

BUSINESS ASSOCIATE AGREEMENT BETWEEN THE DEPARTMENT OF
VETERANS AFFAIRS VETERANS HEALTH ADMINISTRATION AND
EN-VISION AMERICA, INC.

Purpose. The purpose of this Business Associate Agreement (Agreement) is to establish requirements for the Department of Veterans Affairs (VA) Veterans Health Administration (VHA) and **En-Vision America, Inc.** in accordance with the Health Insurance Portability and Accountability Act (HIPAA), the Health Information Technology for Economic and Clinical Health Act (HITECH) Act, and the HIPAA Privacy, Security, Breach Notification, and Enforcement Rules ("HIPAA Rules"), 45 C.F.R. Parts 160 and 164, for the Use and Disclosure of Protected Health Information (PHI) under the terms and conditions specified below.

With respect solely to the subject matter herein, the terms and conditions in this National Business Associate Agreement supersede any previous National Business Associate Agreement, as well as any local Business Associate Agreement between **En-Vision America, Inc.** and a component of VHA. Accordingly, this National Business Associate Agreement, unless otherwise provided, will control and cannot be superseded, modified, or nullified by any local Business Associate Agreement or Data Use Agreement.

Scope. Under this Agreement and other applicable contracts or agreements, **En-Vision America, Inc.** will provide **audible prescription reading device** services to, for, or on behalf of VHA.

In order for **En-Vision America, Inc.** to provide such services, VHA will disclose PHI to **En-Vision America, Inc.**, and **En-Vision America, Inc.** will use or disclose PHI in accordance with this Agreement.

Definitions. Unless otherwise provided, the following terms used in this Agreement have the same meaning as defined by the HIPAA Rules: Breach, Data Aggregation, Designated Record Set, Disclosure, Health Care Operations, Individual, Minimum Necessary, Notice of Privacy Practices, PHI, Required by Law, Secretary, Security Incident, Subcontractor, Unsecured PHI, and Use.

"Business Associate" shall have the same meaning as described at 45 C.F.R. § 160.103. For the purposes of this Agreement, Business Associate shall refer to **En-Vision America, Inc.**, including its employees, officers, or any other agents that create, receive, maintain, or transmit PHI as described below.

"Covered Entity" shall have the same meaning as the term is defined at 45 C.F.R. § 160.103. For the purposes of this Agreement, Covered Entity shall refer to VHA.

"Protected Health Information" or "PHI" shall have the same meaning as described at 45 C.F.R. § 160.103. "Protected Health Information" and "PHI" as used in this Agreement include "Electronic Protected Health Information" and "EPHI." For the purposes of this Agreement and unless otherwise provided, the term shall also refer to PHI that Business Associate creates, receives, maintains, or transmits on

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behalf of Covered Entity or receives from Covered Entity or another Business Associate.

"Subcontractor" shall have the same meaning as the term is defined at 45 C.F.R. § 160.103. For the purposes of this Agreement, Subcontractor shall refer to a contractor of any person or entity, other than Covered Entity, that creates, receives, maintains, or transmits PHI under the terms of this Agreement.

Terms and Conditions. Covered Entity and Business Associate agree as follows:

1. Ownership of PHI. PHI is and remains the property of Covered Entity as long as Business Associate creates, receives, maintains, or transmits PHI, regardless of whether a compliant Business Associate agreement is in place.
2. Use and Disclosure of PHI by Business Associate. Unless otherwise provided, Business Associate:
 - A. May not use or disclose PHI other than as permitted or required by this Agreement, or in a manner that would violate the HIPAA Privacy Rule if done by Covered Entity, except that it may use or disclose PHI:
 - (1) As required by law or to carry out its legal responsibilities;
 - (2) For the proper management and administration of Business Associate; or
 - (3) To provide Data Aggregation services relating to the health care operations of Covered Entity.
 - B. Must use or disclose PHI in a manner that complies with Covered Entity's minimum necessary policies and procedures.
 - C. May de-identify PHI created or received by Business Associate under this Agreement at the request of the Covered Entity, provided that the de-identification conforms to the requirements of the HIPAA Privacy Rule.
3. Obligations of Business Associate. In connection with any Use or Disclosure of PHI, Business Associate must:
 - A. Consult with Covered Entity before using or disclosing PHI whenever Business Associate is uncertain whether the Use or Disclosure is authorized under this Agreement.
 - B. Implement appropriate administrative, physical, and technical safeguards and controls to protect PHI and document applicable policies and procedures to prevent any Use or Disclosure of PHI other than as provided by this Agreement.
 - C. Provide satisfactory assurances that PHI created or received by Business Associate under this Agreement is protected to the greatest extent feasible.

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D. Notify Covered Entity within twenty-four (24) hours of Business Associate's discovery of any potential access, acquisition, use, disclosure, modification, or destruction of either secured or unsecured PHI in violation of this Agreement, including any Breach of PHI.

(1) Any incident as described above will be treated as discovered as of the first day on which such event is known to Business Associate or, by exercising reasonable diligence, would have been known to Business Associate.

(2) Notification shall be sent to the Director, Health Information Governance, by email to VHABAAIssues@va.gov.

(3) Business Associate shall not notify individuals or the Department of Health and Human Services directly unless Business Associate is not acting as an agent of Covered Entity but in its capacity as a Covered Entity itself.

E. Provide a written report to Covered Entity of any potential access, acquisition, use, disclosure, modification, or destruction of either secured or unsecured PHI in violation of this Agreement, including any Breach of PHI, within ten (10) business days of the initial notification.

(1) The written report of an incident as described above will document the following:

(a) The identity of each Individual whose PHI has been, or is reasonably believed by Business Associate to have been, accessed, acquired, used, disclosed, modified, or destroyed;

(b) A description of what occurred, including the date of the incident and the date of the discovery of the incident (if known);

(c) A description of the types of secured or unsecured PHI that was involved;

(d) A description of what is being done to investigate the incident, to mitigate further harm to Individuals, and to protect against future incidents; and

(e) Any other information as required by 45 C.F.R. §§ 164.404(c) and 164.410.

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(2) The written report shall be addressed to:

Director, Health Information Governance
Department of Veterans Affairs – Veterans Health Administration
Office of Informatics and Analytics (10P2)
810 Vermont Avenue NW
Washington, DC 20420

and submitted by email at VHABAAIssues@va.gov

F. To the greatest extent feasible, mitigate any harm due to a Use or Disclosure of PHI by Business Associate in violation of this Agreement that is known or, by exercising reasonable diligence, should have been known to Business Associate.

G. Use only contractors and Subcontractors that are physically located within a jurisdiction subject to the laws of the United States, and ensure that no contractor or Subcontractor maintains, processes, uses, or discloses PHI in any way that will remove the information from such jurisdiction. Any modification to this provision must be approved by Covered Entity in advance and in writing.

H. Enter into Business Associate Agreements with contractors and Subcontractors as appropriate under the HIPAA Rules and this Agreement.
Business Associate:

(1) Must ensure that the terms of any Agreement between Business Associate and a contractor or Subcontractor are at least as restrictive as Business Associate Agreement between Business Associate and Covered Entity.

(2) Must ensure that contractors and Subcontractors agree to the same restrictions and conditions that apply to Business Associate and obtain satisfactory written assurances from them that they agree to those restrictions and conditions.

(3) May not amend any terms of such Agreement without Covered Entity's prior written approval.

I. Within five (5) business days of a written request from Covered Entity:

(1) Make available information for Covered Entity to respond to an Individual's request for access to PHI about him/her.

(2) Make available information for Covered Entity to respond to an Individual's request for amendment of PHI about him/her and, as determined by and under the direction of Covered Entity, incorporate any amendment to the PHI.

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(3) Make available PHI for Covered Entity to respond to an Individual's request for an accounting of Disclosures of PHI about him/her.

J. Business Associate may not take any action concerning an individual's request for access, amendment, or accounting other than as instructed by Covered Entity.

K. To the extent Business Associate is required to carry out Covered Entity's obligations under Subpart E of 45 CFR Part 164, comply with the provisions that apply to Covered Entity in the performance of such obligations.

L. Provide to the Secretary of Health and Human Services and to Covered Entity records related to Use or Disclosure of PHI, including its policies, procedures, and practices, for the purpose of determining Covered Entity's, Business Associate's, or a Subcontractor's compliance with the HIPAA Rules.

M. Upon completion or termination of the applicable contract(s) or agreement(s), return or destroy, as determined by and under the direction of Covered Entity, all PHI and other VA data created or received by Business Associate during the performance of the contract(s) or agreement(s). No such information will be retained by Business Associate unless retention is required by law or specifically permitted by Covered Entity. If return or destruction is not feasible, Business Associate shall continue to protect the PHI in accordance with the Agreement and use or disclose the information only for the purpose of making the return or destruction feasible, or as required by law or specifically permitted by Covered Entity. Business Associate shall provide written assurance that either all PHI has been returned or destroyed, or any information retained will be safeguarded and used and disclosed only as permitted under this paragraph.

N. Be liable to Covered Entity for civil or criminal penalties imposed on Covered Entity, in accordance with 45 C.F.R. §§ 160.402 and 160.410, and with the HITECH Act, 42 U.S.C. §§ 17931(b), 17934(c), for any violation of the HIPAA Rules or this Agreement by Business Associate.

4. Obligations of Covered Entity. Covered Entity agrees that it:

A. Will not request Business Associate to make any Use or Disclosure of PHI in a manner that would not be permissible under Subpart E of 45 C.F.R. Part 164 if made by Covered Entity, except as permitted under Section 2 of this Agreement.

B. Will promptly notify Business Associate in writing of any restrictions on Covered Entity's authority to use or disclose PHI that may limit Business Associate's Use or Disclosure of PHI or otherwise affect its ability to fulfill its obligations under this Agreement.

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- C. Has obtained or will obtain from Individuals any authorization necessary for Business Associate to fulfill its obligations under this Agreement.
- D. Will promptly notify Business Associate in writing of any change in Covered Entity's Notice of Privacy Practices, or any modification or revocation of an Individual's authorization to use or disclose PHI, if such change or revocation may limit Business Associate's Use and Disclosure of PHI or otherwise affect its ability to perform its obligations under this Agreement.
5. Amendment. Business Associate and Covered Entity will take such action as is necessary to amend this Agreement for Covered Entity to comply with the requirements of the HIPAA Rules or other applicable law.
6. Termination.
- A. Automatic Termination. This Agreement will automatically terminate upon completion of Business Associate's duties under all underlying Agreements or by termination of such underlying Agreements.
- B. Termination Upon Review. This Agreement may be terminated by Covered Entity, at its discretion, upon review as provided by Section 9 of this Agreement.
- C. Termination for Cause. In the event of a material breach by Business Associate, Covered Entity:
- (1) Will provide an opportunity for Business Associate to cure the breach or end the violation within the time specified by Covered Entity and;
 - (2) May terminate this Agreement and underlying contract(s) if Business Associate does not cure the breach or end the violation within the time specified by Covered Entity.
- D. Effect of Termination. Termination of this Agreement will result in cessation of activities by Business Associate involving PHI under this Agreement.
- E. Survival. The obligations of Business Associate under this Section shall survive the termination of this Agreement as long as Business Associate creates, receives, maintains, or transmits PHI, regardless of whether a compliant Business Associate Agreement is in place.
7. No Third Party Beneficiaries. Nothing expressed or implied in this Agreement confers any rights, remedies, obligations, or liabilities whatsoever upon any person or entity other than Covered Entity and Business Associate, including their respective successors or assigns.

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8. Other Applicable Law. This Agreement does not abrogate any responsibilities of the parties under any other applicable law.
9. Review Date. The provisions of this Agreement will be reviewed by Covered Entity every two years from Effective Date to determine the applicability and accuracy of the Agreement based on the circumstances that exist at the time of review.
10. Effective Date. This Agreement shall be effective on the last signature date below.

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Department of Veterans Affairs
Veterans Health Administration

En-Vision America, Inc.

By: _____

Name: Charles E. Stroup, Jr.

Title: Deputy Director, National
Data Systems

Date: _____

By: Philip Raistrick

Name: Philip Raistrick

Title: President

Date: 8/24/17