Center Manager, as a workforce member and agent of Lincare, provided access to the PHI of the 278 Lincare patients to the Complainant and, thereby, impermissibly disclosed said PHI of the 278 patients to an unauthorized person. While Lincare has argued that the Complainant stole the PHI from the vehicle, OCR has determined that such argument is irrelevant to the determination of the impermissible disclosure of the PHI of the 278 patients because the Center Manager provided the Complainant access to the PHI in the vehicle and/or in the home and the provision of access to PHI constitutes a disclosure pursuant to the definition of disclosure at 45 C.F.R. § 160.103. Moreover, the Center Manager abandoned the PHI of the 278 Lincare patients when she left the shared home on or about August, 2008. The impermissible disclosure of each individual patient's PHI by the Center Manager, who was a Lincare work force member and agent at the time of the provision of access, constitutes a separate violation of 45 C.F.R. § 164.502(a). The Center Manager knew or, by exercising reasonable diligence, would have known that her acts and omissions violated the requirements of the Privacy Rule but she did not act or fail to act with willful neglect.

2. **Failure to Safeguard Protected Health Information** 45 C.F.R. § 164.530(c).
The Center Manager, as a workforce member and agent of Lincare, maintained the PHI of 278 Lincare patients in either a vehicle or in the home she shared with the Complainant without reasonable and appropriate safeguards to protect the PHI from disclosure during the period from at least February 1, 2008, until November 2008. Each day that the Center Manager failed to implement appropriate safeguards to reasonably protect the PHI from use or disclosure to unauthorized persons constitutes a separate violation of 45 C.F.R. § 164.530(c). The Center Manager knew or, by exercising reasonable diligence, would have known that her acts and omissions violated the requirements of the Privacy Rule but she did not act or fail to act with willful neglect.

3. **Administrative Requirements: Policies and Procedures** 45 C.F.R. § 164.530(i)(1).
Lincare implemented policies and procedures that allowed its workforce members at the operating center in Wynne, Arkansas, to remove PHI from the center and maintain it in vehicles overnight and for indefinite periods of time without specifying reasonable and appropriate administrative and/or physical safeguards for workforce members to follow to protect PHI from disclosure under such circumstances. This omission in Lincare's policies and procedures, which existed during the period of approximately February 1, 2008, to at least July 29, 2009, violates the standard at 45 C.F.R. § 164.530(i)(1) that requires Lincare to implement policies and procedures that are reasonably designed to ensure compliance with the other standards of the Privacy Rule, which in this instance is the safeguards standard at 45 C.F.R. § 164.530(c). Lincare knew or, with the exercise of reasonable diligence, would have known that its acts and omissions violated the requirements of the Privacy Rule but it did not act or fail to act with willful neglect.

IV. No Affirmative Defenses

By its letter of July 11, 2013, OCR offered Lincare the opportunity to provide written evidence of mitigating factors or affirmative defenses and/or its written evidence in support of a waiver of a CMP within thirty (30) days from the date of receipt of that letter. By letter dated August 15, 2013, Lincare submitted its response to OCR's July 11, 2013, letter. OCR has determined that the information contained therein did not provide a sufficient basis for an affirmative defense to the findings of violations pursuant to 45 C.F.R. § 160.410.

With respect to the violations that occurred prior to February 18, 2009, OCR determined that no affirmative defenses are available. Lincare, through its workforce members and agents, knew of the violations or, by exercising reasonable diligence, would have known of the violations (Findings #10, 12, and 17). See 45 C.F.R. §160.410(b)(1).

With respect to each of the violations, whether they occurred before, on or after February 18, 2009, Lincare did not correct the violation within a 30-day period from the first date that it knew,

or, by exercising reasonable diligence, would have known of the violations. *See* 45 C.F.R. §160.410(b)(2) and (c)(2).

V. Factors in Determining the Amount of the Civil Money Penalty

In determining the amount of the CMP for each violation, OCR has considered the following factors in accordance with 45 C.F.R. § 160.408.

OCR considered Lincare's assertion that the CMP should be mitigated because no similar incidents of impermissible disclosures of PHI at any other Lincare operating center had been reported. In consideration of Lincare's assertion of this mitigating factor, OCR has proposed the minimum penalty amount of \$1,000 per day for the violations on or after February 18, 2009, that were due to reasonable cause and not willful neglect under 45 C.F.R. § 160.404(b)(2)(ii)(A).

Each of the factors listed below was considered an aggravating factor in determining the amount of the CMP:

The amount of time that Lincare continued to follow policies and practices that allowed workforce members to transport PHI away from the operating center without appropriate and reasonable safeguards. *See* 45 C.F.R. § 160.408(a)(2); and Lincare's failure to promptly review and revise its HIPAA policies and procedures regarding physical and administrative safeguards for PHI transported away from the operating center after it was notified of the disclosure of PHI in November, 2008. *See* 45 C.F.R. § 160.408(c)(2).

VI. Waiver

In considering the imposition of the CMP, OCR has determined that there is no basis for waiver of the CMP amount based on 45 C.F.R. § 160.412 because no evidence has been presented that the payment of the CMP would be excessive relative to the violations found here and described in OCR's letter to Lincare of July 11, 2013.

VII. Amount of the Civil Money Penalty

Based on the foregoing, OCR finds that Lincare is liable for the following CMP amounts for the violations described in Section III:

Amount of CMP per Violation

1. Impermissible Disclosure of Protected Health Information 45 C.F.R. § 164.502(a): The CMP is \$25,000 (see attached chart). This CMP amount is based on 45 C.F.R. § 160.404(b)(1).

2. Failure to Safeguard Protected Health Information 45 C.F.R. § 164.530(c): The CMP is \$25,000 (see attached chart). This CMP amount is based on 45 C.F.R. § 160.404(b)(1).
3. Administrative Requirements: Policies and Procedures 45 C.F.R. § 164.530(i)(1): The CMP is \$189,800 (see attached chart). This CMP amount is based on 45 C.F.R. § 160.404(b)(1) for the daily violations that occurred prior to February 18, 2009. This CMP amount is also based on 45 C.F.R. § 160.404(b)(2)(ii) for the daily violations that occurred on and after February 18, 2009.

Total Amount of Civil Money Penalty

The total amount of the CMP for which OCR finds Lincare liable with regard to the violations of the Privacy Rule described in Section III is **\$239,800** (see enclosed chart).

VIII. Right to a Hearing

Lincare has the right to a hearing before an administrative law judge to challenge this proposed CMP. To request a hearing to challenge this proposed CMP, Lincare must mail a request, via certified mail with return receipt request, under the procedures set forth at 45 C.F.R. Part 160 within 90 days of your receipt of this letter. Such a request must: (1) clearly and directly admit, deny, or explain each of the findings of fact contained in this notice; and (2) state the circumstances or arguments that you allege constitute the grounds for any defense, and the factual and legal basis for opposing the proposed CMP. See 45 C.F.R. § 160.504(c). If you wish to request a hearing, you must submit your request to:

Karen Robinson, Esquire
Chief, Civil Remedies Division
Departmental Appeals Board, MS 6132
330 Independence Ave, SW Cohen Building, Room G-644
Washington, D.C. 20201
Telephone: (202) 565-9462

A failure to request a hearing within 90 days permits the imposition of the proposed CMP without a right to a hearing under 45 C.F.R. § 160.504 or a right of appeal under 45 C.F.R. § 160.548. If you choose not to contest this proposed CMP, you should submit a written statement accepting its imposition within 90 days of receipt of this notice.

If Lincare does not request a hearing within 90 days, then we will notify you of the imposition of the CMP through separate letter, including instructions on how Lincare can make payment, and the CMP will become final upon receipt of such notice.

Mr. Paul Tripp
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If you have any questions concerning this letter, please contact Jorge Lozano, Regional Manager, Region VI, at 214-767-4058.

Sincerely,

A handwritten signature in black ink, appearing to read 'Leon Rodriguez', with a long, sweeping flourish extending to the right.

Leon Rodriguez
Director

cc: Marshall Ney
Mitchell Williams
5414 Pinnacle Point Drive
Suite 500
Rogers, Arkansas 72758

Enclosure: Civil Money Penalty Chart for Lincare, Inc.

Civil Money Penalty Chart for Lincare, Inc.

Regulatory Requirement	Time Period of Violation	Amount of CMP for each violation and time period	Occurrence	Calendar Year Limit	CMP Amount
45 CFR 164.530(c)(i) – Standard: Safeguard PHI	2/01/2008-11/17/2008 (290 days)	\$100	Daily	\$25,000	\$25,000
45 CFR 164.530(i)(1) – Standard: Policies & Procedures	2/01/2008-12/31/2008 (334 days)	\$100	Daily	\$25,000	\$25,000
	01/01/2009-02/17/2009 (48 days)	\$100	Daily	N/A	\$4,800
	02/18/2009-07/28/2009 (160 days)	\$1,000	Daily	\$1,500,000	\$160,000
45 CFR 164.502 (a) Impermissible Disclosure	11/2008	\$100	Per Individual whose PHI was disclosed (278)	\$25,000	\$25,000
Total					\$239,800