

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. Center for Children’s Digestive Health, S.C. (“CCDH”), which is a covered entity, as defined at 45 C.F.R. § 160.103, and therefore is required to comply with the HIPAA Rules. CCDH is a small, for-profit health care provider that operates a pediatric subspecialty practice in seven clinic locations across Illinois.

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

2. **Factual Background and Covered Conduct.** On August 13, 2015, HHS initiated a compliance review of CCDH to determine whether CCDH’s disclosure of protected health information (PHI) to Filefax, Incorporated (“Filefax”), a third-party vendor that stored inactive paper medical records for patients of CCDH, was permissible under the Privacy Rule.

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

- A. CCDH failed to obtain satisfactory assurances from Filefax, in the form of a written business associate agreement, that Filefax would appropriately safeguard the PHI that was in Filefax’s possession or control. *See* 45 C.F.R. § 164.502(e).
- B. CCDH impermissibly disclosed the PHI of at least 10,728 individuals to Filefax when CCDH transferred the PHI to Filefax without obtaining Filefax’s satisfactory assurances, in the form of a written business associate agreement,

that Filefax would appropriately safeguard the PHI. *See* 45 C.F.R. § 164.502(a).

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

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

5. **Intention of Parties to Effect Resolution.** This Agreement is intended to resolve HHS Transaction No. 15-217590, and any violations of the HIPAA Rules for 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 further investigation and 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 CCDH has agreed to pay HHS, the amount of \$31,000.00 ("Resolution Amount"). CCDH 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.** CCDH 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 CCDH breaches the CAP, and fails to cure the breach as set forth in the CAP, then CCDH 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 CCDH's performance of its obligations under this Agreement, HHS releases CCDH from any actions it may have against CCDH under the HIPAA Rules for the Covered Conduct specified in paragraph I.2 of this Agreement. HHS does not release CCDH from, nor waive any rights, obligations, or causes of action other than those for 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 Party.** CCDH 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. CCDH waives all procedural rights granted under section 1128A of the Social Security Act (42 U.S.C. § 1320a-7a), 45 C.F.R. Part 160, Subpart E, and HHS' Claims Collection provisions, 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 CCDH and its successors, heirs, transferees, and assigns. Notwithstanding the above sentence, if Advocate Health Care Network or one of its subsidiaries purchases some or all of CCDH's assets, and that asset purchase results in CCDH's facilities and employees being subject to the corrective active obligations

outlined in the Resolution Agreement and Corrective Action Plan Advocate Health Care Network entered into with HHS on July 8, 2016, this Agreement shall not be binding on Advocate Health Care Network and its subsidiaries.

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 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 must be in writing and signed by both Parties.

14. **Execution of Agreement and Effective Date.** The Agreement shall become effective (*i.e.*, final and binding) on the date of signing of this Agreement and the CAP by the last signatory ("Effective Date").

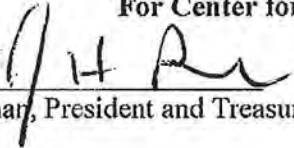
15. **Tolling of Statute of Limitations.** Pursuant to 42 U.S.C. § 1320a-7a(c)(1), a civil money penalty ("CMP") must be imposed within six (6) years from the date of the occurrence of the violation. To ensure that this six-year period does not expire during the term of this Agreement, CCDH agrees that the time between the Effective Date of this Agreement and the date this Agreement may be terminated by reason of CCDH'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. CCDH waives and will not plead any statute of limitations, laches, or similar defenses to any administrative action relating to the Covered Conduct identified in paragraph I.2 that is filed by HHS within the time period set forth above, except to the extent that such defenses would have been available had an administrative action been filed on the Effective Date of this Agreement.

16. **Disclosure.** HHS places no restriction on the publication of the Agreement. In addition, HHS may be required to disclose this Agreement and related material to any person upon request consistent with the applicable provisions of the Freedom of Information Act, 5 U.S.C. § 552, and its implementing regulations, 45 C.F.R. Part 5.

17. **Execution in Counterparts.** This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same agreement.

18. **Authorizations.** The individual(s) signing this Agreement on behalf of CCDH represent and warrant that they are authorized by CCDH 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 Center for Children's Digestive Health

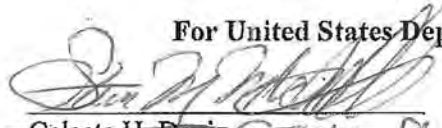

James Bermar, President and Treasurer-CCDH

04-14-17
Date


Thirumazhisai Gunasekaran, CEO and Secretary- CCDH

04-14-2017
Date

For United States Department of Health and Human Services


~~Celeste H. Davis~~ *STEVEN R. MITCHELL*
Regional Manager
Office for Civil Rights, Midwest Region

4/17/2017
Date

SMM
ACTING

Appendix A
CORRECTIVE ACTION PLAN
BETWEEN THE
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
CENTER FOR CHILDREN'S DIGESTIVE HEALTH

I. Preamble

Center for Children's Digestive Health ("CCDH") hereby enters into this Corrective Action Plan ("CAP") with the United States Department of Health and Human Services, Office for Civil Rights ("HHS" or "OCR"). Contemporaneously with this CAP, CCDH is entering into a Resolution Agreement ("Agreement") with HHS, and this CAP is incorporated by reference into the Agreement as Appendix A. CCDH enters into this CAP as part of the consideration for the release in paragraph II.8 of the Agreement.

II. Contact Persons and Submissions

A. Contact Persons

CCDH 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:

James Berman,
President and Treasurer-CCDH
1675 Dempster Street
Park Ridge, IL 60068
akhenaten55jb@gmail.com
Phone: (847) 217-3580
Facsimile: (847) 723-9418

Thirumazhisai Gunasekaran
CEO and Secretary- CCDH
1675 Dempster Street
Park Ridge, IL 60068
tsgunasekaran@yahoo.com
Phone: (847) 217-4008
Facsimile: (847) 723-9418

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

4/17/2017
SM
Admin

~~Celeste H. Davis~~ *STEVEN M. MITCHELL*
Regional Manager
Office for Civil Rights, Midwest Region
U.S. Department of Health and Human Services
~~233 N. Michigan Avenue, Suite 240~~ *601 EAST 12TH, SUITE 353*
~~Chicago, Illinois 60601~~ *KANSAS CITY, MO 64106*
~~Celeste.Davis@hhs.gov~~ *STEVEN.MITCHELL@HHS.GOV*
Telephone: ~~312-353-8101~~ *816-426-7278*
Facsimile: ~~312-886-1807~~ *816-426-3686*

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

B. Proof of Submissions. Unless otherwise specified, all notifications and reports required by this CAP may be made by any means, including certified mail, overnight mail, or hand delivery, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

III. Effective Date and Term of CAP

The Effective Date for this CAP shall be calculated in accordance with paragraph II.14 of the Agreement ("Effective Date"). The period for compliance ("Compliance Term") with the obligations assumed by CCDH 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 CCDH under Section VIII hereof of its determination that CCDH breached this CAP, or CCDH ceases to be a "covered entity" under 45 C.F.R. § 160.103. In the event HHS notifies CCDH of a breach under section VIII hereof, the Compliance Term shall not end until HHS notifies CCDH that HHS has determined CCDH failed to meet the requirements of section VIII.C of this CAP and issues a written notice of intent to proceed with an imposition of a civil money penalty against CCDH pursuant to 45 C.F.R. Part 160. In the event CCDH ceases to operate as a "covered entity" as that term is defined in 45 C.F.R. § 160.103, the Compliance Term shall not end until CCDH complies with the requirements in section V.G. After the Compliance Term ends, CCDH shall still be obligated to: (a) submit the final Annual Report as required by section VI; (b) comply with the document retention requirement in section VII; (c) report to HHS regarding vendor contracts as required under section V.D; and (d) comply with the safeguarding requirements in section V.G. Nothing in this CAP is intended to eliminate or modify CCDH's 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 that is not one of the aforementioned days.

V. Corrective Action Obligations

CCDH agrees to the following:

A. Policies and Procedures

1. CCDH shall develop, maintain, and revise, as necessary, its written policies and procedures to comply with the Federal standards that govern the privacy and security of individually identifiable health information (45 C.F.R. Part 160 and Subparts A, C, and E of Part 164, the Privacy and Security Rules). CCDH's policies and procedures shall include, but not be limited to, the minimum content set forth in section V.C.
2. CCDH shall provide such policies and procedures, consistent with paragraph 1 above, to HHS within 60 days of the Effective Date for review and approval. Upon receiving any recommended changes to such policies and procedures from HHS, CCDH shall have 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 the policies and procedures.
3. CCDH shall finalize and officially adopt the policies and procedures in accordance with its applicable administrative procedures within 30 days of receipt of HHS' final approval.

B. Distributing and Updating of Policies and Procedures

1. CCDH shall distribute the policies and procedures identified in section V.A. to all members of the workforce within sixty 30 days of HHS approval of such policies and procedures, and to new members of the workforce within 30 days of their beginning of service.
2. CCDH shall require, at the time of distribution of such policies and procedures, assigned written or electronic initial compliance certification from all members of the workforce stating that the workforce members have read, understand, and shall abide by such policies and procedures.
3. CCDH shall assess, update, and revise, as necessary, the policies and procedures as appropriate at least annually (and more frequently if appropriate).

C. Minimum Content of Revised Policies and Procedures

The revised policies and procedures shall include, but not be limited to, measures that address the following Privacy and Security Rule provisions:

1. Business Associate Agreements – 45 C.F.R §§ 164.308(b) and 164.502(e), including: (a) the designation of one or more individual(s) who are responsible for ensuring that CCDH enters into a business associate agreement with each of its business associates, as defined by the HIPAA Rules, prior to disclosing PHI to the business associate; (b) the creation of a standard template business associate agreement; (c) a process for assessing current and future business relationships to determine whether each relationship is with a “business associate” as that term is defined under the HIPAA Rules; (d) a process for negotiating and entering into business associate agreements with business associates prior to disclosing PHI to the business associates; (e) a process for maintaining documentation of business associate agreements for at least 6 years beyond the date of when the business associate relationship is terminated; and (f) a process to limit disclosures of PHI to business associates to the minimum necessary amount of PHI that is reasonably necessary for business associates to perform their duties.
2. Training – 45 C.F.R. § 164.530(b)(1) & 164.308(a)(5)(i).

D. Reporting to HHS Regarding Business Associate and Certain Vendor Agreements.

Within 30 days of the Effective Date and one year following the Effective Date, CCDH shall provide HHS with the following: (a) the names of all of CCDH’s business associates and/or vendors that create, receive, maintain or transmit PHI on behalf of CCDH, and (b) copies of the service agreements and/or business associate agreements that CCDH maintains with such business associates and/or vendors.

E. Training

1. Within thirty (30) days of HHS’ approval of the policies and procedures referenced in section V.B, CCDH shall forward proposed training materials on the revised policies and procedures to HHS for its review and approval. Upon receiving any required revisions to the training materials from HHS, CCDH shall have thirty (30) days in which to revise the training materials, and then submit the revised training materials to HHS for review and approval.
2. Within sixty (60) days of HHS’ approval of the training materials, CCDH shall provide documentation that: (a) all workforce members who have access to PHI have received such training; (b) that these workforce members will continue to receive such training annually; and (c) that each new CCDH workforce member with access to PHI will receive such training within fifteen (15) days of beginning work at CCDH.

3. CCDH 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.

F. Reportable Events

1. During the Compliance Term, CCDH shall, upon receiving information that a workforce member may have failed to comply with its policies and procedures described in Section V.B.1, promptly investigate the matter. If CCDH, after review and investigation, determines that a workforce member has violated its policies and procedures, CCDH shall notify HHS in writing as provided in Section VI. Such violations shall be known as "Reportable Events." The report to HHS shall include the following:
 - a. A complete description of the event, including relevant facts, the person(s) involved, and the implicated provision(s) of CCDH's policies and procedures; and
 - b. A description of actions taken and any further steps CCDH plans to take to address the matter, to mitigate the harm, and to prevent it from recurring, including the application of appropriate sanctions against workforce members who failed to comply with its policies and procedures.
2. If no Reportable Events occur during any one Reporting Period, as defined in section VI.A.1 of this CAP, CCDH shall so inform HHS in its Annual Report for that Reporting Period.

G. Safeguarding of PHI After Asset Sale. Upon the closing date of any asset sale that will result in CCDH no longer operating as a "covered entity" under 45 C.F.R. § 160.103, CCDH will provide sufficient assurances, approved by HHS, that any PHI it will continue to possess or control after the closing date will be appropriately safeguarded. CCDH may establish "sufficient assurances" by providing HHS with copies of executed agreements between CCDH and any vendors it will engage to store the PHI in CCDH's possession or control, so long as such agreements contain requirements that meet or exceed the applicable obligations for business associate contracts outlined in 45 C.F.R. § 164.504(e).

VI. Annual Reports

The one-year period beginning on the Effective Date and each subsequent one-year period during the course of the period of compliance obligations shall be referred to as "the Reporting Periods." CCDH shall submit to HHS a report with respect to the status of and findings regarding AB's compliance with this CAP for each Reporting Period ("Annual Report"). CCDH shall submit each Annual Report to HHS no later than thirty (30) days after the end of each corresponding Reporting Period. Each Annual Report shall include:

1. A summary of the corrective action measures, pursuant to section V of this CAP, that CCDH has taken during the Reporting Period;
2. A summary of Reportable Events, as defined in Section V.D of this CAP, that CCDH identified during the Reporting Period and the status of any corrective actions related to all such Reportable Events; and
3. An attestation signed by an owner or officer of CCDH 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

CCDH 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. Requests for Extensions and Breach Provisions

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

A. Timely Written Requests for Extensions. CCDH may, in advance of any due date 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 (5) business days prior to the date by which any act is due to be performed. This requirement may be waived by HHS only.

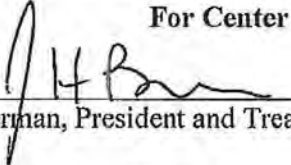
B. Notice of Breach and Intent to Impose Civil Monetary Penalty. The Parties agree that a breach of this CAP by CCDH constitutes a breach of the Agreement. Upon a determination by HHS that CCDH has breached this CAP, HHS may notify CCDH of: (1) AB's breach and (2) HHS' intent to impose a civil monetary penalty (CMP), pursuant to 45 C.F.R. Part 160, or other remedies for the Covered Conduct in paragraph I.2 of the Agreement and for any other conduct that constitutes a violation of the HIPAA Rules ("Notice of Breach and Intent to Impose CMP").

C. CCDH's Response. CCDH 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. CCDH is in compliance with the obligations of this CAP that HHS cited as the basis for the breach;
2. The alleged breach has been cured; or
3. The alleged breach cannot be cured within the 30-day period, but that: (a) CCDH has begun to take action to cure the breach; (b) CCDH is pursuing such action with due diligence; and (c) CCDH has provided to HHS a reasonable timetable for curing the breach.

D. Imposition of CMP. If at the conclusion of the 30-day period, CCDH fails to meet the requirements of section VIII.C of this CAP to HHS' satisfaction, HHS may proceed with the imposition of the CMP against CCDH pursuant to 45 C.F.R. Part 160 for any violations of the HIPAA Rules related to the Covered Conduct 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 CCDH in writing of its determination to proceed with the imposition of a CMP.

For Center for Children's Digestive Health



James Berman, President and Treasurer-CCDH

4-14-17
Date


Thirumazhisai Gunasekaran, CEO and Secretary- CCDH

04-14-2017
Date

For United States Department of Health and Human Services


~~Celeste H. Davis~~ *STEVEN M. MITCHELL*
Regional Manager
Office for Civil Rights, Midwest Region

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