

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. Care New England Health System, on behalf of each of the covered entities under its common ownership or control set forth in Appendix A, attached hereto and incorporated by reference, that have been designated as a single Affiliated Covered Entity pursuant to the Privacy Rule, 45 C.F.R. § 164.105(b) (hereinafter collectively referred to as “CNE”).

HHS and CNE shall together hereinafter be referred to as the “Parties.”

2. **Factual Background and Covered Conduct.**

On November 5, 2012, the HHS Office for Civil Rights (“OCR”) received notification from Woman & Infants Hospital of Rhode Island (“WIH”), a covered entity member of CNE, regarding a breach of its unsecured electronic protected health information (“PHI”). Specifically, WIH reported it had discovered unencrypted backup tapes containing electronic PHI were missing from two of its facilities. Care New England Health System provides centralized corporate support to the covered entities under its common ownership and control, including technical support and information security for WIH’s information systems as its business associate. WIH provided OCR with a business associate agreement with Care New England Health System effective March 15, 2005, that was not updated until August 28, 2015, as a result of OCR’s investigation.

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

- (1) From September 23, 2014, until August 28, 2015, WIH disclosed PHI and allowed its business associate to create, receive, maintain, or transmit PHI on its behalf, without obtaining satisfactory assurances in accordance with 45 C.F.R. §§ 164.504(e)(2) and 164.314(a). WIH failed to renew or

modify its existing written business associate agreement with Care New England Health System, its business associate, to include the applicable implementation specifications required by the Privacy and Security Rules. *See* 45 C.F.R. §§ 164.502(e), 164.308(a), 164.532(d).

(2) From September 23, 2014, until August 28, 2015, WIH impermissibly disclosed the PHI of at least 14,004 individuals to its business associate when WIH provided Care New England Health System with access to PHI without obtaining satisfactory assurances, in the form of a written business associate agreement, that Care New England Health System would appropriately safeguard the PHI. *See* 45 C.F.R. § 164.502(a).

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

4. No Concession. This Agreement is not a concession by HHS that CNE is not in violation of the HIPAA Rules and not liable for civil money penalties.

5. Intention of Parties to Effect Resolution. This Agreement is intended to resolve OCR Transaction Number: 01-15-204886 and any violations of the HIPAA Rules related to the Covered Conduct specified in paragraph I.2 of this Agreement. In consideration of the Parties' interest in avoiding the uncertainty, burden, and expense of 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 CNE has agreed to pay HHS, the amount of \$ 400,000.00 ("Resolution Amount"). CNE agrees to pay the Resolution Amount on the Effective Date of this Agreement as defined in paragraph II.14 by automated clearing house transaction pursuant to written instructions to be provided by HHS.

7. Corrective Action Plan. CNE 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 CNE breaches the CAP, and fails to cure the breach as set forth in the CAP, then CNE will be in breach of this Agreement and HHS will not be subject to the Release set forth in paragraph II.8 of this Agreement.

8. Release by HHS. In consideration of and conditioned upon CNE's performance of its obligations under this Agreement, HHS releases CNE from any actions it may have against CNE under the HIPAA Rules arising out of or related to the Covered Conduct identified in paragraph I.2 of this Agreement. HHS does not release CNE 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 Parties. CNE 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. CNE 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 regulations at 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 each of the covered entities designated as CNE 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 or by 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 shall 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, CNE agrees that the time between the Effective Date of this Agreement and the date the Agreement may be terminated by reason of CNE’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. CNE 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.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. Care New England Health System represents and warrants that they are authorized to execute this Agreement and bind the covered entities designated as the CNE

Affiliated Covered Entity, as set forth in Appendix A. 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 Care New England Affiliated Covered Entities

_____/s/_____
Joseph Iannoni
Executive Vice President
and Chief Financial Officer

Date

For Department of Health and Human Services

_____/s/_____
Susan M. Pezzullo Rhodes
Regional Manager, New England Region
Office for Civil Rights

Date

Appendix A

Covered Entities designated as the Care New England (CNE) Affiliated Covered Entity:

1. Women & Infants Hospital of Rhode Island
2. Butler Hospital
3. Kent County Memorial Hospital
4. The Memorial Hospital d/b/a Memorial Hospital of Rhode Island
5. The Providence Center
6. VNA of Care New England
7. Affinity Physicians, LLC
8. Women & Infants Health Care Alliance, LLC
9. Any other covered entity that is or becomes designated as a member of the CNE affiliated covered entity

Appendix B
CORRECTIVE ACTION PLAN
BETWEEN THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
CARE NEW ENGLAND

I. Preamble

Care New England Health System, on behalf of the covered entities set forth in Appendix A designated as the CNE Affiliated Covered Entity, 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, CNE is entering into a Resolution Agreement (“Agreement”) with HHS, and this CAP is incorporated by reference into the Resolution Agreement as Appendix B. CNE enters into this CAP as part of consideration for the release set forth in paragraph II.8 of the Agreement.

II. Contact Persons and Submissions

A. Contact Persons

CNE 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:

Florie Munroe CIA CHC CHPC
Chief Compliance Officer
Care New England Compliance Services
800 Butler Drive
Providence, RI 02906
fmunroe@carene.org
Telephone: 401-277-3660 x2
Facsimile: 401-277-3665

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

Ms. Susan Pezzullo Rhodes, Regional Manager
Office for Civil Rights, New England Region
Department of Health and Human Services
JFK Federal Building, Room 1875

Boston, MA 02203
Susan.Rhodes@hhs.gov
Telephone: 617-565-1347
Facsimile: 617-565-3809

CNE 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 CNE 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 CNE under section VIII hereof of its determination that CNE 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 CNE that it has determined that the breach has been cured.

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

CNE agrees to the following:

A. Policies and Procedures

1. CNE shall review and revise, as necessary, its written policies and procedures to comply with the Federal Standards for Privacy of Individually Identifiable Health Information and/or 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). CNE’s policies and procedures shall include, but not be limited to, the minimum content set forth in section V.C below.

2. CNE shall provide such policies and procedures, consistent with Paragraph V.A.1 above, to HHS within ninety (90) days of the Effective Date for review and approval. Upon receiving any recommended changes to such policies and procedures

from HHS, CNE shall have sixty (60) days to revise such policies and procedures accordingly and provide the revised policies and procedures to HHS for review and approval.

3. CNE shall adopt and begin implementation of such policies and procedures within thirty (30) days of receipt of HHS' final approval.

B. Distribution and Updating of Policies and Procedures

1. CNE shall distribute the policies and procedures identified in section V.A to all members of its workforce within thirty (30) days of HHS' approval of such policies and procedures and to new members of the workforce within thirty (30) days of their beginning of service.

2. CNE shall require, at the time of distribution of such policies and procedures, a signed written or electronic initial compliance certification from each member of the workforce, stating that the workforce member has read, understands, and shall abide by such policies and procedures.

3. CNE shall assess and update and revise, as necessary, the policies and procedures at least annually. CNE shall distribute such revised policies and procedures to all members of its workforce, and to new members as required by Section V.B.1, and shall require new compliance certifications.

4. CNE shall not involve any member of its workforce in the use or disclosure of protected health information ("PHI") if that workforce member has not signed or provided the written or electronic certification required by Paragraphs V.B.2 and V.B.3 of this section.

C. Minimum Content of the Policies and Procedures.

The Policies and Procedures shall include, but not be limited to:

1. Measures that address the following Privacy and Security Rule provisions:

a. Business Associate Agreements – 45 C.F.R. § 164.308(b), including (i) the designation of one or more individual(s) who are responsible for ensuring that the covered entity enters into a business associate agreement with each of its business associates, as defined by the HIPAA Rules, prior to disclosing PHI to the business associate; (ii) a process for assessing the current and future business relationships to determine whether each relationship is with a business associate as defined under the HIPAA Rules; (iii) a process for negotiating and entering into business associate agreements with business associates prior to disclosing PHI to the business associates; (iv) a process for maintaining documentation of a business associate agreement for at least six (6) years beyond the date of when the business associate relationship is terminated; and (vi) a process to limit disclosures of PHI to business associates to the

minimum necessary amount of PHI that is reasonably necessary for business associates to perform their duties.

b. Training – 45 C.F.R. § 164.530(b)(1) & 164.308(a)(5)(i)

c. Security Incident Procedures – 45 C.F.R. § 164.308(a)(6), including a requirement that all members of CNE’s workforce report to the designated Privacy/Security Officer at the earliest possible time, any attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations in an information system (“security incident”) of which they become aware.

2. Measures providing that:

a. CNE’s workforce members will report any violation of the policies and procedures identified in section V.A to the designated Privacy/Security Officer;

b. upon receiving information that a member of its workforce may have violated these policies and procedures, CNE shall promptly investigate and address the violation in an appropriate and timely manner; and

c. the application of appropriate sanctions (which may include re-training or other instructive corrective action, depending on the circumstances) against members of CNE’s workforce, including supervisors and managers, who fail to comply with the policies and procedures.

D. Training.

1. All members of CNE’s workforce shall receive training on the policies and procedures to comply with the Privacy & Security Rules within ninety (90) days of the implementation of the policies and procedures, or within ninety (90) days of when they become a member of CNE’s workforce.

2. At a minimum, training shall cover all of the topics that are necessary and appropriate for each member of the workforce to carry out that workforce member’s function within CNE.

3. Each workforce member shall certify, in writing or in electronic form, that she or he has received and understands the required training. The training certification shall specify the date on which training was received. All course materials shall be retained in compliance with section VII below.

4. CNE shall review the training annually, and, where appropriate, update the training to reflect changes in Federal law or HHS guidance, any issues discovered during internal or external audits or reviews, and any other relevant developments.

5. CNE shall not involve any member of its workforce in the use or disclosure, of PHI if that workforce member has not provided written or electronic training certification required by Paragraph V.D.3 of this section.

E. Reportable Events.

During the Compliance Term, CNE shall, upon receiving information that a workforce member may have failed to comply with its Privacy, Security or Breach Notification Rule Policies and Procedures, promptly investigate this matter. If CNE determines, after review and investigation, that a member of its workforce has failed to comply with these policies and procedures, CNE shall notify in writing HHS within thirty (30) days. Such violations shall be known as Reportable Events. The report to HHS shall include the following information:

- 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 CNE 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 its Security Rule Policies and Procedures.

VI. Implementation Report

A. Implementation Report. Within one hundred and twenty (120) days after the receipt of HHS' approval of the training required by section V.D, CNE shall submit a written report to HHS summarizing the status of its implementation of the requirements of this CAP. This report, known as the "Implementation Report," shall include:

1. A copy of all training materials used for the training required by this CAP, a description of the training, including a summary of the topics covered, the length of the session(s) and a schedule of when the training session(s) were held;
2. An attestation signed by an owner or officer representing CNE that all members of the workforce have completed the initial training required by this CAP and have executed the training certifications required by section V.D.3. and;
3. An attestation signed by an owner or officer representing CNE that they have reviewed the Implementation Report, have made a reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.

VII. Document Retention

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

VIII. Breach Provisions

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

A. Timely Written Requests for Extensions

CNE 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 Monetary Penalty. The parties agree that a breach of this CAP by CNE constitutes a breach of the Agreement. Upon a determination by HHS that CNE has breached this CAP, HHS may notify CNE of: (1) CNE’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 I.2 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. CNE Responses. CNE 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. CNE 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 30-day period, but that: (a) CNE has begun to take action to cure the breach; (b) CNE is pursuing such action with due diligence; and (c) CNE has provided to HHS a reasonable timetable for curing the breach.

D. Imposition of CMP. If at the conclusion of the 30-day period, CNE 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 CNE pursuant to 45 C.F.R. Part 160 for any violations of the Covered Conduct set forth in paragraph I.2 of the Agreement and for any other act or failure to act that constitutes a violation of the HIPAA Rules. HHS shall notify CNE in writing of its determination to proceed with the imposition of a CMP.

For Care New England (CNE)

_____/s/_____
Joseph Iannoni
Executive Vice President
and Chief Financial Officer

Date

For United States Department of Health and Human Services

_____/s/_____
Susan M. Pezzullo Rhodes
Regional Manager, New England Region
Office for Civil Rights

Date