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 ("PHI") (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. Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America ("FMCNA") on behalf of each of the following entities under FMCNA's common ownership or control, which meet the definition of "covered entity" under 45 C.F.R. § 160.103 and therefore are required to comply with the HIPAA Rules:

      1. Bio-Medical Applications of Florida, Inc. d/b/a Fresenius Medical Care Duval Facility ("FMC Duval")

      2. Bio-Medical Applications of Alabama, Inc. d/b/a Fresenius Medical Care Magnolia Grove ("FMC Magnolia Grove")

      3. Renal Dimensions, LLC d/b/a Fresenius Medical Care Ak-Chin ("FMC Ak-Chin")

      4. Fresenius Vascular Care Augusta, LLC ("FVC Augusta")

      5. WSKC Dialysis Services, Inc. d/b/a Fresenius Medical Care Blue Island Dialysis ("FMC Blue Island")

These five covered entities identified in subparagraphs 1.b.1.–b.5. are also collectively referred to herein as "FMCNA Covered Entities" and each individually as an "FMCNA Covered Entity."

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

2. **Factual Background and Covered Conduct**

On January 21, 2013, FMCNA submitted five breach reports to HHS regarding breaches of the FMCNA Covered Entities' unsecured electronic protected health information ("ePHI"). Each breach report pertained to a separate and distinct incident involving loss or theft of ePHI of one of the FMCNA Covered Entities. FMCNA provides centralized corporate support to the FMCNA Covered Entities involved in the breaches, including centrally storing their patients' medical records, creating and disseminating HIPAA policies and procedures, and investigating the circumstances of each breach reported to it by the FMCNA Covered Entities.

a. FMC Duval Breach: On February 23, 2012, two desktop computers were stolen during a break-in at FMC Duval, one of which contained the ePHI of 200 individuals, including patient name, admission date, date of first dialysis, days and times of treatments, date of birth, and social security number.

b. FMC Magnolia Grove Breach: On April 3, 2012, an unencrypted USB drive was stolen from a workforce member's car while it was parked in the lot at FMC Magnolia Grove. The USB drive contained the ePHI of 245 individuals, including patient name, address, date of birth, telephone number, insurance company, insurance account number (a potential social security number derivative for some patients) and the covered entity location where each patient was seen.

c. FMC Ak-Chin Breach: On June 18, 2012, the FMCNA compliance line received an anonymous report that a hard drive from a desktop computer, which had been taken out of service to be replaced, was missing from FMC Ak-Chin on April 6, 2012. The hard drive contained the ePHI of 35 individuals, including name, date of birth, social security number and zip code. The workforce member whose hard drive was missing promptly notified the Area Manager; however, the Area Manager failed to report the incident to the FMCNA Corporate Risk Management Department.

d. FVC Augusta Breach: On June 16, 2012, a workforce member's unencrypted laptop was stolen from her car while parked overnight at her home, where it was stored in a bag with a list of her passwords. The laptop contained the ePHI of 10 individuals, including patient name, insurance account number (which could be a social security number derivative) and other insurance information.

e. FMC Blue Island Breach: On or around June 17-18, 2012, three desktop computers and one encrypted laptop were stolen from the Blue Island Facility location. One of the desktop computers contained the ePHI of 31 individuals, including patient name, dates of birth, address, telephone

number, social security number or partial social security number.

On July 15, 2013, HHS initiated a compliance review to investigate the five breach reports. HHS's investigation indicated that the following conduct occurred ("Covered Conduct")

a. The FMCNA Covered Entities failed to conduct an accurate and thorough risk analysis of potential risks and vulnerabilities to the confidentiality, integrity, and availability of all of their ePHI. *See* 45 C.F.R. §164.308(a)(l)(ii)(A).

b. The FMCNA Covered Entities impermissibly disclosed the ePHI of their patients by providing access to such ePHI for a purpose not permitted by the Privacy Rule. *See* 45 C.F.R. § 164.502(a)

c. FMC Duval and FMC Blue Island failed to implement policies and procedures to safeguard their facilities and the equipment therein from unauthorized access, tampering, and theft. *See* 45 C.F.R. §164.310(a)(2)(ii)

d. FMC Magnolia Grove failed to implement policies and procedures that govern the receipt and removal of hardware and electronic media that contain ePHI into and out of the facility, and the movement of these items within the facility. *See* 45 C.F.R. § 164.310(d)(l).

e. FMC Magnolia Grove and FVC Augusta failed to implement a mechanism to encrypt and decrypt ePHI. *See* 45 C.F.R. §164.312(a)(2)(iv).

f. FMC Ak-Chin failed to implement policies and procedures to address security incidents. *See* 45 C.F.R. § 164.308(a)(6)(i).

3. No Admission. This Agreement is not an admission, concession, or evidence of liability by FMCNA, any of the FMCNA Covered Entities, or any of their agents or affiliates or of any fact or any violation of any law, rule, or regulation, including any violation of the HIPAA Rules. This Agreement is made without trial or adjudication of any alleged issue of fact or law and without any finding of liability of any kind, and FMCNA's agreement, on behalf of the FMCNA Covered Entities, to undertake any obligation under this Agreement shall not be construed as an admission of any kind.

4. No Concession. This Agreement is not a concession by HHS that the FMCNA Covered Entities are not in violation of the HIPAA Rules and not liable for civil money penalties ("CMPs").

5. Intention of Parties to Effect Resolution. This Agreement is intended to resolve HHS Transaction Number: 01-13-160065 and any potential 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. HHS also agrees to provide technical assistance to the FMCNA Affiliated Covered Entity ("FMCNA ACE") where HHS identifies any HIPAA compliance issues.

II. Terms and Conditions

6. Payment. HHS has agreed to accept, and FMCNA, on behalf of the FMCNA Covered Entities, has agreed to pay HHS, the amount of $3,500,000.00 ("Resolution Amount"). FMCNA 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. FMCNA, on behalf of the FMCNA Covered Entities, 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 any FMCNA Covered Entity breaches the CAP, and fails to cure the breach as set forth in the CAP, then that FMCNA Covered Entity 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 with respect to that entity.

8. Release by HHS. In consideration of and conditioned upon FMCNA Covered Entities' performance of their obligations under this Agreement, HHS releases FMCNA, the FMCNA Covered Entities, and any of their successors, transferees, assigns, parents, subsidiaries, members, shareholders, agents, directors, officers, affiliates, and employees from any claims, actions, or causes of action it may have against the FMCNA Covered Entities 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 the FMCNA Covered Entities 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. FMCNA 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. FMCNA 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 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 FMCNA and FMCNA Covered Entities and their 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 HHS and the FMCNA Covered Entities with respect to the five incidents and the Covered Conduct described in paragraph I.2. of this Agreement. All material representations, understandings, and promises of the Parties with respect to those incidents and that Covered Conduct are contained in this Agreement. Any modifications to this Agreement shall be set forth in writing and signed by both HHS and FMCNA, on behalf of the FMCNA Covered Entities. Nothing in this Agreement is intended to, or shall, be used as any basis for the denial of any license, authorization, approval, or consent that FMCNA, the FMCNA Covered Entities, or any of their parents, subsidiaries, or affiliates may require under any law, rule, or regulation.

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)(l), a 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, the FMCNA Covered Entities agree that the time between the Effective Date of this Agreement and the date the Agreement may be terminated by reason of any of the FMCNA Covered Entities' breach, plus one-year thereafter, will not be included in calculating the six (6) year statute of limitations applicable to the alleged violations which are the subject of this Agreement for the FMCNA Covered Entity in question. The FMCNA Covered Entities waive 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 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 (collectively, "FOIA"), provided, however, that HHS will use its best efforts to prevent the disclosure of information, documents, and any other item produced by FMCNA to HHS as part of HHS' review, to the extent such items constitute trade secrets and/or confidential commercial or financial information, or information that would unreasonably invade the personal privacy of individuals named therein, that is exempt from turnover in response to a FOIA request under 45 C.F.R. § 5.65, or any other applicable exemption under FOIA and its implementing regulations.

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 FMCNA represents and warrants that they are authorized to execute this Agreement and bind the FMCNA Covered Entities, 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 Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America

_____//s//_____ ____1/24/18_____

Karen A. Gledhill Date
Senior Vice President and General Counsel

For Department of Health and Human Services

_____//s//_____ _____1/25/18_____

Susan M. Pezzullo Rhodes Date
Regional Manager, New England Region
Office for Civil Rights

Appendix A

CORRECTIVE ACTION PLAN

BETWEEN THE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

AND

FRESENIUS MEDICAL CARE NORTH AMERICA (FMCNA)

I. Preamble

Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America ("FMCNA"), on behalf of the FMCNA Covered Entities set forth in paragraph 1.1.b of the Resolution Agreement (the "Agreement"), 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, FMCNA, on behalf of the FMCNA Covered Entities, is entering into the Agreement with HHS, and this CAP is incorporated by reference into the Agreement as Appendix A. FMCNA 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 the FMCNA Covered Entities regarding the implementation of this CAP and for receipt and submission of notifications and reports ("FMCNA Contact") is:

Ms. Louise Bucolo
Sr. Director of Ethics and Compliance, Privacy & Security
Fresenius Medical Care North America
920 Winter Street
Waltham, MA 02451
louise.bucolo@fmc-na.com
Telephone: 781-699-4297
Facsimile: 781-699-9433

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

Ms. Susan M. Pezzullo Rhodes, Regional Manager
Office for Civil Rights, New England Region

Department of Health and Human Services
JFK Federal Building, Room 1875
Boston, MA 02203
Susan.Rhodes@hhs.gov
Telephone: 617-565-1347
Facsimile: 617-565-3809

The FMCNA Covered Entities 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, 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 each of the FMCNA Covered Entities under this CAP shall begin on the Effective Date of this CAP and end two (2) years from the Effective Date, unless, before the expiration of that two (2)-year period, HHS issues a written notice of intent to proceed with an imposition of a civil money penalty ("CMP") against any FMCNA Covered Entit(y)(ies) pursuant to 45 C.F.R. Part 160 and section VIII.D of this CAP. If HHS issues such a notice during the two-year term, the Compliance Term shall end upon issuance of such notice but only with respect to the FMCNA Covered Entit(y)(ies) to which HHS has issued such notice. The Compliance Term for any FMCNA Covered Entities that are not the subject of such a notice shall be unaffected by the issuance of such notice. After the Compliance Term ends, the FMCNA Covered Entities 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 FMCNA'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 which is not one of the aforementioned days.

V. Corrective Action Obligations

The FMCNA Covered Entities agree to the following:

A. Conduct Risk Analysis

1. The FMCNA Covered Entities shall conduct an accurate and thorough assessment of the potential security risks and vulnerabilities to the confidentiality, integrity, and availability of the FMCNA Covered Entities' electronic protected health information ("ePHI") ("Risk Analysis"). The Risk Analysis shall incorporate the FMCNA Covered Entities' facilities, whether owned or rented, and evaluate the risks to the ePHI on their electronic equipment, data systems, and applications controlled, administered or owned by the FMCNA Covered Entities, that contain, store, transmit, or receive ePHI. Prior to conducting the Risk Analysis, the FMCNA Covered Entities shall develop a complete inventory of all of their facilities, categories of electronic equipment, data systems, and applications that contain or store ePHI, which will then be incorporated into their Risk Analysis.

2. Within fourteen (14) days of the Effective Date, the FMCNA Covered Entities shall submit to HHS the scope and methodology by which they propose to conduct the Risk Analysis described in paragraph V.A.1. HHS shall notify the FMCNA Covered Entities whether the proposed scope and methodology is or is not consistent with 45 C.F.R. § 164.308 (a)(1)(ii)(A).

3. The FMCNA Covered Entities shall provide the Risk Analysis, consistent with paragraph V.A.l , to HHS within one hundred eighty (180) days of HHS' approval of the FMCNA Covered Entities' methodology described in paragraph V.A.2 for HHS' review. Within ninety (90) days of its receipt of the FMCNA Covered Entities' Risk Analysis, HHS will inform FMCNA Contact in writing as to whether HHS approves of the Risk Analysis or, if necessary to ensure compliance with 45 C.F.R. § 164.308(a)(1)(ii)(A), requires revisions to the Risk Analysis. If HHS requires revisions to the Risk Analysis, HHS shall provide FMCNA Contact with a detailed, written explanation of such required revisions and with comments and recommendations in order for the FMCNA Covered Entities to be able to prepare a revised Risk Analysis. Upon receiving notice of required revisions to the Risk Analysis from HHS and a description of any required changes to the Risk Analysis, the FMCNA Covered Entities shall have sixty (60) days in which to revise their Risk Analysis accordingly and submit the revised Risk Analysis to HHS for review and approval. This submission and review process shall continue until HHS approves the Risk Analysis.

B. Develop and Implement a Risk Management Plan

1. The FMCNA Covered Entities shall develop a written risk management plan or plans 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 the FMCNA Covered Entities' implementation, evaluation, and revision of their risk remediation activities.

2. Within ninety (90) days of HHS' final approval of the Risk Analysis described in section V.A above, the FMCNA Covered Entities shall submit their Risk Management Plan to HHS for HHS' review. Within sixty (60) days of its receipt of the Risk Management Plan, HHS will inform FMCNA Contact in writing as to whether HHS approves of the Risk Management Plan or, if necessary to ensure compliance with 45 C.F.R. § 164.308(a)(1)(ii)(B), requires revisions to the Risk Management Plan. If HHS requires revisions to the Risk Management Plan, HHS shall provide FMCNA Contact with detailed comments and recommendations in order for the FMCNA Covered Entities to be able to prepare a revised Risk Management Plan. Upon receiving notice of required revisions to the Risk Management Plan from HHS and a description of any required changes to the Risk Management Plan, the FMCNA Covered Entities shall have sixty (60) days in which to revise their Risk Management Plan accordingly, and submit the revised Risk Management Plan to HHS for review and approval. This submission and review process shall continue until HHS approves the Risk Management Plan.

3. Within sixty (60) days of HHS' approval of the Risk Management Plan, the FMCNA Covered Entities shall begin implementation of the Risk Management Plan and distribute the plan to workforce members involved with implementation of the plan.

C. Implement Process for Evaluating Environmental and Operational Changes

1. The FMCNA Covered Entities shall develop a written process(es) to regularly evaluate any environmental or operational changes that affect the security of ePHI in the FMCNA Covered Entities' possession or control ("Evaluation Process").

2. Within ninety (90) days of HHS' final approval of the Risk Analysis described in section V.A above, the FMCNA Covered Entities shall submit the Evaluation Process to HHS for HHS' review. Within sixty (60) days of its receipt of the FMCNA Covered Entities' proposed Evaluation Process, HHS will inform FMCNA Contact in writing as to whether HHS approves of the

Evaluation Process or, if necessary to ensure compliance with 45 C.F.R. § 164.308(a)(8), requires revisions to the Evaluation Process. If HHS requires revisions to the Evaluation Process, HHS shall provide FMCNA Contact with detailed comments and recommendations in order for the FMCNA Covered Entities to be able to prepare a revised Evaluation Process. Upon receiving notice of required revisions from HHS and a listing or description of any required revisions to such Process, the FMCNA Covered Entities shall have thirty (30) days in which to revise the Evaluation Process accordingly and submit the revised Evaluation Process to HHS for review and approval. This submission and review process shall continue until HHS approves the Evaluation Process.

3. Within sixty (60) days of HHS' approval of the Evaluation Process, the FMCNA Covered Entities shall implement the Evaluation Process and distribute copies of it to workforce members of the FMCNA Covered Entities involved with performing such evaluations.

D. Develop Encryption Report

1. Within one hundred eighty (180) days of HHS' final approval of the Risk Management Plan required in section V.B, the FMCNA Covered Entities shall develop, and FMCNA Contact shall submit to HHS, a written report or reports regarding the status of the FMCNA Covered Entities' implementation of encryption ("Encryption Report"), which shall consist of:

    a. The total number of all FMCNA Covered Entities' devices and equipment including, but not limited to, desktop computers, laptop computers, tablets, mobile phones, USB drives, and medical equipment, that may be used to access, store, download, or transmit the FMCNA Covered Entities' ePHI as of the date of the Encryption Report ("Covered Electronic Media").

    b. The total number of Covered Electronic Media that are encrypted as of the date of the Encryption Report, as well as evidence of such encryption.

c. For any Covered Electronic Media that are not encrypted as of the date of the Encryption Report, either: (i) a description of the FMCNA Covered Entities' plan to encrypt such Covered Electronic Media and an estimate of when such Covered Electronic Media will be encrypted; or (ii) a description of why encrypting such Covered Electronic Media is not reasonable and appropriate and a description of the compensating alternative measures implemented to safeguard the ePHI accessed, stored, downloaded or transmitted by such Covered Electronic Media.

2. The Covered Electronic Media included in the Encryption Report may be described and organized by category. Further, for each category of Covered Electronic Media, the Encryption Report shall document the encryption solution used (e.g., native or third party encryption product) including the version number of the encryption solution as well as the encryption algorithms/ciphers the encryption solution is configured to use. The evidence of encryption required under paragraph V.D.1.b may be provided in the form of a screenshot that demonstrates encryption for a particular category of Covered Electronic Media, a copy of the license for the encryption software deployed on a particular category of Covered Electronic Media, or other reasonable means of demonstrating such Covered Electronic Media are encrypted.

E. Review and Revise Policies and Procedures on Device and Media Controls

1. The FMCNA Covered Entities shall review, and to the extent necessary, revise their policies and procedures related to the receipt, removal and movement of Covered Electronic Media (the "Device and Media Controls Policies and Procedures"). The policies shall identify criteria for the use of such Covered Electronic Media and procedures for obtaining authorization for the use of Covered Electronic Media that utilize the FMCNA Covered Entities' ePHI systems.

2. Within ninety (90) days of HHS' final approval of the Risk Analysis described in section V.A above, the FMCNA Covered Entities shall submit the Device and Media Controls Policies and Procedures required by paragraph V.E.1 to HHS for HHS' review. Within sixty (60) days of its receipt of the FMCNA Covered Entities' Device and Media Controls Policies and Procedures, HHS will inform FMCNA Contact in writing as to whether HHS approves of the Device and Media Controls Policies and Procedures or, if necessary to ensure compliance with 45 C.F.R. § 164.310(d)(1), requires revisions to the Device and Media Controls Policies and

Procedures. If HHS requires revisions to the Device and Media Controls Policies and Procedures, HHS shall provide FMCNA Contact with detailed, written requirements and recommendations in order for the FMCNA Covered Entities to be able to prepare acceptable, revised Device and Media Controls Policies and Procedures. Upon receiving any notice of required revisions to the Device and Media Controls Policies and Procedures from HHS, the FMCNA Covered Entities shall have thirty (30) days in which to revise the Device and Media Controls Policies and Procedures accordingly and submit the revised Device and Media Controls Policies and Procedures to HHS for review and approval. This submission and review process shall continue until HHS approves the Device and Media Controls Policies and Procedures.

3. Within thirty (30) days of HHS' approval of the Device and Media Controls Policies and Procedures, the FMCNA Covered Entities shall finalize and officially adopt the Device and Media Controls Policies and Procedures in accordance with their applicable administrative procedures, and provide evidence of implementation of such policies and procedures to HHS.

F. Review and Revise Policies and Procedures on Facility Access Controls

1. The FMCNA Covered Entities shall review, and to the extent necessary, revise their policies and procedures to limit physical access to all of their electronic information systems and the facilities in which they are housed, while ensuring that properly authorized access is allowed ("Physical Access Policies and Procedures"). The FMCNA Covered Entities shall develop a facility security plan that defines and documents the physical security controls to safeguard the facility or facilities and the equipment therein from unauthorized physical access, tampering, and theft ("Physical Security Plan").

2. Within ninety (90) days of HHS' final approval of the Risk Analysis described in section V.A above, the FMCNA Covered Entities shall submit the Physical Access Policies and Procedures, including the Physical Security Plan(s), required by paragraph V.F.1 to HHS for HHS' review. Within sixty (60) days of its receipt of the FMCNA Covered Entities' Physical Access Policies and Procedures, HHS will inform FMCNA Contact in writing as to whether HHS approves of the Physical Access Policies and Procedures or, if necessary to ensure compliance with 45 C.F.R. § 164.310(a)(1), requires revisions to the Physical Access Policies and Procedures. If HHS requires revisions to the Physical Access Policies and Procedures, HHS shall provide FMCNA Contact with detailed, written comments and recommendations in order for the FMCNA Covered Entities to be able to prepare acceptable, revised Physical

Access Policies and Procedures. Upon receiving any such notice of required revisions from HHS, the FMCNA Covered Entities shall have thirty (30) days in which to revise the Physical Access Policies and Procedures accordingly, and submit the revised Physical Access Policies and Procedures to HHS for review and approval. This submission and review process shall continue until HHS approves the Physical Access Policies and Procedures.

3. Within thirty (30) days of HHS' approval of the Physical Access Policies and Procedures, the FMCNA Covered Entities shall finalize and officially adopt the Physical Access Policies and Procedures in accordance with their applicable administrative procedures, and provide evidence of implementation of such Physical Access Policies and Procedures to HHS.

G. Develop an Enhanced Privacy and Security Awareness Training Program

1. The FMCNA Covered Entities shall augment their existing mandatory Health Information Privacy and Security Awareness Training Program ("Training Program") for all the FMCNA Covered Entities' workforce members who have access to PHI, including ePHI. The Training Program shall include general instruction on workforce members' obligation to comply with the FMCNA Covered Entities' policies and procedures related to the HIPAA Rules. The Training Program shall also include training on the new or revised Evaluation Process and all of the new or revised Device and Media Controls Policies and Procedures and Physical Access Policies and Procedures (collectively, the "Policies and Procedures"), to the extent such new or revised Policies and Procedures are developed and existing policies and procedures are revised.

2. Within ninety (90) days of HHS' final approval of the Risk Management Plan required in section V.B above, the FMCNA Covered Entities shall submit the proposed training materials for HHS' review. Within sixty (60) days of its receipt of the FMCNA Covered Entities' training materials, HHS will inform FMCNA Contact in writing as to whether HHS approves of the proposed training materials or, if necessary to ensure compliance with 45 C.F.R. §§ 164.308(a)(5)(i) or 164.530(b), requires revisions to the proposed training materials. If HHS requires revisions to the proposed training materials, HHS shall provide FMCNA Contact with detailed, written comments and recommendations in order for the FMCNA Covered Entities to be able to prepare acceptable, revised training materials. Upon receiving notice of required revisions to their proposed training materials from HHS, the FMCNA Covered Entities shall have thirty (30) days in which to

revise the training materials accordingly, and submit the revised training materials to HHS for review and approval. This submission and review process shall continue until HHS approves the training materials.

3. Within sixty (60) days of HHS' approval of the FMCNA Covered Entities' training materials, the FMCNA Covered Entities shall provide training on the approved Policies and Procedures to workforce members of the FMCNA Covered Entities, as necessary and appropriate for such workforce members to carry out their functions. In addition, the FMCNA Covered Entities shall train workforce members who return to the workforce after this sixty (60) day period and any workforce members who commence working for the FMCNA Covered Entities, or that are given access to PHI, including ePHI, after the development of the Training Program, within forty-five (45) days of the commencement of their employment or affiliation with the FMCNA Covered Entities or return to the workforce, as applicable.

4. Each individual who is required to attend training shall certify, in writing or in electronic form that he or she has received the required training and the date the training was completed. The FMCNA Covered Entities shall retain copies of such certifications for no less than six (6) years following the date training was provided.

5. The FMCNA Covered Entities shall review the Training Program annually, and, where appropriate, update the Training Program to reflect any HIPAA compliance related changes in: (i) the FMCNA Covered Entities' policies and procedures; (ii) applicable federal law; and/or (iii) any material compliance issue(s) discovered during audits or reviews conducted by the FMCNA Covered Entities or their designee(s), or HHS.

6. The FMCNA Covered Entities shall provide training on the policies and procedures related to the HIPAA Rules to active workforce members of the FMCNA Covered Entities, as necessary and appropriate for such workforce members to carry out their functions, annually.

G. Reportable Events

1. After the implementation of the Policies and Procedures in accordance with paragraphs V.E.3 and V.F.3, the FMCNA Covered Entities shall, during the remainder of the Compliance Term, upon receiving information that a workforce member may have failed to comply with such policies and procedures, promptly investigate the matter. If any of the FMCNA

Covered Entities, after review and investigation, determines that a member of its workforce has failed to comply with such policies and procedures, the FMCNA Contact shall report such event(s) to HHS as provided in section VI.B.4. Such violations shall be known as "Reportable Events." The report to HHS shall include the following:

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 FMCNA and the FMCNA Covered Entities' plan to take to address the matter to mitigate any harm, and to prevent it from recurring, including application of appropriate sanctions against workforce members who failed to comply with the Policies and Procedures.

VI. Training Report and Annual Reports

A. Training Report. Within one hundred and twenty (120) days after the receipt of HHS' approval of the Training Program required by section V.G, the FMCNA Covered Entities shall submit a written report to HHS known as the "Training Report," which shall consist of:

1. 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;

2. An attestation signed by an officer or director of FMCNA that all applicable members of the workforce of the FMCNA Covered Entities have completed the initial training required by section V.G and have executed the training certifications required by paragraph V.G.4; and

3. An attestation signed by an officer or director of FMCNA that he/she has reviewed the Training Report, made a reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.

B. Annual Reports. The one (1) year period after the Effective Date and each subsequent one (1) year period during the course of the Compliance Term shall be known as a "Reporting Period." Within sixty (60) days after the close of each corresponding Reporting Period, the FMCNA Covered Entities shall submit a report or reports to HHS regarding the FMCNA Covered Entities'

compliance with this CAP for each corresponding Reporting Period ("Annual Report"). The Annual Report shall include:

1. A copy of the schedule, topic outline, and training materials for the training programs provided during the Reporting Period that is the subject of the Annual Report;

2. An attestation signed by an officer or director of FMCNA attesting that the FMCNA Covered Entities obtain and maintain written or electronic training certifications from all persons who are required to attend training under this CAP;

3. An attestation signed by an officer or director of FMCNA 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 the FMCNA Covered Entities distributed the revised Policies and Procedures to all appropriate members of the FMCNA Covered Entities' workforce within sixty (60) days of HHS' approval of the revision(s); and

4. A summary of Reportable Events, 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 FMCNA stating that no Reportable Events occurred during the Compliance Term.

VII. Document Retention

The FMCNA Covered Entities 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. Nothing in this Agreement shall be construed to constitute a waiver by FMCNA or any of the FMCNA Covered Entities of any applicable legal privilege against disclosure, including the attorney-client privilege and the work product doctrine. If HHS requests access to information or documentation which FMCNA or any of the FMCNA Covered Entities seeks to withhold on the basis of an applicable legal privilege against disclosure, including the attorney-client privilege or the attorney work product doctrine, FMCNA shall provide HHS with a description of such information and the type of privilege asserted.

VIII. Breach Provisions

The FMCNA Covered Entities are expected to fully and timely comply with all provisions contained in this CAP.

A. Timely Written Requests for Extensions. The FMCNA Covered Entities may, in advance of any due date set forth in this CAP, submit a timely written request for an extension of time to perform any act required by this CAP. A "timely written request" is defined as a request in writing received

by HHS at least five (5) days prior to the date such an act is required or due to be performed. This requirement may be waived by HHS only.

B. Notice of Breach of this CAP and Intent to Impose CMP. The Parties agree that a breach of this CAP by a FMCNA Covered Entity constitutes a breach of the Agreement by that FMCNA Covered Entity. Upon a determination by HHS that any FMCNA Covered Entity has breached this CAP, HHS may notify FMCNA Contact of: (1) the FMCNA Covered Entity'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. FMCNA Covered Entities' Response. Any FMCNA Covered Entity named in a Notice of Breach and Intent to Impose CMP 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. The FMCNA Covered Entity 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 the FMCNA Covered Entity: (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. Imposition of CMP. If at the conclusion of the thirty (30) day period, the FMCNA Covered Entity 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 that FMCNA Covered Entity 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 FMCNA 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 Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America

_____//s//_____ _____1/24/18_____
Karen A. Gledhill Date
Senior Vice President and General Counsel

For Department of Health and Human Services

_____//s//_____ _____1/25/18_____
Susan M. Pezzullo Rhodes Date
Regional Manager, New England Region
Office for Civil Rights