RESOLUTION AGREEMENT

I. <u>Recitals</u>

- 1. <u>Parties</u>. 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. Sharp HealthCare (SHARP), doing business as Sharp Rees-Stealy Medical Centers ("SRMC"), is a covered entity, as defined at 45 C.F.R. § 160.103, and therefore is required to comply with the HIPAA Rules. SRMC is located in San Diego, California.
 - C. HHS and SRMC shall together be referred to herein as the "Parties."
- 2. Factual Background and Covered Conduct

On June 11, 2019, a complaint was filed with OCR alleging that SRMC failed to provide the complainant's client (the Affected Party), electronic access to his medical records as requested in writing on April 2, 2019. On June 25, 2019, OCR closed the case by providing technical assistance to SRMC. On August 19, 2019, the Complainant filed a second complaint against SRMC with the same allegations that SRMC still had not responded to the Affected Party's request for medical records. SRMC did not provide the Affected Party with access to his requested records until October 15, 2019.

OCR's investigation indicated the following conduct occurred ("Covered Conduct"):

SRMC failed to timely respond to the Affected Party's request to have an electronic copy of protected health information in an electronic health record sent to a third party recipient. *See* 45 C.F.R. § 164.524.

- 3. <u>No Admission</u>. This Agreement is not an admission of liability by SRMC.
- 4. <u>No Concession</u>. This Agreement is not a concession by HHS that SRMC 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: 19-354486 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. <u>Terms and Conditions</u>

- 6. <u>Payment</u>. HHS has agreed to accept, and SRMC has agreed to pay HHS, the amount of <u>\$70,000</u> ("Resolution Amount"). SRMC agrees to pay the Resolution Amount on the Effective Date of this Agreement as defined in paragraph II.14 by automated clearinghouse transaction pursuant to written instructions to be provided by HHS.
- 7. <u>Corrective Action Plan</u>. SRMC 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 SRMC breaches the CAP, and fails to cure the breach as set forth in the CAP, then SRMC 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. <u>Release by HHS</u>. In consideration of and conditioned upon SRMC's performance of its obligations under this Agreement, HHS releases SRMC from any actions it may have against SRMC 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 SRMC 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. <u>Agreement by Released Parties</u>. SRMC 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. SRMC 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. <u>Binding on Successors</u>. This Agreement is binding on SRMC 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. <u>Execution of Agreement and Effective Date</u>. 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. <u>Tolling of Statute of Limitations</u>. 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, SRMC agrees that the time between the Effective Date of this Agreement (as set forth in Paragraph 14) and the date the Agreement may be terminated by reason of SRMC'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. SRMC 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. <u>Execution in Counterparts</u>. 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 SRMC represents and warrants that they are authorized to execute this Agreement and bind SRMC, 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 SRMC HealthCare (SRMC)

/s/

01/28/2021

Stacey HrountasDateChief Executive Officer, Sharp Rees-Stealy Medical CentersSRS Executive Administration5651 Copley DriveSan Diego, CA 92111

For Department of Health and Human Services

/s/

02/03/2021

Barbara Stampul Acting Regional Manager, Southeast Region Office for Civil Rights Date

Appendix A

CORRECTIVE ACTION PLAN

BETWEEN THE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

AND

SRMC HEALTHCARE

I. <u>Preamble</u>

Sharp HealthCare (SHARP), doing business as Sharp Rees-Stealy Medical Centers ("SRMC"), hereby enters into this Corrective Action Plan ("CAP") with the United States Department of Health and Human Services, Office for Civil Rights. Contemporaneously with this CAP, SRMC is entering into a Resolution Agreement ("Agreement") with HHS, and this CAP is incorporated by reference into the Agreement as Appendix A. SRMC 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

SRMC has identified the following individual ("SRMC Contact") as its authorized representative and contact person regarding the implementation of this CAP and for receipt and submission of notifications and reports:

Caitlin Holleran VP, Corporate Compliance 8695 Spectrum Center Boulevard San Diego, CA 92123 <u>Caitlin.Holleran@Sharp.com</u> (858) 499-4015

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

Ms. Barbara Stampul, Acting Regional Manager Office for Civil Rights, Southeast Region Department of Health and Human Services Sam Nunn Federal Building, Suite 16T70 61 Forsyth Street, S.W. Atlanta, GA 30303 Barbara.Stampul@hhs.gov

Telephone: 404-562-2799 Facsimile: 404-562-7881

SRMC 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 SRMC 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 SRMC under Section VIII hereof of its determination that SRMC 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 SRMC that it has determined that the breach has been cured. After the Compliance Term ends, SRMC shall still be obligated to: (a) submit the final Annual Report asrequired by Section VI; and (b) comply with the document retention requirement in Section VII. Nothing in this CAP is intended to eliminate or modify SRMC's obligation to comply with the document retention requirements in 45 C.F.R. §§ 164.316(b) and 164.530(j), and in Section VII.

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>

SRMC agrees to the following:

A. Policies and Procedures

1. SRMC 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"). SRMC's policies and procedures shall address, but not be limited to, the Covered Conduct specified in Section I.2 of the Agreement

and also meet the Minimum Content set out in Section V.C. below.

- 2. SRMC 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, SRMC 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. This process shall continue until HHS approves such policies and procedures.
- 3. Within 60 days after receiving HHS' final approval of any revisions to the policies and procedures described in Section V.A.1, SRMC shall implement and distribute the policies and procedures to all appropriate workforce members.
- B. Distribution and Updating of Policies and Procedures
 - 1. SRMC shall distribute the policies and procedures identified in Section V.A to all members of the workforce within thirty (30) days of HHS approval of such policies and to new members of the SRMC workforce within thirty (30) days of their beginning of service.
 - 2. SRMC shall provide proof of such distribution to HHS.
 - 3. SRMC shall assess, update, and revise, as necessary, the policies and procedures at least annually or as needed. SRMC 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, SRMC shall distribute such revised policies and procedures to all members of its workforce and shall provide proof of such distribution to HHS.

C. Minimum Content of Policies and Procedures

The Policies and Procedures required under Section V.A. shall include, but not be limited to:

- 1. All obligations required under 45 C.F.R. §164.524 and all its subparts;
- 2. Accurate definition of a "Designated Record Set" as defined in the Privacy Rule; and
- 3. Protocols for training all SRMC'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.
- D. Privacy Training on Individual Access to Protected Health Information
 - 1. Within sixty (60) calendar days of the Effective Date, SRMC shall provide

training materials regarding the individual's right of access to PHI consistent with 45 C.F.R. § 164.524 to HHS for review and approval.

- 2. Upon receiving notice from HHS specifying any required changes, SRMC shall make the required changes and provide revised training materials to HHS within thirty (30) days.
- 3. Within sixty (60) calendar days of HHS's approval and annually while under the Term of this CAP, SRMC shall provide training on the Privacy Rule requirements concerning the individual's right of access to PHI to all SRMC workforce members whose job duties relate to receiving, reviewing, processing, or fulfilling individual requests for access to health records, including but not limited to, all managers and supervisors, all Health Information Management staff, all compliance department staff, all legal department staff, and all risk management department staff.
- 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. SRMC 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. <u>Reportable Events</u>

During the Compliance Term, SRMC shall, upon receiving information that a workforce member may have failed to comply with its access policies and procedures, promptly investigate this matter. If SRMC determines, after review and investigation, that a member of its workforce has failed to comply with these policies and procedures, SRMC 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 SRMC 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. <u>Implementation Report</u>.

Within 120 days after the receipt of HHS' approval of the policies and procedures required by Section V.A., SRMC 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 SRMC attesting that:
 - a. the Policies and Procedures approved by HHS in Section V.A. have been distributed to all members of the workforce; and that
 - b. SRMC has obtained all of the compliance certifications required by SectionV.D.4.;
- 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 SRMC attesting that all appropriate members of the workforce have completed the initial training required by this CAP;
- 4. An attestation signed by an owner or officer of SRMC 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. <u>Annual Reports</u>.

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 thirty (30) days after the close of each corresponding Reporting Period, SRMC shall submit a report or reports to HHS regarding SRMC'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 of SRMC 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 of SRMC 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 SRMC distributed the revised Policies and Procedures to all members of SRMC's workforce within thirty (30) days of HHS' approval of the revision(s); and

- 4. A summary of Reportable Events (defined in section V.E.), if any, the status of any corrective and preventative action(s) relating to all such Reportable Events, or an attestation signed by an officer of SRMC stating that no Reportable Events occurred during the Compliance Term.
- 5. An attestation signed by an owner or officer of SRMC 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

SRMC 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

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

- A. <u>Timely Written Requests for Extensions.</u> SRMC 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. <u>Notice of Breach of this CAP and Intent to Impose CMP.</u> The Parties agree that a breach of this CAP by SRMC constitutes a breach of the Agreement. Upon a determination by HHS that SRMC has breached this CAP, HHS may notify SRMC Contact of: (1) SRMC'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>SRMC's Response</u>. If SRMC is named in a Notice of Breach and Intent to Impose CMP, SRMC 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. SRMC 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 SRMC: (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, SRMC 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 SRMC, 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 SRMC 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 SRMC HealthCare (SRMC)

/s/

01/28/2021

Stacey HrountasDateChief Executive Officer, Sharp Rees-Stealy Medical CentersSRS Executive Administration5651 Copley DriveSan Diego, CA 92111

For Department of Health and Human Services

/s/

02/03/2021

Barbara Stampul Acting Regional Manager, Southeast Region Office for Civil Rights Date