

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. Diabetes, Endocrinology & Lipidology Center, Inc. (“DELIC”), which is a covered entity, as defined at 45 C.F.R. § 160.103, and therefore is required to comply with the HIPAA Rules. DELIC is a healthcare provider located in Martinsburg, West Virginia, operated by Dr. Philip J.A. Ryan, and specializing in endocrinology. HHS and DELIC shall together be referred to herein as the “Parties.”

2. Factual Background and Covered Conduct. On August 6, 2019, OCR received a complaint alleging DELIC is not in compliance with the Privacy Rule. The complaint alleged DELIC refused to provide the Complainant with access to her sons’ protected health information. On October 30, 2019, OCR notified DELIC of its investigation of DELIC’s noncompliance with the HIPAA Rules promulgated by HHS pursuant to the administrative simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub.L. 104-191, 110 Stat. 1936.

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

- a. DELIC has failed to provide the Complainant with timely access to her minor son’s protected health information since July 8, 2019. *See* 45 C.F.R. § 164.524.

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

4. No Concession. This Agreement is not a concession by HHS that DELIC 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 OCR Transaction Number 19-352898 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 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 DELC has agreed to pay HHS, the amount of \$5,000 ("Resolution Amount"). DELC agrees to pay the Resolution Amount within 30 days of 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. DELC 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 DELC breaches the CAP, and fails to cure the breach as set forth in the CAP, then DELC 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 DELC's performance of its obligations under this Agreement, HHS releases DELC from any actions it may have against DELC 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 DELC 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 Party. DELC 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. DELC 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 DELC 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 (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, DELC 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 DELC’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. DELC 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 DELC represent and warrant that they are authorized by DELC 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 DELC

/s/	04/27/2021
_____	_____
Dr. Philip J.A. Ryan	Date

For the United States Department of Health and Human Services

/s/	04/28/2021
_____	_____
Jamie Rahn Ballay Acting Regional Manager Office for Civil Rights Mid-Atlantic Region	Date

Appendix A

CORRECTIVE ACTION PLAN BETWEEN THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND DELIC

I. Preamble

DELIC 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, DELIC is entering into a Resolution Agreement (“Agreement”) with HHS, and this CAP is incorporated by reference into the Agreement as Appendix A. DELIC 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.

DELIC 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:

Dr. Philip J.A. Ryan
DELIC
2011 Professional Court
Martinsburg, VA 25401

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

Jamie Rahn Ballay
Acting Regional Manager
Office for Civil Rights, Mid-Atlantic Region
U.S. Department of Health and Human Services
801 Market St., Suite 9300
Philadelphia, PA 19107
Voice Phone (215) 861-4432
Fax: (215) 861-4431
jamie.rahm@hhs.gov

DELIC 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 DELC 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 DELC under section VIII hereof of its determination that DELC has breached this CAP. In the event of such a notification by HHS under section VIII hereof, the Compliance Term shall not end until HHS notifies DELC that it has determined that the breach has been cured. After the Compliance Term ends, DELC 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.

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

DELC agrees to the following:

A. Review and Revise Policies and Procedures for Individual Access to PHI

1. Within thirty (30) calendar days of the Effective Date, DELC shall review, and to the extent necessary, revise its policies and procedures related to access to protected health information (“PHI”) consistent with 45 C.F.R. § 164.524. The revised policies and procedures shall identify DELC’s methods for calculating a reasonable cost-based fee for access to PHI, including the methods for calculating costs for: (1) labor for copying the PHI requested by the individual, whether in paper or electronic form (e.g., hourly wage for workforce member copying the requested PHI); (2) supplies for creating the paper copy or electronic media (e.g., CD or USB drive) if the individual requests that the electronic copy be provided on portable media; (3) postage, when the individual requests that the copy, or the summary or explanation, be mailed; and (4) preparation of an explanation or summary of the PHI, if agreed to by the individual.

2. HHS shall review and, if necessary, recommend changes to the aforementioned policies and procedures for individual access to PHI. Upon receiving recommended changes from HHS, DELC shall have thirty (30) calendar days to provide revised policies and procedures for individual access to PHI for HHS's approval.

B. Privacy Training on Individual Access to Protected Health Information

1. Within sixty (60) calendar days of the Effective Date, DELC 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. Within thirty (30) calendar days of HHS's approval and annually while under the Term of this CAP, DELC shall provide training to all workforce members at its facilities on the Privacy Rule requirements concerning the individual's right of access to PHI.

C. Mitigation

- a. Within fifteen (15) days following the Effective Date of the Agreement, DELC shall make a good faith effort to provide the complainant with access to the 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.

D. Access Request Status Requirements

1. Within ninety (90) calendar days of receipt of HHS's approval of the policies and procedures required by section V.A.1, and every ninety (90) days thereafter while under the Term of this CAP, DELC shall submit to HHS a list of requests for access to PHI received by DELC, including the date request received, date request completed, format requested, format provided, number of pages (if provided in paper format), and cost, excluding postage.
2. If DELC denied any request for access, in whole or in part, DELC shall submit to HHS all documentation consistent with 45 C.F.R. § 164.524(d).

E. Reportable Events

1. During the Compliance Term, DELC shall, upon receiving information that a workforce member may have failed to comply with its access policies and procedures, promptly investigate this matter. If DELC determines, after review and investigation, that a member of its workforce has failed to comply with these policies and procedures, DELC shall notify HHS in writing within thirty (30) days. Such violations shall be known as Reportable Events. The report to HHS shall

include the following information:

- a. A complete description of the event, including the relevant facts, the persons involved, and the provision(s) of the policies and procedures implicated; and
- b. A description of the actions taken and any further steps DELC 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.

1. Within one hundred twenty (120) calendar days after the receipt of HHS's approval of the policies and procedures required by section V.A.1, DELC 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:
 - a. An attestation signed by an owner or officer of DELC attesting that the policies and procedures approved by HHS in section V.A are being implemented;
 - b. An attestation signed by an owner or officer of DELC attesting that all members of the workforce have completed the initial training required by section V.B.2;
 - c. An attestation signed by an owner or officer of DELC 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.

1. 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) calendar days after the close of each corresponding Reporting Period, DELC shall submit a report to HHS regarding DELC's compliance with this CAP for each corresponding Reporting Period ("Annual Report").
2. An attestation signed by an owner or officer of DELC attesting that all members of the workforce have completed the training required by section V.B.2 during the Reporting Period;
3. An attestation signed by an officer or owner of DELC attesting that any revision(s)

to the policies and procedures required by section V.A. were finalized and adopted within thirty (30) calendar days of HHS's approval of the revision(s), which shall include a statement affirming that DELC distributed the revised policies and procedures to all appropriate members of DELC's workforce within sixty (60) calendar days of HHS's approval of the revision(s);

4. A summary of Reportable Events (defined in V.D.), 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 DELC stating that no Reportable Events occurred during the Compliance Term.
5. An attestation signed by an owner or officer of DELC 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

DELC 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

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

- A. Timely Written Requests for Extensions. DELC 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) calendar days prior to the date such an act is required or due to be performed.
- B. Notice of Breach of this CAP and Intent to Impose Civil Monetary Penalty. The parties agree that a breach of this CAP by DELC constitutes a breach of the Agreement. Upon a determination by HHS that DELC has breached this CAP, HHS may notify DELC of: (1) DELC's breach; and (2) HHS' intent to impose a civil money penalty ("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 for any other conduct that constitutes a violation of the HIPAA Privacy, Security, and Breach Notification Rules ("Notice of Breach and Intent to Impose CMP").
- C. DELC Response. DELC shall have thirty (30) calendar days from the date of receipt of the Notice of Breach and Intent to Impose CMP to demonstrate to HHS' satisfaction that:
 1. DELC 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: (a) DELC has begun to take action to cure the breach; (b) DELC is pursuing such action with due diligence; and (c) DELC has provided to HHS a reasonable timetable for curing the breach.
- D. Imposition of CMP. If at the conclusion of the thirty (30) day period, DELC fails to meet the requirements of section VIII.C of this CAP to HHS's satisfaction, HHS may proceed with the imposition of the CMP against DELC pursuant to 45 C.F.R. Part 160 for any violations of the Covered Conduct set forth in paragraph 2 of the Agreement and for any other act or failure to act that constitutes a violation of the HIPAA Rules. HHS shall notify DELC in writing of its determination to proceed with the imposition of the CMP.

For DELC:

/s/

04/27/2021

Dr. Philip J.A. Ryan
Owner

Date

For the United States Department of Health and Human Services

/s/

04/28/2021

Jamie Rahn Ballay
Acting Regional Manager
Office for Civil Rights
Mid-Atlantic Region

Date