

RESOLUTION AGREEMENT

I. Recitals

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

1. 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 (“PHI”) (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).
2. Medical Informatics Engineering, Inc. and its wholly-owned subsidiaries including NoMoreClipboard, LLC. (collectively “MIE”), provide electronic medical record services to healthcare providers, thus MIE meets the definition of a “business associate” under 45 C.F.R. § 160.103 and therefore is required to comply with the HIPAA Rules.

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

B. **Factual Background and Covered Conduct.** On May 26, 2015, MIE discovered suspicious activity on one of its servers. Upon further investigation, MIE discovered unauthorized access to its network beginning on May 7, 2015, which contained MIE client information. The servers subject to the cyberattack contained the protected health information (PHI) of approximately 3.5 million individuals. The PHI included names, addresses, dates of birth, Social Security numbers, email addresses, clinical information and health insurance information.

HHS’s investigation indicated that the following conduct occurred (“Covered Conduct”)

1. MIE impermissibly disclosed the ePHI of 3.5 million individuals. *See* 45 C.F.R. § 164.502(a).

2. MIE failed to conduct an accurate and thorough risk analysis of potential risks and vulnerabilities to the confidentiality, integrity, and availability of all of their ePHI. *See* 45 C.F.R. § 164.308(a)(1)(ii)(A).

C. **No Admission.** This Agreement is not an admission of liability by MIE.

D. **No Concession.** This Agreement is not a concession by HHS that MIE is not in violation of the HIPAA Rules and not liable for civil money penalties (“CMPs”).

E. **Intention of Parties to Effect Resolution.** This Agreement is intended to resolve HHS Transaction Number: 15-216342 and any potential violations of the HIPAA Rules related to the Covered Conduct specified in paragraph I.B of this Agreement. In consideration of the Parties’ interest in avoiding the uncertainty, burden, and expense of further investigation, formal proceedings, the Parties agree to resolve this matter according to the Terms and Conditions below.

II. Terms and Conditions

A. **Payment.** HHS has agreed to accept, and MIE has agreed to pay HHS, the amount of **\$100,000.00** (“Resolution Amount”). MIE agrees to pay the Resolution Amount on the Effective Date of this Agreement as defined in paragraph I. of this Section, pursuant to written instructions to be provided by HHS.

B. **Corrective Action Plan.** MIE has entered into and agrees to comply with the Corrective Action Plan (“CAP”), attached as Appendix A, which is incorporated into this Agreement by reference. If MIE breaches the CAP, and fails to cure the breach as set forth in the CAP, then MIE will be in breach of this Agreement and HHS will not be subject to the Release set forth in paragraph II.A.2 of this Agreement with respect to that entity.

C. **Release by HHS.** In consideration of and conditioned upon MIE’s performance of its obligations under this Agreement, HHS releases MIE from any actions it may have against MIE under the HIPAA Rules arising out of or related to the Covered Conduct identified in paragraph I.B of this Agreement. HHS does not release MIE 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 section. 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.

D. **Agreement by Released Parties.** MIE 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. MIE waives all procedural rights granted under Section 1128A of the Social Security Act (42 U.S.C. § 1320a- 7a), 45 C.F.R. Part 160 Subpart E, and HHS claims collection regulations at 45 C.F.R. Part 30, including, but not limited to, notice, hearing, and appeal with respect to the Resolution Amount.

E. **Binding on Successors.** This Agreement is binding on MIE and its successors, heirs, transferees, and assigns.

F. **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.

- G. **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 or by any other person or entity.
- H. **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 shall be set forth in writing and signed by all Parties.
- I. **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).
- J. **Tolling of Statute of Limitations.** Pursuant to 42 U.S.C. § 1320a-7a(c)(1), a 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, MIE agrees that the time between the Effective Date of this Agreement (as set forth in Paragraph 8) and the date the Agreement may be terminated by reason of MIE's breach, plus one-year thereafter, will not be included in calculating the six (6) year statute of limitations applicable to the indicated violations which are the subject of this Agreement. MIE waives and will not plead any statute of limitations, laches, or similar defenses to any administrative action relating to the Covered Conduct identified in paragraph I.B 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.
- K. **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.
- L. **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.

M. **Authorizations.** The individual(s) signing this Agreement on behalf of MIE represent and warrant that they are authorized 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 Medical Informatics Engineering

//signed//

4/23/2109

Douglas R. Horner
Chief Executive Officer
Medical Informatics Engineering, Inc.

Date

For Department of Health and Human Services

//signed//

4/23/2019

Steven M. Mitchell
Acting Regional Manager, Midwest Region
Office for Civil Rights

Date

Appendix A
CORRECTIVE ACTION PLAN
BETWEEN THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
MEDICAL INFORMATICS ENGINEERING (“MIE”)

I. Preamble

Medical Informatics Engineering (“MIE”), 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, MIE is entering into the Resolution Agreement with HHS, and this CAP is incorporated by reference into the Agreement as Appendix A. MIE enters into this CAP as part of consideration for the release set forth in Section II.A.2 of the Agreement. Capitalized terms without definition in this CAP shall have the same meaning assigned to them under the Agreement.

II. Contact Persons and Submissions

A. Contact Persons

The contact person for MIE regarding the implementation of this CAP and for receipt and submission of notifications and reports (“MIE Contact”) is:

Andrew Horner
Chief Information Officer
6302 Constitution Dr.
Fort Wayne, IN 46804
ahorner@mieweb.com
Telephone: (260) 459-6270 x 306
Facsimile: (260) 459-6271

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

Steven M. Mitchell, Acting Regional Manger
Office for Civil Rights, Midwest Region
Department of Health & Human Services
601 East 12th Street, Room 353
Kansas City, MO 64106
Steven.Mitchell@hhs.gov

Telephone: (816) 426-7278
Facsimile: (816)426-3686

MIE and HHS agree to promptly notify each other of any changes in the contact person 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, electronic 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 Section II.I of the Resolution Agreement (“Effective Date”). The period for compliance (“Compliance Term”) with the obligations assumed by MIE under this CAP shall begin on the Effective Date of this CAP and end two (2) years from the date of HHS’ final approval of all corrective action obligations set forth in Section V below, unless HHS has notified MIE under Section VIII hereof of its determination that MIE 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 MIE that HHS has determined MIE failed to meet the requirements of section VIII.C of this CAP and issues a written notice of intent to proceed with an imposition of a civil money penalty against MIE pursuant to 45 C.F.R. Part 160. After the Compliance Term ends, MIE shall still be obligated to: (a) submit the final Annual Report as required by section VI; and (b) comply with the document retention requirement in section VII. Nothing in this CAP is intended to eliminate or modify MIE’s obligation to comply with the document retention requirements in 45 C.F.R. §§ 164.316(b) and 164.530(j).

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 which is not one of the aforementioned days.

V. Corrective Action Obligations

MIE agrees to the following:

A. Conduct Risk Analysis

1. MIE shall conduct an accurate and thorough assessment of the potential security risks and vulnerabilities to the confidentiality, integrity, and availability of MIE's electronic protected health information ("ePHI") ("Risk Analysis"). The Risk Analysis shall evaluate the risks to the ePHI on its electronic equipment, data systems, and applications controlled, administered or owned by the MIE, that create, receive, transmit, or maintain ePHI. Prior to conducting the Risk Analysis, MIE shall develop a complete inventory of all of its facilities, categories of electronic equipment, data systems, and applications that create, receive, transmit, or maintain ePHI, which will then be incorporated into its Risk Analysis.
2. MIE shall provide the Risk Analysis, consistent with paragraph V.A.1 to HHS within thirty (30) days of the Effective Date for HHS' review. HHS will inform MIE Contact in writing as to whether HHS approves of the Risk Analysis or, if necessary to ensure compliance with 45 C.F.R. § 164.308(a)(1)(ii)(A), requires revisions to the Risk Analysis. Upon receiving notice of required revisions to the Risk Analysis from HHS and a description of any required changes to the Risk Analysis, MIE shall have thirty (30) days in which to revise its Risk Analysis accordingly and submit the revised Risk Analysis to HHS for review and approval. This submission and review process shall continue until HHS approves the Risk Analysis.
3. MIE shall review the Risk Analysis annually. MIE shall also promptly update the Risk Analysis in response to environmental or operational changes affecting the security of ePHI. Following an update to the Risk Analysis, MIE shall assess whether its existing security measures are sufficient to protect its ePHI, and revise its Risk Management Plan, policies and procedures, and training materials, as needed.

B. Develop and Implement a Risk Management Plan

1. MIE shall develop a written risk management plan or plans sufficient to address and mitigate any security risks and vulnerabilities identified in the Risk Analysis described in section V.A above ("Risk Management Plan"). The Risk Management Plan shall include a process and timeline for MIE's implementation, evaluation, and revision of their risk remediation activities.
2. Within thirty (30) days of HHS' final approval of the Risk Analysis described in section V.A above, MIE shall submit their Risk Management Plan to HHS for HHS' review. Upon receiving notice of required revisions to the Risk Management Plan from HHS and a description of any required changes to the Risk Management Plan, MIE shall have fifteen (15) days in which to revise its Risk Management Plan accordingly, and submit the revised

Risk Management Plan to HHS for review and approval. This submission and review process shall continue until HHS approves the Risk Management Plan.

3. Within thirty (30) days of HHS' approval of the Risk Management Plan, MIE shall begin implementation of the Risk Management Plan and distribute the plan to workforce members involved with implementation of the plan.

E. Reportable Events

1. MIE shall, for the duration of the Compliance Term, upon receiving information that a workforce member may have failed to comply with MIE's written policies and procedures to comply with the Federal standards that govern the privacy and security of individually identifiable health information (45 C.F.R. Part 160 and Subparts A, C and E of Part 164, the "Privacy Rule" and the "Security Rule"), promptly investigate the matter. If MIE, after review and investigation, determines that a member of its workforce has failed to comply with such policies and procedures, the MIE Contact shall report such event(s) to HHS. 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 the Policies and Procedures implicated; and
 - b. A description of the actions taken and any further steps MIE plans to take to address the matter to mitigate any harm, and to prevent it from recurring, including application of appropriate sanctions against workforce members who failed to comply with the Policies and Procedures.

VI. Annual Reports

- A. Annual Reports. The one (1) year period beginning on the Effective Date and each subsequent one (1) year period during the course of the Compliance Term shall be known as a "Reporting Period." Within sixty (60) days after the close of each corresponding Reporting Period, MIE shall submit a report to HHS regarding MIE's compliance with this CAP for each Reporting Period ("Annual Report"). The Annual Report shall include:

1. An attestation signed by an officer or director of MIE attesting that any revision(s) to the Policies and Procedures required by section V were finalized and adopted within thirty (30) days of HHS' approval of the revision(s), which shall include a statement affirming that MIE distributed the revised Policies and Procedures to all appropriate members of MIE's workforce within sixty (60) days of HHS' approval of the revision(s); and

2. A summary of Reportable Events, if any, and the status of any corrective and preventative action(s) relating to all such Reportable Events, or an attestation signed by an officer or director of MIE stating that no Reportable Events occurred during the Compliance Term.

VII. Document Retention

MIE 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

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

A. Timely Written Requests for Extensions. MIE 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. This requirement may be waived by HHS only.

B. Notice of Breach of this CAP and Intent to Impose CMP. The Parties agree that a breach of this CAP by MIE constitutes a breach of the Agreement. Upon a determination by HHS that MIE has breached this CAP, HHS may notify MIE Contact of: (1) MIE’s breach; and (2) HHS’ intent to impose a CMP pursuant to 45 C.F.R. Part 160, for the Covered Conduct set forth in paragraph I.B of the Agreement and 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. MIE’s Response. MIE 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. MIE 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 MIE: (a) has begun to take action to cure the breach; (b) is pursuing such action with due diligence; and (c) has provided to HHS a reasonable timetable for curing the breach.

D. Imposition of CMP. If at the conclusion of the thirty (30) day period, MIE fails to meet the requirements of section VIII.C of this CAP to HHS’ satisfaction, HHS may proceed with the imposition of a CMP against MIE pursuant to the rights and obligations set forth in

45 C.F.R. Part 160 for any violations of the HIPAA Rules applicable to the Covered Conduct set forth in paragraph I.B of the Agreement and for any other act or failure to act that constitutes a violation of the HIPAA Rules. HHS shall notify MIE Contact in writing of its determination to proceed with the imposition of a CMP pursuant to 45 C.F.R. §§ 160.312(a)(3)(i) and (ii).

For Medical Informatics Engineering

//signed//

4/23/2019

Douglas R. Horner
Chief Executive Officer
Medical Informatics Engineering, Inc.

Date

For Department of Health and Human Services

//signed//

4/23/2019

Steven M. Mitchell
Acting Regional Manager, Midwest Region
Office for Civil Rights

Date