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. NY Spine Medicine ("NYSM"), which meets the definition of "covered entity" under 45 C.F.R. § 160.103 and therefore is required to comply with the HIPAA Rules.

C. HHS and NYSM shall together be referred to herein as the "Parties."

2. Factual Background and Covered Conduct

On July 22, 2019, OCR received a complaint against NYSM from a patient ("Complainant"). Complainant alleged that she requested access to her protected health information (PHI) numerous times beginning on June 10, 2019, to include a written request via certified mail received by NYSM on June 26, 2019 and had not been provided access to her requested PHI the date of her complaint. To date, she has not received X-ray, MRI and CT scan images she specifically requested.

OCR sent correspondence to NYSM on October 9, 2019 informing NYSM of the allegations, OCR's authority to investigate, and provided a Data Request requiring a response within 14 days. On January 10, 2020, OCR sent similar additional correspondence via certified mail. This was received by NYSM on January 13, 2020.

OCR further attempted to contact NYSM via telephone at its New York, NY Office on December 26, 2019 and January 24, 2020 and left messages with NYSM's answering service, and attempted to contact NYSM's Miami Beach, FL office on March 6, 2020 and left a similar message. OCR received a phone call from NYSM on March 6, 2020 from an individual in NYSM's records department, who was informed of OCR's correspondence and NYSM's obligation to cooperate.

HHS' investigation indicated that the following covered conduct occurred ("Covered Conduct"):

A. NYSM failed to provide access to protected health information about the individual in a designated record set (*see* 45 C.F.R. § 164.524).

- 3. No Admission. This Agreement is not an admission of liability by NYSM.
- 4. <u>No Concession</u>. This Agreement is not a concession by HHS that NYSM is not in violation of the HIPAA Rules and not liable for civil money penalties.
- 5. <u>Intention of Parties to Effect Resolution</u>. This Agreement is intended to resolve HHS Transaction Number: 01-20-352299 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 NYSM has agreed to pay HHS, the amount of \$100,000.00 ("Resolution Amount"). NYSM 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. NYSM 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 NYSM breaches the CAP, and fails to cure the breach as set forth in the CAP, then NYSM 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 NYSM's performance of its obligations under this Agreement, HHS releases NYSM from any actions it may have against NYSM 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 NYSM 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. NYSM 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. NYSM waive 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. <u>Binding on Successors</u>. This Agreement is binding on NYSM and its successors, heirs, transferees, and assigns.

- 11. <u>Costs</u>. 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. <u>No Additional Releases</u>. 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. <u>Effect of Agreement</u>. 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, NYSM agrees that the time between the Effective Date of this Agreement and the date the Agreement may be terminated by reason of NYSM'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. NYSM 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. <u>Disclosure</u>. 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. <u>Authorizations</u>. The individual(s) signing this Agreement on behalf of NYSM represents and warrants that they are authorized to execute this Agreement and bind NYSM, as set forth in paragraph I.1.b. 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 NY Spine Medicine:

/s/	9/29/2020
Dr. Douglas Schottenstein NY Spine Medicine	Date
For Department of Health and Human Service	ces
/s/	9/29/2020
Susan M. Pezzullo Rhodes Regional Manager, New England Region Office for Civil Rights	Date

Appendix A

CORRECTIVE ACTION PLAN

BETWEEN THE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

AND

NY SPINE MEDICINE

I. Preamble

NY Spine Medicine ("NYSM") 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, NYSM is entering into the Agreement with HHS, and this CAP is incorporated by reference into the Agreement as Appendix A. NYSM enters into this CAP as part of consideration for the release set forth in paragraph II.8 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 NYSM regarding the implementation of this CAP and for receipt and submission of notifications and reports ("NYSM Contact") is:

Pearl Chan; Office Manager

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

Ms. Susan M. 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

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

B. <u>Proof of Submissions</u>. 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 paragraph II.14 of the Agreement ("Effective Date"). The period for compliance ("Compliance Term") with the obligations assumed by NYSM 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 NYSM under Section VIII hereof of its determination that NYSM 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 NYSM that it has determined that the breach has been cured. After the Compliance Term ends, NYSM 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 NYSM's obligation to comply with the document retention requirements in 45 C.F.R. §§ 164.316(b) and 164.530(j).

IV. <u>Time</u>

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. <u>Corrective Action Obligations</u>

NYSM agrees to the following:

A. Provide the Complainant with a complete copy of her records as requested.

B. Policies and Procedures

- 1. NYSM shall develop, maintain, and revise, as necessary, its written policies and procedures to comply with 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"). NYSM's policies and procedures shall address, but not be limited to, the Covered Conduct specified in paragraph I.2 of the Agreement.
- 2. NYSM shall provide such policies and procedures, consistent with paragraph 1 above, to HHS within sixty (60) days of the Effective Date for review and approval. Upon receiving any recommended changes to such policies and procedures from HHS, NYSM shall have

thirty (30) days to revise such policies and procedures accordingly and provide the revised policies and procedures to HHS for review and approval.

- 3. NYSM shall implement such policies and procedures within thirty (30) days of receipt of HHS' approval.
- 4. NYSM shall designate a privacy official who is responsible for the development and implementation of the policies and procedures of the entity and a contact person or office who is responsible for receiving complaints under this section and who is able to provide further information about matters covered by the notice required by 45 C.F.R. § 164.520 (45 C.F.R. Part 164.530(a)(1)).
- 5. NYSM shall make and provide such designations, consistent with paragraph 4 above, to HHS within sixty (60) days of the Effective Date for review and approval. Upon receiving any recommended changes to such policies and procedures from HHS, NYSM shall have thirty (30) days to revise such policies and procedures accordingly and provide the revised policies and procedures to HHS for review and approval.

B. <u>Distribution and Updating of Policies and Procedures</u>

- 1. NYSM shall distribute the policies and procedures identified in section V.A. to all members of the workforce and relevant business associates within thirty (30) days of HHS approval of such policies and to new members of the workforce within thirty (30) days of their beginning of service.
- 2. NYSM shall require, at the time of distribution of such policies and procedures, a signed written or electronic initial compliance certification from all members of the workforce and relevant business associates stating that the workforce members have read, understand, and shall abide by such policies and procedures.
- 3. NYSM shall assess, update, and revise, as necessary, the policies and procedures at least annually or as needed. NYSM shall provide such revised policies and procedures to HHS for review and approval. Within thirty (30) days of the effective date of any approved substantive revisions, NYSM shall distribute such revised policies and procedures to all members of its workforce and relevant business associates and shall require new compliance certifications.

C. Minimum Content of Policies and Procedures

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

- 1. Review and update as necessary NYSM's Right of Access to PHI policy to ensure comprehensive responses to requests for records.
- 2. Protocols for training all NYSM's workforce members that are involved in receiving or fulfilling access requests as necessary and appropriate to ensure compliance with the policies and procedures provided for in section V(A) above.

- 3. Application of appropriate sanctions against NYSM workforce members who fail to comply with policies and procedures provided for in subparagraph (1) above.
- 4. Review and update as necessary NYSM's policy for cooperation with investigations and compliance reviews conducted by the Secretary to ensure comprehensive responses to compliance investigations and reviews.
- 5. Protocols for training all NYSM's workforce members that are involved with cooperating with investigations and compliance reviews conducted by the Secretary to ensure compliance with the policies and procedures provided for in section V(A) above.
- 6. Application of appropriate sanctions against NYSM workforce members who fail to comply with policies and procedures provided for in subparagraph (1) above.

D. Training

- 1. NYSM shall provide HHS with training materials per section V.C. above for all members of the workforce within sixty (60) days of the approval of its policies and procedures per section V.A.
- 2. Upon receiving notice from HHS specifying any required changes, NYSM shall make the required changes and provide revised training materials to HHS within thirty (30) days.
- 3. Upon receiving approval from HHS, NYSM shall provide training for each workforce member within sixty (60) days of HHS approval and at least every twelve (12) months thereafter. NYSM shall also provide such training to each new member of the workforce or relevant new business associate within thirty (30) days of their beginning of service.
- 4. Each workforce member who is required to attend training shall certify, in electronic or written form, that he or she has received the training. The training certification shall specify the date training was received. All course materials shall be retained in compliance with section VII.
- 5. NYSM shall review the training at least 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.

E. Mitigation

1. Within fifteen (15) days following the Effective Date of the Agreement, NYSM shall make a good faith effort to provide the complainant with access to her requested records, in whole or in part, and/or provide a denial, in whole or in part, consistent with 45 C.F.R. 164.524.

F. Reportable Events

During the Compliance Term, NYSM shall, upon receiving information that a workforce member may have failed to comply with its access policies and procedures or a business associate may have failed to comply with the provision of access requirements in its business

associate agreement with NYSM, promptly investigate this matter. If NYSM determines, after review and investigation, that a member of its workforce has failed to comply with these policies and procedures or a business associate has filed to comply with the provision of access requirements in its business associate agreement, NYSM shall notify HHS in writing within thirty (30) days. Such violations shall be known as Reportable Events. The report to shall include the following information:

- 1. A complete description of the event, including the relevant facts, the persons involved, and the provision(s) of the policies and procedures implicated; and
- 2. A description of the actions taken and any further steps NYSM 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 Privacy Rule policies and procedures.

VI. Implementation Report and Annual Reports

A. Implementation Report.

Within 120 days after the receipt of HHS' approval of the policies and procedures required by section V.A.1, NYSM 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. An attestation signed by an owner or officer of NYSM attesting that the Policies and Procedures are being implemented, have been distributed to all appropriate members of the workforce and relevant business associates and that NYSM has obtained all of the compliance certifications required by sections V.B.2. and V.B.3.;
- 2. 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;
- 3. An attestation signed by an owner or officer of NYSM attesting that all members of the workforce and relevant business associates have completed the initial training required by this CAP and have executed the training certifications required by section V.D.2.;
- 4. An attestation signed by an owner or officer of NYSM stating that he or she has reviewed the Implementation Report, has made a reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.

B. Annual Reports.

The one (1) year period after 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, NYSM shall submit a report or reports to HHS regarding NYSM's compliance with this CAP for each corresponding Reporting Period ("Annual Report"). The Annual Report shall include:

- 1. A copy of the schedule, topic outline, and training materials for the training programs provided during the Reporting Period that is the subject of the Annual Report;
- 2. An attestation signed by an officer or director of NYSM attesting that it is obtaining and maintaining written or electronic training certifications from all persons who are required to attend training under this CAP;
- 3. An attestation signed by an officer or director of NYSM 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 NYSM distributed the revised Policies and Procedures to all appropriate members of NYSM's workforce within sixty (60) days of HHS' approval of the revision(s); and
- 4. A summary of Reportable Events (defined in section VII), if any, 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 NYSM stating that no Reportable Events occurred during the Compliance Term.
- 5. An attestation signed by an owner or officer of NYSM 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. Reportable Events

- A. Reportable Events. After the implementation of the Policies and Procedures in accordance with paragraph V.B.1, NYSM shall, during the remainder of the Compliance Term, upon receiving information that a workforce member may have failed to comply with such policies and procedures, promptly investigate the matter. If NYSM, after review and investigation, determines that a member of its workforce has failed to comply with such policies and procedures, NYSM shall report such event(s) to HHS as provided in section VI.B.4. Such violations shall be known as "Reportable Events." The report to HHS shall include the following:
 - 1. A complete description of the event, including the relevant facts, the persons involved, and the provision(s) of the Policies and Procedures implicated; and
 - 2. A description of the actions taken and any further steps NYSM 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.

VIII. <u>Document Retention</u>

NYSM 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.

IX. Breach Provisions

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

- A. <u>Timely Written Requests for Extensions.</u> NYSM 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 NYSM constitutes a breach of the Agreement. Upon a determination by HHS that NYSM has breached this CAP, HHS may notify NYSM Contact of: (1) NYSM'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.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. <u>NYSM's Response</u>. If NYSM is named in a Notice of Breach and Intent to Impose CMP, NYSM 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. NYSM 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 NYSM: (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. <u>Imposition of CMP</u>. If at the conclusion of the thirty (30) day period, NYSM fails to meet the requirements of section IX.C. of this CAP to HHS' satisfaction, HHS may proceed with the imposition of a CMP against NYSM 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.2 of the Agreement and for any other act or failure to act that constitutes a violation of the HIPAA Rules. HHS shall notify NYSM 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 NY SPINE MEDICINE	
/s/	9/29/2020
Dr. Douglas Schottenstein NY Spine Medicine	Date
For Department of Health and Human Services	
/s/	9/29/2020
Susan M. Pezzullo Rhodes Regional Manager, New England Region	Date

Office for Civil Rights