

RESOLUTION AGREEMENT

I. Recitals

1. Parties. The Parties to this Resolution Agreement (“Agreement”) are:

A. The United States Department of Health and Human Services, Office for Civil Rights (“HHS”), which enforces the Federal standards that govern the privacy of individually identifiable health information (45 C.F.R. Part 160 and Subparts A and E of Part 164, the “Privacy Rule”), the Federal standards that govern the security of electronic individually identifiable health information (45 C.F.R. Part 160 and Subparts A and C of Part 164, the “Security Rule”), and the Federal standards for notification in the case of breach of unsecured protected health information (45 C.F.R. Part 160 and Subparts A and D of 45 C.F.R. Part 164, the “Breach Notification Rule”). HHS has the authority to conduct compliance reviews and investigations of complaints alleging violations of the Privacy, Security, and Breach Notification Rules (the “HIPAA Rules”) by covered entities and business associates, and covered entities and business associates must cooperate with HHS compliance reviews and investigations. *See* 45 C.F.R. §§ 160.306(c), 160.308, and 160.310(b).

B. The Board of Regents of the University of Washington, on behalf of University of Washington (“UW”), which is a “covered entity” under 45 C.F.R. § 160.103 that has designated its health care components as a “hybrid entity” under 45 C.F.R. § 164.105(a)(2), and the health care providers under its common ownership or control, each of which meet the definition of “covered entity” under 45 C.F.R. § 160.103. UW’s health care components and the health care providers set forth in Appendix A, attached hereto and incorporated by reference, have been designated as a single Affiliated Covered Entity pursuant to 45 C.F.R. § 164.105(b) (hereinafter referred to as “UW Medicine”) and are required to comply with the HIPAA Rules.

HHS and UW shall together be referred to herein as the “Parties.”

2. Factual Background and Covered Conduct.

On November 27, 2013, HHS received notification from UW Medicine regarding a breach of its unsecured electronic protected health information (e-PHI). On December 26, 2013, HHS notified UW Medicine of this investigation regarding UW Medicine’s compliance with the Privacy, Security, and Breach Notification Rules. HHS’s investigation indicated that the following conduct occurred (“Covered Conduct”).

A. UW Medicine failed to implement policies and procedures to prevent, detect, contain, and correct security violations. Specifically it has failed to conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of e-PHI. (*See* 45 C.F.R. § 164.308(a)(1)(i)).

3. No Admission. This Agreement is not an admission of liability by UW.

4. No Concession. This Agreement is not a concession by HHS that UW is not in violation of the Privacy Rule, the Security Rule, or the Breach Notification Rule and that UW is not liable for civil money penalties.

5. Intention of Parties to Effect Resolution. This Agreement is intended to resolve HHS Transaction Number: 14-171563 and any violations of the HIPAA Privacy, Security, and Breach Notification Rules related to the Covered Conduct specified in paragraph 1.2 of this Agreement. In consideration of the Parties' interest in avoiding the uncertainty, burden, and expense of further investigation and formal proceedings, the Parties agree to resolve this matter according to the Terms and Conditions below.

II. Terms and Conditions

6. Payment. HHS has agreed to accept, and UW has agreed to pay HHS, the amount of \$750,000 ("Resolution Amount"). UW agrees to pay the Resolution Amount on the Effective Date of this Agreement as defined in paragraph 11.14 by automated clearing house transaction pursuant to written instructions to be provided by HHS.

7. Corrective Action Plan. UW has entered into and agrees to comply with the Corrective Action Plan ("CAP"), attached as Appendix B, which is incorporated into this Agreement by reference. If UW breaches the CAP, and fails to cure the breach as set forth in the CAP, then UW will be in breach of this Agreement and HHS will not be subject to the Release set forth in paragraph 11.8 of this Agreement.

8. Release by HHS. In consideration of and conditioned upon UW's performance of its obligations under this Agreement, HHS releases UW from any actions it may have against UW under the HIPAA Rules arising out of or related to the Covered Conduct specified in paragraph 1.2 of this Agreement. HHS does not release UW from, nor waive any rights, obligations, or causes of action other than those arising out of or related to the Covered Conduct and referred to in this paragraph. This release does not extend to actions that may be brought under section 1177 of the Social Security Act, 42 U.S.C. § 1320d-6.

9. Agreement by Released Party. UW shall not contest the validity of its obligation to pay nor the amount of, the Resolution Amount or any other obligations agreed to under this Agreement. UW waives all procedural rights granted under Section 1128A of the Social Security Act (42 U.S.C. § 1320a-7a) and 45 C.F.R. Part 160, Subpart E, and HHS claims collection provisions, 45 C.F.R. Part 30, including, but not limited to, notice, hearing, and appeal with respect to the Resolution Amount.

10. Binding on Successors. This Agreement is binding on UW and its successors, heirs, transferees, and assigns.

11. Costs. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

12. No Additional Releases. This Agreement is intended to be for the benefit of the Parties only, and by this instrument the Parties do not release any claims against any other person or entity.

13. Effect of Agreement. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement. Any modifications to this Agreement must be set forth in writing and signed by all Parties.

14. Execution of Agreement and Effective Date. The Agreement shall become effective (i.e., final and binding) upon the date of signing of this Agreement and the CAP by the last signatory (“Effective Date”).

15. Tolling of Statute of Limitations. Pursuant to 42 U.S.C. § 1320a-7a(c)(1), a civil money penalty (“CMP”) must be imposed within six years from the date of the occurrence of the violation. To ensure that this six-year period does not expire during the term of this Agreement, UW agrees that the time between the Effective Date of this Agreement and the date this Agreement may be terminated by reason of UW’s breach, plus one-year thereafter, will not be included in calculating the six (6) year statute of limitations applicable to the violations which are the subject of this Agreement. UW waives and will not plead any statute of limitations, laches, or similar defenses to any administrative action relating to the Covered Conduct specified in paragraph 1.2 that is filed by HHS within the time period set forth above, except to the extent that such defenses would have been available had an administrative action been filed on the Effective Date of this Agreement.

16. Disclosure. HHS places no restriction on the publication of the Agreement. In addition, HHS may be required to disclose material related to this Agreement to any person upon request consistent with the applicable provisions of the Freedom of Information Act, 5 U.S.C. § 552, and its implementing regulations, 45 C.F.R. Part 5.

17. Execution in Counterparts. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same agreement.

18. Authorizations. The individual(s) signing this Agreement on behalf of UW represent and warrant that they are authorized by the Board of Regents of the University of Washington to execute this Agreement. The individual(s) signing this Agreement on behalf of HHS represent and warrant that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement.

For Board of Regents of the University of Washington

Johnese Spisso
Chief Health System Officer, UW Medicine
Privacy Official, University of Washington

Date

For United States Department of Health and Human Services

Michael Leoz
Regional Manager, Pacific
Region
Office for Civil Rights

Date

Appendix A

University of Washington Health Care Components and Health Care Providers Designated as UW Medicine Affiliated Covered Entity

1. Harborview Medical Center and Clinics
2. Northwest Hospital & Medical Center and Clinics
3. King County Public Hospital District No. 1 d/b/a Valley Medical Center and Clinics
4. The UW Medical Center and Clinics
5. UW Neighborhood Clinics (UW Physicians Network)
6. The Association of University Physicians d/b/a UW Physicians
7. Airlift Northwest
8. Hall Health Primary Care Center
9. Department of Pediatrics Molecular Development Lab
10. Laboratory Medicine Reference Lab
11. Neurosurgical Consultants of Washington
12. Pathology Reference Lab
13. Summit Cardiology
14. UW Male Fertility Lab
15. Any other entity that is or becomes designated as a member of UW Medicine affiliated covered entity

Appendix B

CORRECTIVE ACTION PLAN

BETWEEN THE

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES AND

THE BOARD OF REGENTS OF THE UNIVERSITY OF WASHINGTON

I. Preamble

The Board of Regents of the University of Washington on behalf of the University of Washington (“UW”) and the affiliated Covered Entity, UW Medicine, hereby enters into this Corrective Action Plan (“CAP”) with the United States Department of Health and Human Services, Office for Civil Rights (“HHS”). Contemporaneously with this CAP, UW is entering into a Resolution Agreement (“Agreement”) with HHS, and this CAP is incorporated by reference into the Agreement as Appendix B. UW enters into this CAP as part of the consideration for the release set forth in paragraph II.8 of the Agreement.

II. Contact Persons and Submissions

A. Contact Persons

UW has identified the following individual as its authorized representative and contact person regarding the implementation of this CAP and for receipt and submission of notifications and reports:

*Randy Gainer
Baker & Hostetler LLP
999 Third Ave., Suite 3600
Seattle, WA 98104-4040
Telephone: (206) 332-1381
Facsimile: (206) 624-7317*

HHS has identified the following individual as its contact person with whom UW is to report information regarding the implementation of this CAP:

*Evelyn Zeller, Supervisor, OCR Pacific Region
U.S. Department of Health & Human Services, Office for Civil Rights
701 Fifth Avenue, Suite 1600, MS-11
Seattle, WA 98104
Telephone: (206) 615-2290
Facsimile: (206) 615-2297*

UW and HHS agree to promptly notify each other of any changes in the contact persons or the other information provided above.

B. Proof of Submissions. Unless otherwise specified, all notifications and reports required by this CAP may be made by any means, including certified mail, overnight mail, or hand delivery, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

III. Effective Date and Term of CAP

The Effective Date for this CAP shall be calculated in accordance with paragraph II. 14 of the Agreement (“Effective Date”). The period for compliance (“Compliance Term”) with the obligations assumed by UW under this CAP shall begin on the Effective Date of this CAP and end two (2) years from the Effective Date unless HHS has notified UW under section VIII hereof of its determination that UW has breached this CAP. In the event of such a notification by HHS under section VIII hereof, the Compliance Term shall not end until HHS notifies UW that it has determined that the breach has been cured. After the Compliance Term ends, UW shall still be obligated to submit the final Annual Report as required by section VI and comply with the document retention requirement in section VII.

IV. Time

In computing any period of time prescribed or allowed by this CAP, all days referred to shall be calendar days. The day of the act, event, or default from which the designated period of time begins to run shall not be included. The last day of the period so computed shall be included, unless it is a Saturday, a Sunday, or a legal holiday, in which event the period runs until the end of the next day that is not one of the aforementioned days.

V. Corrective Action Obligations

UW agrees to the following:

A. Security Management Process.

1. Risk Analysis.

- i. UW shall develop a current, comprehensive and thorough Risk Analysis of security risks and vulnerabilities to include the electronic protected health information (e-PHI) created, received, maintained or transmitted by UW Medicine facilities and applications which had been excluded from its August 2014 “HIPAA Meaningful Use Risk Assessment” to the extent such excluded facilities and applications are part of or are used by the health care components and providers listed in Appendix A of the Agreement. Within ninety (90) days of the Effective Date, UW shall submit the Risk Analysis to HHS for review, and either approval or disapproval.

- ii. Upon receiving notice from HHS specifying any required changes to the Risk Analysis, UW shall have sixty (60) days in which to revise its Risk Analysis accordingly, and then submit the revised Risk Analysis to HHS for review, and approval or disapproval. This process shall continue until HHS approves the Risk Analysis.
- iii. UW shall review its risk analysis annually (or more frequently, if appropriate) and shall promptly conduct an evaluation, and update the risk analysis, as necessary, in response to environmental or operational changes affecting the security of e-PHI throughout UW Medicine, as defined in Appendix A of the Agreement. Following any updates to its risk analysis, UW shall assess whether its existing security measures are sufficient to protect its e-PHI, develop a strategy to mitigate any risks to e-PHI, and revise policies and procedures, training materials, and implement additional security measures, as needed.

2. Risk Management.

- i. Within ninety (90) days of HHS' final approval of the Risk Analysis conducted pursuant to section V.A.1 above, UW shall provide HHS with a Risk Management Plan that addresses the risks identified for HHS' review, and either approval or disapproval.
- ii. Upon receiving notice from HHS specifying any required changes to the Risk Management Plan, UW shall have sixty (60) days to make the required changes accordingly, and then submit the revised Risk Management Plan to HHS for review, and either approval or disapproval. This process shall continue until HHS approves the Risk Management Plan.
- iii. UW shall promptly implement the Risk Management Plan upon HHS' final approval in accordance with its applicable administrative procedures.

B. Compliance Program Reorganization.

- 1. Within one hundred eighty (180) days of the Effective Date, UW will provide documentation regarding the development and implementation of the recent structural reorganization undertaken by UW Medicine of its compliance program to include administration of the programmatic elements for Security Rule compliance.

C. Reportable Events

1. During the Compliance Term, UW shall, upon receiving information that a UW Medicine workforce member may have failed to comply with its Privacy and Security Rule policies and procedures, promptly investigate the matter. If UW Medicine determines, after review and investigation, that a member of its workforce has failed to comply with its Privacy and Security Rule policies and procedures, UW shall notify HHS in writing within thirty (30) days. Such violations shall be known as “Reportable Events.” The report to HHS shall include the following:
 - a. A complete description of the event, including the relevant facts, the persons involved, and the provision(s) of UW Medicine’s Privacy and Security Rule policies and procedures implicated; and
 - b. A description of the actions taken and any further steps UW Medicine plans to take to address the matter, to mitigate any harm, and to prevent it from recurring, including the application of appropriate sanctions against the workforce member(s) who failed to comply with its Privacy and Security Rule policies and procedures.
2. If no Reportable Events have occurred within the Compliance Term, UW shall so inform HHS in its Annual Reports.

VI. Annual Reports

The one-year period beginning on the Effective Date and the subsequent one-year period during the course of the period of compliance obligations shall be referred to as “the Reporting Periods.” UW shall submit to HHS Annual Reports with respect to the status of and findings regarding UW’s compliance with this CAP for each Reporting Period. UW shall submit each Annual Report to HHS no later than sixty (60) days after the end of each corresponding Reporting Period. The Annual Report shall include the following items:

1. A summary of the security measures, if any, implemented pursuant to section V.A.2.iii and V.A.1.iii during the Reporting Period, including documentation of any training conducted related to those measures;
2. A summary of Reportable Events (defined in section V.C.1.) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events; and
3. An attestation signed by an owner or officer of UW attesting that UW has complied with the obligations of this CAP; and
4. An attestation signed by an officer of UW attesting that he or she has reviewed the Annual Report, has made a reasonable inquiry regarding its content, and believes, based upon such inquiry, that the information is accurate and truthful.

VII. Document Retention

UW shall maintain for inspection and copying, and shall provide to HHS upon request, all documents and records relating to compliance with this CAP for six (6) years from the Effective Date.

VIII. Breach Provisions

UW is expected to fully and timely comply with all provisions contained in this CAP.

A. Timely Written Requests for Extensions. UW may, in advance of any due date set forth in this CAP, submit a timely written request for an extension of time to perform any act required by this CAP. A “timely written request” is defined as a request in writing received by HHS at least five (5) days prior to the date such an act is required or due to be performed.

B. Notice of Breach of this CAP and Intent to Impose Civil Money Penalty. The Parties agree that a breach of this CAP by UW constitutes a breach of the Agreement. Upon a determination by HHS that UW has breached this CAP, HHS may notify UW of (1) UW’s breach; and (2) HHS’ intent to impose a civil money penalty (CMP), pursuant to 45 C.F.R. Part 160, or other remedies for the Covered Conduct set forth in paragraph 1.2 of the Agreement and for any other conduct that constitutes a violation of the HIPAA Privacy, Security, or Breach Notification Rules (“Notice of Breach and Intent to Impose CMP”).

C. UW Response. UW shall have thirty (30) days from the date of receipt of the Notice of Breach and Intent to Impose CMP to demonstrate to HHS’ satisfaction that:

1. UW is in compliance with the obligations of the CAP that HHS cited as the basis for the breach;
2. The alleged breach has been cured; or
3. The alleged breach cannot be cured within the thirty (30) day period, but that (a) UW has begun to take action to cure the breach; (b) UW is pursuing such action with due diligence; and (c) UW has provided HHS a reasonable timetable for curing the breach.

D. Imposition of CMP. If at the conclusion of the 30-day period, UW fails to meet the requirements of section VIII.C. of this CAP to HHS’ satisfaction, HHS may proceed with the imposition of the CMP against UW pursuant to 45 C.F.R. Part 160 for any violations of the Privacy, Security, and Breach Notification Rules related to the Covered Conduct set forth in paragraph 1.2. of the Agreement and for any other act or failure to act that constitutes a violation of the HIPAA Privacy, Security, or Breach Notification Rules. HHS shall notify UW in writing of its determination to proceed with the imposition of a CMP.

For Board of Regents of the University of Washington

Johnese Spisso
Chief Health System Officer, UW Medicine
Privacy Official, University of Washington

Date

For United States Department of Health and Human Services

Michael Leoz
Regional Manager, Pacific Region
Office for Civil Rights

Date