

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. BayCare Health System, Inc. (BayCare) which meets the definition of a Covered Entity under 45 C.F.R. § 160.103 and therefore is required to comply with the HIPAA Rules.

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

2. Factual Background and Covered Conduct

On October 23, 2018, OCR received a complaint alleging that on October 8, 2018, an unknown third-party accessed her printed and electronic medical record from St. Joseph’s Hospital. OCR’s investigation indicated that the following conduct occurred (“Covered Conduct”):

A. BayCare failed to implement policies and procedures for authorizing access to electronic protected health information that are consistent with the applicable requirements of the Privacy Rule, specifically, the requirement to make reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request, as required by 45 C.F.R. §164.308(a)(4).

B. BayCare failed to implement security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level as required by 45 C.F.R. §164.308(a)(1)(ii)(B).

C. BayCare failed to implement procedures to regularly review records of information system activity as required by 45 C.F.R. §164.308(a)(1)(ii)(D).

3. No Admission. This Agreement is not an admission of liability by BayCare, concession or evidence of liability by BayCare, or of any fact or any violation of law, rule, or regulation, including any violation of HIPAA Rules.

4. No Concession. This Agreement is not a concession by HHS that BayCare 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 HHS Transaction Number: 04-19-321467 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 BayCare has agreed to pay HHS, the amount of **\$800,000** ("Resolution Amount"). BayCare agrees to pay the Resolution Amount in one lump sum within ten (10) days of the Effective Date of this Agreement as defined in paragraph II.14 pursuant to written instructions to be provided by HHS.
7. Corrective Action Plan. BayCare 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 BayCare breaches the CAP and fails to cure the breach as set forth in the CAP, then BayCare 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 BayCare's performance of its obligations under this Agreement, HHS releases BayCare from any actions it may have against BayCare 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 BayCare 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. BayCare 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. BayCare 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 BayCare 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, BayCare agrees that the time between the Effective Date of this Agreement and the date the Agreement may be terminated by reason of BayCare’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. BayCare 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.
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. The individual(s) signing this Agreement on behalf of BayCare represents and warrants that they are authorized to execute this Agreement and bind BayCare, 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 BayCare Health System

_____/s

2/14/2025

Stephanie D. Connors
President and CEO
BayCare Health System
2985 Drew Street
Clearwater, FL 33759

Date

For U.S. Department of Health and Human Services

_____/s

2/14/2025

Barbara Stampul
Regional Manager, Southeast Region
Office for Civil Rights

Date

Appendix A
CORRECTIVE ACTION PLAN
BETWEEN THE
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
BAYCARE HEALTH SYSTEM

I. Preamble

BayCare Health System, Inc. (BayCare) 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, BayCare is entering into the Agreement with HHS, and this CAP is incorporated by reference into the Agreement as Appendix A. BayCare 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 BayCare regarding the implementation of this CAP and for receipt and submission of notifications and reports is:

Jeff Durham
Chief Compliance & Privacy Officer
BayCare Health System
2985 Drew Street
Clearwater, FL 33759

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

Barbara Stampul, Regional Manager
Office for Civil Rights, Southeast Region
Department of Health and Human Services
61 Forsyth Street SW, Ste. 16T70
Atlanta, GA 30303
REDACTED

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

B. Proof of Submissions. Unless otherwise specified, all notifications and reports required by this CAP may be made by any means, including certified mail, electronic 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 BayCare 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 BayCare under Section VIII hereof of its determination that BayCare 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 BayCare that it has determined that the breach has been cured. After the Compliance Term ends, BayCare 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 BayCare obligation to comply with the document retention requirements in 45 C.F.R. §§ 164.316(b) and 164.530(j).

IV. Time

In computing any period of time prescribed or allowed by this CAP, all days referred to shall be calendar days. The day of the act, event, or default from which the designated period of time begins to run shall not be included. The last day of the period so computed shall be included, unless it is a Saturday, a Sunday, or a legal holiday, in which event the period runs until the end of the next day which is not one of the aforementioned days.

V. Corrective Action Obligations

BayCare agrees to the following:

A. Conduct Risk Analysis

1. Within thirty (30) days of the Effective Date, BayCare shall forward to HHS for review and approval the most recent version of BayCare's Security Rule Risk Analysis. The Risk Analysis shall incorporate all BayCare's facilities and must include an evaluation of the risks to the security of ePHI in electronic equipment, information systems, devices and media, and applications controlled, administered or owned by BayCare, that contain, store, transmit, or receive ePHI. The Risk Analysis shall also include an assessment of the risks to ePHI security in the physical environment.

2. Upon receiving HHS's notice of required revisions, if any, BayCare shall have 30 days to revise the Risk Analysis accordingly and forward to HHS for review and approval. This process shall continue until HHS approves the Risk Analysis.

3. BayCare shall review the Risk Analysis annually. BayCare shall also promptly update the Risk Analysis in response to environmental or operational changes affecting

the security of ePHI. Following an update to the risk analysis, BayCare shall assess whether its existing security measures are sufficient to protect its electronic PHI, and revise its risk management plan, policies and procedures, and training materials, as needed.

B. Develop and Implement a Risk Management Plan

1. BayCare shall develop a risk management plan sufficient to address and mitigate any security risks and vulnerabilities identified in the Risk Analysis described in section V.A. above (“Risk Management Plan”). The Risk Management Plan shall include a process and timeline for BayCare’s implementation, evaluation, and revision of their risk remediation activities.

2. The risk management plan shall be forwarded to HHS for review and approval within 90 days of HHS’ approval of the Risk Analysis describe in section V.A. above. HHS shall approve, or, if necessary, require revisions to BayCare’s Risk Management Plan.

3. Upon receiving HHS’s written notice of required revisions, if any, BayCare shall have 60 days to revise the Risk Management Plan accordingly and forward to HHS for review and approval. This process shall continue until HHS approves the Risk Management Plan.

4. Within 30 days of HHS’s approval of the Risk Management Plan, BayCare shall finalize and officially adopt the Risk Management Plan in accordance with its applicable administrative procedures.

C. Policies and Procedures

1. As necessary to implement the Risk Management Plan at V.B. above, BayCare shall revise, as necessary, its written policies and procedures (“policies and procedures”) to comply with the Federal standards that govern the privacy and security of individually identifiable health information.

2. Within 30 days of HHS’s approval of the Risk Management Plan identified in Section V.B., BayCare shall provide such policies and procedures, consistent with paragraph 1 above, to HHS for review and approval. Upon receiving any written notice of required changes to such policies and procedures from HHS, BayCare shall have 60 days to revise the 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.

D. Minimum Content of the Policies and Procedures

The Policies and Procedures required by Paragraph V.C. above shall include, but need not be limited to, the following provisions, standards, implementation specifications and obligations:

Security Rule Provisions:

1. Risk Management – 45 C.F.R. § 164.308(a)(1)(ii)(B)
2. Information System Activity Review – 45 C.F.R. §164.308(a)(1)(ii)(D)
3. Information Access Management – 45 C.F.R. §164.308(a)(4)

E. Distribution and Updating of Policies and Procedures

1. Bay Care shall distribute the policies and procedures identified in Section V.D., to all members of the workforce within 60 days of HHS's approval of such policies and to new members of the workforce within 15 days of the beginning of service.

2. BayCare shall provide to HHS evidence of such distribution of the policies and procedures identified in Section V.C. to all members of the workforce.

3. BayCare shall assess, update, and revise, as necessary, the policies and procedures at least annually. BayCare shall provide any revised policies and procedures to HHS for review and approval. Within 60 days of the effective date of any approved substantive revisions by HHS, BayCare shall distribute such revised policies and procedures to all members of its workforce and shall provide HHS with evidence of such distribution.

4. BayCare shall not provide any member of its workforce with access to PHI if that workforce member has not received such policies and procedures.

F. Reportable Events

1. During the Compliance Term, BayCare shall, upon learning that a workforce member may have failed to comply with its policies and procedures described in Section V.D.1., promptly investigate this matter. If BayCare, after review and investigation, determines that a member of its workforce has failed to comply with its policies and procedures, and sanctions such workforce member for such failure, BayCare shall report such events 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:

- a. A complete description of the event, including the relevant facts, the persons involved, and the applicable provision(s) of BayCare's Privacy, Security, and Breach Notification policies and procedures; and
- b. A description of the actions taken and any further steps BayCare plans to take to address the matter, to mitigate any harm, and to prevent it from recurring, including application of any appropriate sanctions against workforce members who failed to comply with its Privacy, Security, and Breach Notification policies and procedures.

2. If no Reportable Events occur during the Compliance Term, BayCare shall so inform HHS in the Implementation Report as specified in Section VI below.

G. Training

1. BayCare shall provide HHS with training materials on the privacy and security of PHI for all members of the workforce that have access to PHI, including with regard to any new or revised Policies and Procedures described under Section V.D., within sixty (60) days of HHS's final written approval of policies and procedures described in section V.D.

2. Upon receiving written notice from HHS specifying any required changes, BayCare shall make the required changes and provide revised training materials to HHS within 60 days.

3. Within 60 days after receiving HHS's final approval of training materials as provided for by Section V.G.1. and 2. above, BayCare shall provide training for each workforce member who requires such training given their job duties. Thereafter, BayCare shall also provide such training to all workforce members as required by BayCare's policies and procedures.

4. BayCare shall provide to HHS evidence of such training. The training evidence shall specify the date training was received. All course materials shall be retained in compliance with section VII.

5. BayCare 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.

VI. Implementation Report and Annual Reports

A. Implementation Report. Within 90 days, after HHS approves the policies and procedures required by section V.D. above as necessary, BayCare shall submit a written report with the documentation described below to HHS for review and approval ("Implementation Report"). The Implementation Report shall include:

1. An attestation signed by an owner or officer of BayCare attesting that the policies and procedures are being implemented and have been distributed to all appropriate members of the workforce as required by Sections V.E.3. and V.E.4;

2. A copy of all training materials used for the training required by Section V.G., 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 BayCare attesting that they have made a reasonable inquiry regarding training and reviewed documentation related to such training and believes to the best of their knowledge, that, upon such inquiry, all members of the workforce have completed the initial training required by this CAP;

4. An attestation signed by an owner or officer of BayCare listing all BayCare locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, and an attestation that they have made a reasonable inquiry regarding CAP obligations and believes that, upon such inquiry, each such location has complied with the obligations of this CAP; and

5. An attestation signed by an owner or officer of BayCare stating that they have 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-year period beginning on the Effective Date and each subsequent one-year period during the period of compliance obligations shall be referred to as “the Reporting Periods.” BayCare also shall submit to HHS Annual Reports with respect to the status of and findings regarding BayCare’s compliance with this CAP for each of the three Reporting Periods. BayCare shall submit each Annual Report to HHS no later than 60 days after the end of each corresponding Reporting Period. The Annual Report shall include:

1. An attestation signed by an owner or officer of BayCare attesting that the policies and procedures required by Section V of this CAP: (a) have been adopted; (b) are being implemented; and (c) have been distributed to all workforce members;

2. A schedule, topic outline, and copies of the training materials for the training programs attended in accordance with this CAP during the Reporting Period that is the subject of the report;

3. An attestation signed by an owner or officer of BayCare attesting that they have made a reasonable inquiry regarding training and believes that, upon such inquiry, to the best of their knowledge, it is maintaining written documentation regarding training for workforce members pursuant to the requirements set forth on this CAP and pursuant to the BayCare’s approved training procedures;

4. A summary of Reportable Events (defined in Section V.F.1) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;

5. An attestation signed by an owner or officer of BayCare attesting that they have 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

BayCare 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.

A. Timely Written Requests for Extensions. BayCare 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 days prior to the date such an act is required or due to be performed. This requirement may be waived by OCR only.

B. Notice of Breach of this CAP and Intent to Impose Civil Monetary Penalty. The parties agree that a breach of this CAP by BayCare constitutes a breach of the Agreement. Upon a determination by HHS that BayCare has breached this CAP, HHS may notify BayCare of: (1) BayCare’s breach; and (2) HHS’s intent to impose a 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. BayCare's Response. BayCare shall have 60 days from the date of receipt of the Notice of Breach and Intent to Impose CMP to demonstrate to HHS's satisfaction that:

1. BayCare 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 60-day period, but that: (a) BayCare has begun to take action to cure the breach; (b) BayCare is pursuing such action with due diligence; and (c) BayCare has provided to HHS a reasonable timetable for curing the breach.

D. Imposition of CMP. If at the conclusion of the 60-day period, BayCare fails to meet the requirements of this CAP to HHS's satisfaction, HHS may proceed with the imposition of a CMP against BayCare 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 BayCare in writing of its determination to proceed with the imposition of a CMP pursuant to 45 C.F.R. Part 160. BayCare reserves all rights to dispute HHS's determination, in law and equity. HHS will offset any CMP amount levied under this section by the amounts already paid by BayCare in lieu of CMPs under the Agreement. Any such offset applies only to Covered Conduct up to and including the Effective Date.

For BayCare Health System

/s

Stephanie D. Conners
President and CEO
BayCare Health System
2985 Drew Street
Clearwater, FL 33759

2/14/2025

Date

For U.S. Department of Health and Human Services

/s

Barbara Stampul
Regional Manager, Southeast Region
Office for Civil Rights

2/14/2025

Date