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Sent via U.S. Certified Mail and Electronic Mail

June 29, 2021

Holly A. Pierson, Esq. 3127 Maple Drive NE Atlanta, Georgia 30305 REDACTED

Re: REDACTED v. Concentra, Inc.

OCR Transaction Number: 19-327813

NOTICE OF PROPOSED DETERMINATION

Dear Ms. Pierson:

Pursuant to the authority delegated by the Secretary of the United States Department of Health and Human Services ("HHS") to the Office for Civil Rights ("OCR"), I am writing to inform you that OCR is proposing to impose a civil money penalty ("CMP") of \$250,000 against Concentra, Inc. This proposed 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 by the Health Information Technology for Economic and Clinical Health ("HITECH") Act, Public Law 111-5, Section 13410, *codified* at 42 U.S.C. § 1320d-5, and under 45 C.F.R. Part 160, Subpart D.

I. The Statutory Basis for the Proposed CMP

The Secretary of HHS is authorized to impose CMPs (subject to the limitations set forth 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* HIPAA, § 262(a), as amended, 42 U.S.C. § 1320d-5(a). This authority includes imposing CMPs for violations of the applicable provisions of the Federal Standards for Privacy of Individually Identifiable Health Information and the Security Standards for the Protection of Electronic Protected Health Information (45 C.F.R. Parts 160 and 164, Subparts A, C, and E, the Privacy and Security Rules), the HIPAA Enforcement Rule (45 CFR Part 160, Subparts A, C, D, and E), and the Breach Notification Rule (45 C.F.R. Parts 160 and 164, Subpart D). The Secretary has delegated enforcement responsibility for the HIPAA Rules to the Director of OCR. *See* 65 Fed. Reg. 82,381 (Dec. 28, 2000) and 74 Fed. Reg. 38630 (July 27, 2009). The Secretary is authorized under the HITECH Act § 13410, 42 U.S.C. § 1320d-5(a)(3), to impose CMPs for

violations occurring on or after February 18, 2009, of:

- A minimum of \$100 for each violation where the covered entity or business associate did not know and, by exercising reasonable diligence, would not have known that the covered entity or business associate violated such provision, except that the total amount imposed on the covered entity or business associate for all violations of an identical requirement or prohibition during a calendar year may not exceed \$25,000.
- A minimum of \$1,000 for each violation due to reasonable cause and not to willful neglect, except that the total amount imposed on the covered entity or business associate for all violations of an identical requirement or prohibition during a calendar year may not exceed \$100,000. Reasonable cause means an act or omission in which a covered entity or business associate knew, or by exercising reasonable diligence would have known, that the act or omission violated an administrative simplification provision, but in which the covered entity or business associate did not act with willful neglect.
- A minimum of \$10,000 for each violation due to willful neglect and corrected within 30 days, except that the total amount imposed on the covered entity or business associate for all violations of an identical requirement or prohibition during a calendar year may not exceed \$250,000.
- A minimum of \$50,000 for each violation due to willful neglect and uncorrected within 30 days, except that the total amount imposed on the covered entity or business associate for all violations of an identical requirement or prohibition during a calendar year may not exceed \$1,500,000.
- As required by law, OCR has adjusted the CMP ranges for each penalty tier for inflation.² The adjusted amounts are applicable only to CMPs whose violations occurred after November 2, 2015.

OCR is precluded from imposing a CMP unless the action is commenced within six years from the date of the violation.³

II. Findings of Fact

- 1. Concentra, Inc. ("Concentra") is a "covered entity" as defined at 45 C.F.R. § 160.103, and, as such, is required to comply with the requirements of the Privacy, Security and Breach Notification Rules.
- 2. Concentra has 520 medical centers in 44 states, and 140 onsite medical facilities that offer a broad range of health services, including occupational medicine, urgent care, and physical therapy.

¹ For violations occurring on or after November 3, 2015, HHS may make annual adjustments to the CMP amounts pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvement Act of 2015. The annual inflation amounts are found at 45 C.F.R. § 102.3

² See Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, Sec. 701 of Public Law 114-74. ³ 45 C.F.R. § 160.104

- 3. Concentra creates, maintains, receives, and transmits the protected health information ("PHI") of patients who receive health care services from Concentra.
- 4. The Complainant in this case is the Affected Party's attorney, who filed the complaint that is the subject of these proceedings on behalf of the Affected Party. The Affected Party was a patient of Concentra.
- 5. On February 15, 2018, the Affected Party sent a request via mail and fax to Concentra asking that a copy of his "designated records including, medical records, billing records, payment and claim records, case management records, clinical laboratory test reports, x-ray reports, and notes from May 25, 2017, to the present" be sent in electronic format to the Complainant ("access request").
- 6. The Affected Party sent his February 15, 2018, access request by mail to Records/Billing Department, Concentra Medical Center, 14155 North 83rd Avenue, Building 8, Suite 148, Peoria, Arizona 85381, and by fax to (623) 487-8647.
- 7. The Affected Party's February 15, 2018, access request was in writing, signed by the Affected Party, and clearly identified the Complainant and where to send the copy of the Affected Party's PHI to the Complainant.
- 8. Concentra uses an electronic health record ("EHR") for its patients' medical records, and it maintained the Affected Party's requested medical records in an EHR.
- 9. Concentra received the Affected Party's February 15, 2018 access request on March 1, 2018. Upon receipt of the Affected Party's request, an employee at Concentra's Peoria office sent the access request to Concentra's Central Billing office where the access request was not processed.
- 10. Using the same number and address as on February 15, 2018, the Affected Party sent follow-up access requests to Concentra's Peoria, Arizona office via mail and fax on May 22, 2018, July 26, 2018, and August 21, 2018. Each time, the Affected Party received confirmation from his fax machine that each fax transmission was successful.
- 11. On August 31, 2018, Concentra sent a fax addressed to the Complainant at the fax number from which the Affected Party had sent his access requests stating, "Please be advised that billing is not located at this facility. All billing inquiries need to be sent to (602) 392-1151."
- 12. On September 5, and September 27, 2018, the Affected Party sent access requests to Concentra again requesting that an electronic copy of his designated records be sent to the Complainant. These requests were sent to the fax number provided by Concentra on August 31, 2018.
- 13. On October 8, 2018, Concentra's business associate ("BA") sent an invoice to the Complainant requesting full payment for the records within 30 days before the

- 14. In response to the invoice, Complainant sent a letter to Concentra and the BA disputing the invoice amount. The letter cited 45 C.F.R § 164.524 to support the position that the fees were excessive and not in compliance with HIPAA.
- 15. On December 17, 2018, BA sent a delinquent notice to the Complainant stating that the debt was past due and that payment was due within 15 days or the account could be forwarded to collection or have legal action taken. Following this notice, on December 28, 2018, the Complainant filed a complaint with OCR alleging that Concentra did not provide him with a copy of the Affected Party's medical records in response to the Affected Party's access requests.
- 16. OCR notified Concentra in writing of the complaint and issued a data request on April 9, 2019. OCR requested data including whether or not the Complainant received access to the medical records and a copy of Concentra's policy regarding providing access to medical records.
- 17. The notification informed Concentra of an individual's right to inspect and obtain a copy of the PHI about the individual in a designated record set, for as long as the PHI is maintained in the designated record set, under the Privacy Rule (45 CFR § 164.524(a)(1)). The Privacy Rule generally requires HIPAA covered entities (e.g., health plans and most health care providers) to provide individuals, upon request, with access to the PHI about them in one or more "designated record sets" maintained by the covered entity.
- 18. The data request informed Concentra that it could do any of the following: (a) respond to the allegation; (b) submit evidence indicating that it was not a covered entity or business associate subject to the Privacy Rule; (c) submit evidence that the alleged violation did not occur as described by the Complainant; (d) submit evidence that the action complied with the Rule; or (e) that the Covered Entity took prompt and effective action to correct the noncompliance.
- 19. Concentra fulfilled the Affected Party right of access request and sent the Complainant the requested records on March 21, 2019, 399 days after the initial request.
- 20. On July 30, 2020, OCR issued a Letter of Opportunity ("LOO"), which informed Concentra that OCR's investigation indicated that Concentra failed to comply with the HIPAA Privacy Rule. The LOO stated that pursuant to 45 C.F.R. § 160.312(a)(3), OCR was informing Concentra of the preliminary indications of noncompliance and providing Concentra with an opportunity to submit written evidence of mitigating factors under 45 C.F.R. § 160.408 or affirmative defenses under 45 C.F.R. § 160.410 for OCR's consideration in making a determination of a CMP pursuant to 45 C.F.R. § 160.404. The letter stated that Concentra could also submit written evidence to support a waiver of a CMP for the indicated areas of non-

⁴ This is the first response from Concentra or its business associate addressing the Affected Party's access requests.

compliance. Each act of noncompliance under the Privacy Rule was described in the letter.

- 21. On September 8, 2020, Counsel for Concentra, submitted a response to the LOO on behalf of Concentra. OCR has determined that the information and arguments submitted by Concentra do not support an affirmative defense pursuant to 45 C.F.R. § 160.410. See Section IV below. OCR considered Concentra's response citing mitigation factors pursuant to 45 C.F.R. § 160.408 in determining the amount of the CMP indicated below. See Section V below. OCR has determined that the information and arguments submitted by Concentra do not support a waiver of the CMP pursuant to 45 C.F.R. § 160.412. See Section VI below.
- 22. 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 CMP

Based on the above findings of fact, we have determined that Concentra is liable for the following violation of the HIPAA Privacy Rule and, therefore, is subject to a CMP.

Concentra failed to provide timely access to medical records in violation of 45 C.F.R. § 164.524(b)(2) after lawful request for such records from the Affected Parry and Complainant. The appropriate penalty tiers for this violation from May 1, 2018, to October 7, 2018, are reasonable cause and willful neglect, uncorrected, as follows:

Calendar Year 2018: 122 days from May 1, 2018, to August 30, 2018 (at \$1,191 per day), and 38 days from August 31, 2018, to October 7, 2018 (at \$59,522 per day) (Maximum potential CMP \$1,785,651).

IV. No Affirmative Defenses

By its July 30, 2020 Letter of Opportunity, OCR offered Concentra the opportunity to provide written evidence of affirmative defenses. Concentra submitted its response to OCR by letter dated September 8, 2020. OCR determined that the information contained in Concentra's response did not provide a basis for an affirmative defense to the finding of violation as set forth at 45 C.F.R. § 160.410.

V. Factors Considered in Determining the Amount of the CMP

In determining the amount of the CMP, OCR has considered the following factors in accordance with 45 C.F.R. § 160.408.⁵

In Concentra's response to OCR's LOO, Concentra asserted the following mitigating factors for OCR to consider in determining the CMP:

⁵ 45 C.F.R. §160.408 Factors considered in determining the amount of a civil money penalty. In determining the amount of any civil money penalty, the Secretary will consider the following factors, which may be mitigating or aggravating as appropriate: (a) The nature and extent of the violation, consideration of which may include but is not limited to: (1) The number of individuals affected; and (2) The time period during which the violation occurred;

1. Nature and Extent of the Violation-Concentra asserted that the violation at issue relates only to a single individual's medical records, and there is no evidence that the individual patient (or his attorney, for that matter) suffered any prejudice by the time period over which the violation occurred.

OCR considered the assertions relevant to the nature and extent of the violation. While the violation only affected one individual, the length of the violation was substantial. OCR's investigation determined that Concentra did not fulfill the Affected Party's access requests until March 21, 2019, 399 days after the Affected Party's initial request. Nonetheless, OCR stopped the violation time period on October 8, 2018.

- 2. Nature and Extent of Harm Resulting from Violation- Concentra contends that no evidence suggests that any harm resulted from the violation at issue. Specifically, there is no evidence of physical harm, financial harm, harm to any individual's reputation, or that the patient was hindered in any way from obtaining health care by the violation. OCR has considered this information in determining the CMP in this matter.
- 3. History of Prior Non-Compliance- Concentra asserts: "Concentra has never had an enforcement action in this area ever proposed against it before." OCR has considered this information in determining the CMP in this matter.
- 4. Financial Condition- In its response to the LOO, Concentra asserted that its financial condition has been gravely harmed since the inception of the COVID-19 pandemic and the resulting crisis in the United States healthcare system.

Concentra did not provide any financial documentation supporting its assertion that its financial condition has been harmed as a result of the COVID-19 pandemic. However, OCR has considered this information in determining the CMP in this matter.

VI. Waiver

OCR has determined that there is no basis for waiver of the proposed CMP amount as set forth at 45 C.F.R. § 160.412. On July 30, 2020, OCR sent Concentra a LOO which described OCR's findings and Concentra's violation of the HIPAA Privacy Rule. In its response to the LOO on September 8, 2020, Concentra presented no evidence that the payment of the CMP would be excessive relative to the violation.

VII. Amount of CMP

A. Amount of CMP Per Violation

OCR finds that Concentra is liable for a CMP for violating the following requirement of the Privacy Rule:

Timely Action by the Covered Entity -45 C.F.R. § 164.524(b)(2). The CMP amount is based on 45 C.F.R. §§ 160.404(b)(2)(ii)(A) and (iv)(A).

B. Total Amount of CMP

The total CMP amount that could be imposed on Concentra with regard to the violation described is \$1,785,651 (See attached chart). However, based on OCR's evaluation of the factors listed in 45 C.F.R. § 160.408, OCR has determined that a CMP of \$250,000.00 is warranted in this matter.

VIII. Right to a Hearing

Concentra has the right to a hearing before an administrative law judge to challenge these proposed CMPs. To request a hearing to challenge these proposed CMPs, you 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 CMPs. *See* 45 C.F.R. § 160.504(c). If you wish to request a hearing, you must submit your request to:

Department of Health & Human Services Departmental Appeals Board, MS 6132 Civil Remedies Division 330 Independence Ave, SW Cohen Building, Room G-644 Washington, D.C. 20201 Telephone: REDACTED

Copy to:
Serena Mosley-Day, Senior Advisor
Office for Civil Rights
200 Independence Avenue, SW
Suite 523E
Hubert H. Humphrey Building
Washington, D.C. 20201
Telephone: REDACTED

A failure to request a hearing within 90 days permits the imposition of the proposed CMPs 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 Concentra does not request a hearing within 90 days, then OCR will notify you of the imposition of the CMPs through a separate letter, including instructions on how you may make payment, and the CMPs will become final upon receipt of such notice.

If you have any questions regarding this matter, please contact Nick Heesters, Senior Advisor for Cybersecurity at REDACTED or at REDACTED.

Sincerely,

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Barbara Stampul Acting Regional Manager

Enclosures: Appendix A (CMP Penalty Chart)