

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. Raleigh Orthopaedic Clinic, P.A. (“ROC”), which is a covered entity, as defined at 45 C.F.R. § 160.103, and therefore is required to comply with the HIPAA Rules. ROC is a for-profit corporation engaged in the practice of orthopaedic and pain management services, which operates in six locations throughout central and eastern North Carolina.

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

2. Factual Background and Covered Conduct.

On April 30, 2013, HHS received notification from ROC regarding a breach of its protected health information (PHI) resulting from an impermissible disclosure of PHI contained in x-ray films to a third party vendor after orally arranging for the vendor to harvest the silver from the films in exchange for transferring the x-rays into electronic media.

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

- i. ROC disclosed protected health information contained in x-ray films to a third party vendor, acting as its business associate, without obtaining satisfactory assurances in the form of a written business associate agreement in violation of the Privacy Rule (*See* 45 C.F.R. § 164.502(e));
- ii. ROC disclosed the PHI of 17,300 individuals in violation of the Privacy Rule

when it conveyed x-ray films to a third party vendor, acting as its business associate, without first obtaining satisfactory assurances in the form of a written business associate agreement from the vendor. to (See 45 C.F.R. § 164.502(a));

3. No Admission. This Agreement is not an admission of liability by ROC.
4. No Concession. This Agreement is not a concession by HHS that ROC is not in violation of the HIPAA Rules and that ROC is not liable for civil money penalties.
5. Intention of Parties to Effect Resolution. This Agreement is intended to resolve HHS Transaction Numbers: 13-159481 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

1. Payment. HHS has agreed to accept, and ROC has agreed to pay HHS, the amount of \$750,000.00 ("Resolution Amount"). ROC agrees to pay the Resolution Amount on the Effective Date of this Agreement as defined in paragraph II.9 by automated clearing house transaction pursuant to written instructions to be provided by HHS.

2. Corrective Action Plan. ROC 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 ROC breaches the CAP, and fails to cure the breach as set forth in the CAP, then ROC will be in breach of this Agreement and HHS will not be subject to the Release set forth in paragraph II.3 of this Agreement.

3. Release by HHS. In consideration and conditioned upon ROC's performance of its obligations under this Agreement, HHS releases ROC from any actions it may have against ROC under the HIPAA Rules for the covered conduct identified in paragraph I.2 of this Agreement. HHS does not release ROC 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.

4. Agreement by Released Parties. ROC 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. ROC 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.

5. Binding on Successors. This Agreement is binding on ROC and its successors, heirs, transferees, and assigns.

6. 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.

7. 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.

8. 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.

9. 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”).

10. 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, ROC agrees that the time between the Effective Date of this Agreement (as set forth in Section II.9) and the date the Agreement may be terminated by reason of ROC’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. ROC 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 Resolution Agreement.

11. Disclosure. HHS places no restriction on the publication of the Agreement. This Agreement and information related to this Agreement may be made public by either Party. 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.

12. 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.

13. Authorizations. The individual(s) signing this Agreement on behalf of ROC represent and warrant that they are authorized by ROC 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 Raleigh Orthopaedic Clinic

/s/

April 14, 2016

Karl F. Stein
Executive Director
Raleigh Orthopaedic Clinic, P.A.

Date

For United States Department of Health and Human Services

/s/

April 14, 2016

Timothy Noonan
Regional Manager, Southeast Region
Office for Civil Rights

Date

Appendix A
CORRECTIVE ACTION PLAN
BETWEEN THE
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
RALEIGH ORTHOPAEDIC CLINIC, P.A.

I. Preamble

The Raleigh Orthopaedic Clinic, P.A. (“ROC”) 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, ROC is entering into a Resolution Agreement (“Agreement”) with HHS, and this CAP is incorporated by reference into the Resolution Agreement as Appendix A. ROC enters into this CAP as consideration for the release set forth in section II.3 of the Agreement.

II. Contact Persons and Submissions

A. Contact Persons

ROC 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:

Karl Stein
Raleigh Orthopaedic Clinic, P.A.
3513 Glenwood Ave
Raleigh, NC 27612
Voice: (919) 863-6801

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

Timothy Noonan, Regional Manager, Office for Civil Rights
61 Forsyth St, Suite 16T70
Atlanta, GA 30303-8909
Voice: (404) 562-7859
Fax: (404) 562-7881

ROC 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 CAP shall become effective (*i.e.*, final and binding) upon the date of signing of the Agreement and the CAP by the last signatory (“Effective Date”). The period of compliance (“Compliance Term”) with the obligations assumed by ROC under this CAP shall begin on the Effective Date of this CAP (“Effective Date”) and end two (2) years from the Effective Date unless HHS has notified ROC under section VIII hereof of its determination that ROC 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 ROC that it has determined that the breach has been cured or HHS proceeds with the imposition of a civil monetary penalty (“CMP”) against ROC pursuant to 45 C.F.R. Part 160 and section VIII.D of the CAP. After the Compliance Term ends, ROC 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

Any reference to number of days refers to number of calendar days. In computing any period of time prescribed or allowed by this CAP, 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 Federal 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

ROC agrees to the following:

A. Business Associate Agreements

1. Within 120 days of the Effective Date and at one year following the Effective Date, ROC shall provide HHS with the following:

a. The total number of ROC business associates and the names of the business associates.

b. Copies of the business associate agreements that ROC maintains with its business associates.

B. Revise Policies and Procedures Related to Business Associate Relationships

1. ROC shall revise its policies and procedures to: a) designate one or more individual(s) who are responsible for ensuring that ROC enters into a business associate agreement with each of its business associates, as defined by the HIPAA Rules, prior to ROC disclosing protected health information (PHI) to the business associate; b) create a process for assessing ROC's current and future business relationships to determine whether each relationship is with a "business associate," as that term is defined under the HIPAA Rules, and requires ROC to enter into a business associate agreement; c) create a process for negotiating and entering into business associate agreements with business associates prior to disclosing PHI to the business associates; d) create a standard template business associate agreement; e) create 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 f) 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. The policies and procedures required by this section shall be forwarded to HHS for its review and approval consistent with section V.B.2 of this CAP.

2. Within sixty (60) calendar days of the Effective Date, ROC shall forward the revised policies and procedures required by section V.B.1 of this CAP to HHS for HHS' review and approval. HHS will inform ROC in writing as to whether HHS approves or disapproves of the proposed policies and procedures. If HHS disapproves of them, HHS shall provide ROC with comments and required revisions. Upon receiving any required revisions to such policies and procedures from HHS, ROC shall have thirty (30) calendar days in which to revise the policies and procedures accordingly, and then submit the revised policies and procedures to HHS for review and approval. This process shall continue until HHS approves the policies and procedures.

3. Within thirty (30) calendar days of HHS' approval of the revised policies and procedures required by section V.B.1 of this CAP, ROC shall finalize and officially adopt the policies and procedures, in accordance with its applicable administrative procedures.

4. Within thirty (30) calendar days of HHS' approval of the revised policies and procedure required by section V.B.1 of this CAP, ROC shall review its existing business associate agreements for compliance with the HIPAA Rules and its policies and procedures and make any modifications necessary to conform to the revised policies and procedure.

C. Training

1. Within thirty (30) days of HHS' approval of any revised policies and procedures required by section V.B.2 of this CAP regarding business associates, ROC shall forward its proposed training materials on the revised policies and procedures for purposes of compliance with C.3 below, to HHS for its review and approval.

2. HHS will inform ROC in writing as to whether HHS approves or disapproves of the proposed training materials. If HHS disapproves of them, HHS shall provide ROC with comments and required revisions. Upon receiving any required revisions to the training materials from HHS, ROC shall have thirty (30) calendar days in which to revise the training materials, and then submit the revised training materials to HHS for review and approval.

3. Within sixty (60) days of HHS' approval of the training materials, ROC shall provide documentation that a) all workforce members who use or disclose PHI have received such training, b) that these workforce members will continue to receive such training annually, and c) that each new ROC workforce member will receive such training within fifteen (15) days of beginning work at ROC.

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

D. Reportable Events.

1. During the Compliance Term, ROC shall, upon receiving information that a workforce member may have failed to comply with its policies and procedures addressing the requirements of the HIPAA Rules, promptly investigate the matter. If ROC, after review and investigation, determines that a member of the workforce has failed to comply with its policies and procedures addressing the requirements of the HIPAA Rules, ROC shall notify HHS in writing within 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 ROC's Privacy, Security, and Breach Notification policies and procedures implicated; and
- b. A description of the actions taken and any further steps ROC plans to take to address the matter, to mitigate any harm, and to prevent it from recurring, including the application of appropriate sanctions against covered health care component workforce members who failed to comply with its Privacy, Security, and Breach Notification policies and procedures.

2. If no Reportable Events have occurred within a Reporting Period, ROC shall so inform HHS in its Annual Report for that Reporting Period in accordance with section VI of this CAP.

VI. Annual Reports

The one-year period beginning on the Effective Date and each one-year period during the course of the period of compliance shall be referred to as "the Reporting Periods." ROC shall submit to HHS Annual Reports with respect to the status of and findings regarding ROC's compliance with this CAP for each of the Reporting Periods. ROC shall submit each Annual Report to HHS no later than 60 days after the end of the Reporting Period. The Annual Report shall include:

A. A summary of the corrective action measures (defined in section V) taken during the Reporting Period;

B. A summary of Reportable Events (defined in section V.D) identified during the

Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events; and

C. An attestation signed by an owner or officer of ROC attesting that he or she has reviewed the Annual Report, has made a reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.

VII. Document Retention

ROC 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

ROC is expected to fully and timely comply with all provisions of its CAP obligations.

A. Timely Written Requests for Extensions. ROC 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 or file any notification or report required by this CAP. A “timely written request” is defined as a request in writing received by HHS at least five days prior to the date by which any act is due to be performed or any notification or report is due to be filed. It is within HHS’s sole discretion as to whether to grant or deny the extension requested.

B. Notice of Breach and Intent to Impose CMP. The Parties agree that a breach of this CAP by ROC constitutes a breach of the Resolution Agreement. Upon a determination by HHS that ROC has breached this CAP, HHS may notify ROC of (a) ROC’s breach; and (b) HHS’s intent to impose a civil money penalty (CMP) pursuant to 45 C.F.R. Part 160 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 (this notification is hereinafter referred to as the “Notice of Breach and Intent to Impose CMP”).

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

1. ROC is in compliance with the obligations of the CAP cited by HHS as being 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 (i) ROC has begun to take action to cure the breach; (ii) ROC is pursuing such action with due diligence; and (iii) ROC has provided to HHS a reasonable timetable for curing the breach.

D. Imposition of CMP. If at the conclusion of the 30 day period, ROC fails to meet the requirements of section VIII.C of this CAP to HHS’s satisfaction, HHS may proceed with the imposition of a CMP against ROC pursuant to 45 C.F.R. Part 160 for the Covered Conduct

set forth in paragraph I.2 of the Resolution Agreement and any other conduct that constitutes a violation of the HIPAA Privacy and Security Rules. HHS shall notify ROC in writing of its determination to proceed with the imposition of a CMP.

For Raleigh Orthopaedic Clinic

/s/

April 14, 2016

Karl F. Stein
Executive Director
Raleigh Orthopaedic Clinic, P.A.

Date

For United States Department of Health and Human Services

/s/

April 14, 2016

Timothy Noonan
Regional Manager, Southeast Region
Office for Civil Rights

Date