



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

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Office for Civil Rights, Pacific Region

90 7th Street, Suite 4-100

San Francisco, CA 94103

VIA PERSONAL SERVICE, CERTIFIED MAIL (RETURN RECEIPT REQUESTED), AND EMAIL

September 9, 2024

Alice Cuprill Comas
OHSU General Counsel
3181 SW Sam Jackson Park Road
Mail Code L585
Portland, OR 97239
Email: legal@ohsu.edu

USPS Certified: REDACTED

Kuli Mavuwa, Chief Privacy and Security Officer
Oregon Health & Science University
3181 SW Sam Jackson Park Road
Portland, OR 97239

Email: **REDACTED**

USPS Certified: REDACTED

Re: Oregon Health & Science University
OCR Transaction Number: 21-411469

NOTICE OF PROPOSED DETERMINATION

Dear Mr. Mavuwa and Ms. Comas:

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 **\$200,000** against Oregon Health & Science University (OHSU).

This proposed action is being taken under the regulations promulgated by 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 a CMP (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), 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. 82381 (Dec. 28, 2000) and 74 Fed. Reg. 38630 (July 27, 2009). OCR is authorized under the HITECH Act § 13410, 42 U.S.C. § 1320d-5(a)(3),¹ to impose a CMP for violations occurring on or after February 18, 2009,² 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.³ The adjusted amounts are applicable only to CMPs whose violations occurred after November 2,

¹The CMP reflects the penalty tiers described in the Notification of Enforcement Discretion (April 30, 2019). *See* <https://www.federalregister.gov/documents/2019/04/30/2019-08530/notification-of-enforcement-discretion-regarding-hipaa-civil-money-penalties>

²For 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, Sec. 701 of Public Law 114-74. The annual inflation amounts are found at 45 C.F.R. § 102.3.

³ *Id.*

2015. OCR is precluded from imposing a CMP unless the action is commenced within six years from the date of the violation.⁴

II. Findings of Fact

1. OHSU is a public academic health center and research university centered in Portland, Oregon. It operates two hospitals (OHSU Hospital and OHSU Doernbecher Children's Hospital) and multiple general and specialty clinics located in Portland and throughout the State of Oregon.
2. OHSU is a "covered entity" within the definition set forth at 45 C.F.R. § 160.103, and, as such, is required to comply with the requirements of the HIPAA Privacy, Security, and Breach Notification Rules.
3. OHSU is a health care provider that transmits health information in electronic form in connection with transactions for which the U.S Department of Health and Human Services has adopted standards.
4. OHSU creates, maintains, receives, and transmits the protected health information (PHI) of patients who receive health care services from OHSU.
5. Under the HIPAA Privacy Rule, an individual or the individual's personal representative⁵ has the right to access PHI about the individual in a designated record set,⁶ for as long as the PHI is maintained by a covered entity in the designated record set.⁷
6. An individual also has a right to direct an electronic copy of PHI in an electronic health record (EHR) to a third party in an electronic format.⁸
7. The Affected Party received healthcare services from OHSU.
8. The Affected Party retained the legal services of an attorney (the Complainant) to represent her in a civil matter.
9. The Affected Party has a Personal Representative, who acted on the Affected Party's behalf through the authority provided under a "Health Care Power of Attorney."

⁴ See 42 U.S.C. § 1320a-7a(c)(1); 45 C.F.R. § 160.414 and § 160.104.

⁵ 45 C.F.R. § 164.502 (g).

⁶ Designated record set means: (1) A group of records maintained by or for a covered entity that is: (i) The medical records and billing records about individuals maintained by or for a covered health care provider; (ii) The enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or (iii) Used, in whole or in part, by or for the covered entity to make decisions about individuals. (2) For purposes of this paragraph, the term record means any item, collection, or grouping of information that includes protected health information and is maintained, collected, used, or disseminated by or for a covered entity. 45 C.F.R. § 164.501.

⁷ 45 C.F.R. § 164.524(a).

⁸ See HITECH Act § 13405(e).

10. On April 24, 2019, the Affected Party's Personal Representative sent a written request for access to the Affected Party's PHI. This request was faxed directly to OHSU and requested that such records be sent in electronic format to the Personal Representative's email address. This request met the requirements of 164.524 and is a valid request for access to PHI. On April 29, 2019, OHSU, through its business associate, Diversified Business Services, Inc. (DBS), provided some but not all of the requested records. OHSU admitted that the Affected Party did not receive all the records requested by her Personal Representative.
11. On November 12, 2019, the Complainant sent a written request on behalf of the Affected Party for access to the Affected Party's PHI. This request was faxed directly to OHSU and requested that such records be sent to the Complainant. This request met the requirements of 164.524 and is a valid request for access to PHI.
12. OHSU assigned the November 12, 2019, request to its business associate, DBS, to process and fulfill. On November 21, 2019, the Complainant received a letter stating that the Affected Party's request for access to her PHI was denied because the request must contain a date in order to be considered a valid request. OHSU admitted that the Complainant submitted a valid request and the denial was erroneous.
13. On November 22, 2019, the Complainant sent a written request on behalf of the Affected Party for access to the Affected Party's PHI. This request was faxed directly to OHSU and requested that such records be sent to the Complainant. This request met the requirements of 164.524 and is a valid request for access to PHI. OHSU admitted that Complainant submitted a valid request and it was erroneously denied due her failure to pay the invoice for the records request.
14. On May 5, 2020, the Affected Party's Personal Representative sent a written request for access to the Affected Party's PHI. This request was sent directly to OHSU and requested that such records be sent to the Personal Representative. This request met the requirements of 164.524 and is a valid request for access to PHI. OHSU admitted that the Affected Party did not receive all the records requested by her Personal Representative.
15. On May 20, 2020, the Complainant sent a written request on behalf of the Affected Party for access to the Affected Party's PHI which she previously requested on November 22, 2019. This request was sent directly to OHSU and requested that such records be sent to the Complainant. This request met the requirements of 164.524 and is a valid request for access to PHI. On May 29, 2020, OHSU provided the Complainant with portions of the Affected Party's medical records; however, OHSU admits that a complete set of records was not provided in response to this request.
16. Also, on May 20, 2020, the Complainant filed a complaint with OCR on behalf of the Affected Party alleging that OHSU was failing to respond to requests for access to the Affected Party's PHI. The complaint alleged specifically that the Affected Party had requested a copy of her medical records from OHSU on November 22, 2019. The

Complainant further alleged that she received some but not all of the requested records in December 2019.

17. On July 24, 2020, the Complainant sent a written request on behalf of the Affected Party for access to the Affected Party's PHI. This request was sent directly to OHSU and requested that such records be sent to the Complainant. This request met the requirements of 164.524 and is a valid request for access to PHI. OHSU admits that this request was erroneously denied.
18. On September 2, 2020, OCR closed the Complainant's May 20, 2020, complaint by providing technical assistance to OHSU regarding OHSU's obligations under the Privacy Rule's Right of Access provision. The closure letter provided identifying details about the Complainant's allegations, including the Affected Party's name. The letter stated that OHSU's failure to provide the requested records could reflect a violation of 45 C.F.R. § 164.524 and encouraged OHSU to assess and determine whether there may have been any noncompliance as alleged by the Complainant and to take any steps necessary to ensure such noncompliance does not occur in the future. This letter was sent by OCR to OHSU's Chief Privacy Officer. OHSU acknowledged that it received OCR's September 2, 2020 letter.
19. On January 27, 2021, the Complainant filed a second complaint with OCR on behalf of the Affected Party alleging that the Affected Party still had not received a complete copy of the records requested from OHSU.
20. After OCR sent OHSU notification of the second complaint on August 12, 2021, OHSU provided all of the records requested by the Affected Party to the Complainant on August 26, 2021. The Complainant acknowledges receipt of these records and advised OCR that they also received additional records on September 29, 2021.
21. The HIPAA Privacy Rule requires that a covered entity "must act on a request for access no later than 30 days after receipt of the request." 45 C.F.R. § 164.524(b)(2).
22. A covered entity may respond to a right of access request by granting or denying the request in whole or in part, or if it is unable to take an action required within the prescribed timeframe, it may extend the timeframe for responding by no more than 30 days, provided that the covered entity provides the requestor with a written statement of the reasons for the delay and the date by which the covered entity will complete its action on the request. The covered entity may have only one such extension of time for action on a request for access. 45 C.F.R. § 164.524(b)(2).
23. OHSU did not invoke any such extension to respond to the Affected Party's requests for access to PHI.
24. The Privacy Rule required OHSU to respond to the Complainant's request for access to the medical records, which was made on behalf of the Affected Party, no later than 30 days after receiving the request.

25. OHSU provided the Affected Party's requested records to the Complainant on August 26, 2021, which was 329 days after it received OCR's September 2, 2020, technical assistance letter.
26. In a letter dated April 1, 2022, OCR informed OHSU of the results of its investigation: that OHSU failed to provide timely access to PHI as required by 45 C.F.R. § 164.524. The letter offered OHSU an opportunity to settle this matter informally.
27. On July 24, 2023, pursuant to 45 C.F.R. § 160.312(a)(3), OCR issued a Letter of Opportunity (LOO) informing OHSU that OCR found preliminary indications of non-compliance and providing OHSU 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 OHSU could also submit written evidence to support a waiver of a CMP for the indicated areas of non-compliance pursuant to 45 C.F.R. § 160.412. The act of noncompliance under the Privacy Rule was described in the LOO which was sent certified mail with return receipt requested.
28. On September 19, 2023, OHSU, through its attorney, provided a response to OCR's LOO.
29. 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, OCR has determined that OHSU is liable for the following violation of the HIPAA Rules and, therefore, is subject to a CMP.

1. From October 2, 2020,⁹ to August 26, 2021,¹⁰ OHSU failed to provide the Affected Party with timely access to all of her PHI in violation of 45 C.F.R. § 164.524(b)(2).

IV. Affirmative Defenses

By its July 24, 2023, LOO, OCR offered OHSU the opportunity to provide written evidence of affirmative defenses per 45 C.F.R. § 160.410. OHSU responded by letter dated September 19, 2023. OCR determined that OHSU's response did not provide a basis for an affirmative defense under 45 C.F.R. § 160.410.

Under 45 C.F.R. § 160.410(c), the Secretary may not impose a CMP on a covered entity for a violation if the covered entity establishes to the satisfaction of the Secretary that the violation is

⁹ OCR selected the start date of this violation as the 31st day after OCR provided technical assistance to OHSU on September 2, 2020, as this is the date that OHSU knew or should have known that it may be in violation of this provision.

¹⁰ This is the date that all of the requested records were provided, thus ending the violation.

not due to willful neglect and was corrected during the 30-day period beginning on the first date the covered entity knew, or, by exercising reasonable diligence, would have known that the violation occurred.

As described above, OHSU received OCR's technical assistance letter in relation to the first complaint on September 2, 2020. However, OHSU failed to provide the Affected Party with access to the requested records until August 26, 2021 (329 days after receipt of OCR's technical assistance letter). OCR finds that the information in the technical assistance letter provided OHSU with enough detailed information to put it on notice of its potential noncompliance. However, OHSU did not correct the potential violation within the 30-day period following its receipt of the technical assistance letter. As described above, OCR began the violation on the 31st day after this letter was sent to OHSU. As such, this affirmative defense does not apply, as the potential violation was not corrected within the 30-day period when OHSU knew, or, by exercising reasonable diligence, would have known that the violation occurred.

In its September 19, 2023, response to the LOO, OHSU attempted to shift its responsibility as a covered entity to provide a timely response to a request for access to PHI to its business associate, DBS. This is not an affirmative defense under the HIPAA Rules¹¹ and further, under the HIPAA Privacy Rule, cover entities, not business associates are responsible for ensuring timely action in response to right of access requests.¹² OHSU did not notify DBS or notify DBS of OCR's technical assistance letter, dated September 2, 2020. Even if a court elects to consider this argument as an affirmative defense, OHSU remains liable for this violation under the Federal common law of agency based on the act or omission of their agent DBS, who was acting within the scope of their agency.¹³

Thus, there is no applicable affirmative defense for OHSU under 45 C.F.R. § 160.410.

V. Factors Considered in Determining the Amount of the CMP Pursuant to 45 C.F.R. § 160.408

In accordance with 45 C.F.R. § 160.408, OCR considered OHSU's response to its LOO and the evidence obtained during its investigation in determining the amount of the CMP. OCR considered the factors as follows:¹⁴

1. 45 C.F.R. § 160.408(a) - The nature and extent of the violation.

The very nature of an individual right under the Privacy Rule is that it protects the rights of an individual. Although the violation in this matter affected only one individual, OCR's investigation determined that OHSU was in violation for a significant period of time. OHSU failed to provide timely access to the request for access, despite multiple follow up communications, until many months after the date of the access request and only after OCR

¹¹ See 45 C.F.R. § 160.410 ("Affirmative defenses").

¹² See 45 C.F.R. § 164.524(b)(2).

¹³ See 45 C.F.R. § 160.402(c)(1).

¹⁴ OCR reserves the right to raise any defenses in response to its computation of the CMP amount or its evaluation of the § 164.408 factors should this become an issue at any future hearing.

opened its investigation into this matter. The evidence shows that the Affected Party's personal representative first made a request for access to the Affected Party's PHI on April 24, 2019. OHSU did not provide all of the requested records until August 26, 2021. As such, OCR will apply this as neither a mitigating nor aggravating factor.

2. *45 C.F.R. § 160.408(b) - The nature and extent of the harm resulting from the violation.*

OCR does not have evidence that this violation resulted in physical, financial, or reputational harm or hindered the Complainant's ability to obtain healthcare. However, the fact that there is no indication of such harm cannot be attributed to any actions taken by OHSU such that would justify mitigating the CMP. As such, OCR finds this is neither a mitigating nor aggravating factor.

3. *45 C.F.R. § 160.408(c) - The history of prior compliance with the administrative simplification provisions, including violations, by the covered entity.*

Based on a review of OCR's history with OHSU, there have been no previous investigations of OHSU that involve the same or similar noncompliance at issue in this matter, except for the first complaint involving the Affected Party which was closed September 2, 2020, without investigation or a determination. As such, OCR finds that this is neither a mitigating nor aggravating factor.

4. *45 C.F.R. § 160.408(d) - The financial condition of the covered entity.*

OCR found no evidence to suggest that OHSU experienced financial difficulties that affected its ability to comply with HIPAA requirements. OCR found no evidence that the imposition of the CMP would jeopardize OHSU's ability to continue to provide health care to its patients.

As such, OCR finds that this is neither a mitigating nor aggravating factor.

5. *45 C.F.R. § 160.408(e) - Such other matters as justice may require.*

OCR has not identified other matters that justice may require in its consideration of aggravating or mitigating factors. OCR considers this factor to be neither mitigating nor aggravating.

VI. Waiver

By its July 24, 2023, LOO, OCR offered OHSU the opportunity to provide written evidence supporting a waiver of the proposed CMP amount. OHSU, through legal counsel, responded by letter dated September 19, 2023. OCR determined that the information contained in OHSU's response did not provide a basis for a waiver of the proposed CMP amount pursuant to 45 C.F.R. § 160.412 because payment of the penalty is not excessive relative to the violation.

VII. Amount of CMP

OCR finds OHSU is liable for the CMP due to its violation of 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 calculated under 45 C.F.R. § 160.404(b)(2)(ii)(A) [Reasonable Cause] as follows:

Calendar Year 2020: 91 days from October 2, 2020, to December 31, 2020, at \$1,379 per day = \$125,489, capped at \$100,000

Calendar Year 2021: 238 days from January 1, 2021, to August 25, 2021, at \$1,379 per day = \$326,823, capped at \$100,000

Total Maximum CMP:

Actual: \$452,312, capped at \$200,000¹⁵

VIII. Right to a Hearing

OHSU has the right to a hearing before an administrative law judge to challenge the proposed CMP. To request a hearing to challenge the proposed CMP, OHSU must mail a request, via certified mail with return receipt requested, 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:

U.S. 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: (202) 565-9462

Copy to:

Michael Leoz, Regional Manager
Office for Civil Rights
U.S. Department of Health and Human Services
90 7th Street, Suite 4-100
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Voice: (800) 368-1019
Fax: (415) 437-8329
TDD: (800) 537-7697
Email: Reg10.OCRmail@hhs.gov

¹⁵ See OCR Notification of Enforcement Discretion (April 30, 2019) <https://www.federalregister.gov/documents/2019/04/30/2019-08530/notification-of-enforcement-discretion-regarding-hipaa-civil-money-penalties>.

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

Sincerely,

/s/

Michael Leoz
Regional Manager

CC:

Via Certified Mail (Return Receipt Requested) & Via Email

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