

Smart Diagnostic Devices Business Associate Agreement

This Agreement is made effective as of the date of such acceptance (whether by “click-through” or otherwise) (the “Effective Date”) by and between **you**, hereinafter referred to as “Customer” or “Covered Entity”, and **Smart Diagnostic Devices**, hereinafter referred to as “SDD” or “Business Associate”, (individually, a “Party” and collectively, the “Parties”).

WITNESSETH:

WHEREAS, Sections 261 through 264 of the federal Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, known as “the Administrative Simplification provisions,” direct the Department of Health and Human Services to develop standards to protect the security, confidentiality and integrity of health information;

WHEREAS, pursuant to the Administrative Simplification provisions, the Secretary of Health and Human Services has issued regulations modifying 45 CFR Parts 160 and 164 (the “HIPAA Privacy Rule” and the “HIPAA Security Rule”);

WHEREAS, Title XIII of the American Recovery and Reinvestment Act, known as “the HITECH Act” has amended HIPAA and the HIPAA regulations, including HIPAA’s Administrative Simplification provisions;

WHEREAS, amendments to the HIPAA Regulations contained in the HIPAA Omnibus Final Rule became defective on March 26, 2013, and amended HIPAA’s Privacy, Security, Breach Notification and Enforcement Rules;

WHEREAS, The requirements of the HIPAA Administrative Simplification Regulations (including the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules) implement sections 1171-1180 of the Social Security Act (the Act), sections 262 and 264 of Public Law 104-191, section 105 of 492 Public Law 110-233, sections 13400-13424 of Public Law 111-5, and section 1104 of Public Law 111-148;

WHEREAS, the Parties wish to enter into or have entered into an arrangement whereby Business Associate shall provide certain services to Covered Entity, and, pursuant to such arrangement, Business Associate may be considered a “Business Associate” of Covered Entity as defined in the HIPAA Privacy Rule; and

WHEREAS, Business Associate may have access to Protected Health Information (as defined below) to fulfill its responsibilities under such arrangement;

THEREFORE, in consideration of the Parties’ continuing obligations under the HIPAA Privacy Rule and Security Rule, and other good and valuable consideration, the receipt and sufficiency of which hereby acknowledged, the Parties as follows:

I. DEFINITIONS

Except as otherwise defined herein, all terms in this Agreement shall have the definitions set forth in the current HIPAA Rules. In the event of an inconsistency between the provision of this Agreement and mandatory provisions of the HIPAA Rules, as amended, the HIPAA Rules shall control. Where provisions of this Agreement are different than those mandated in the HIPAA Rules, but are nonetheless permitted by the HIPAA Rules, the provisions of this Agreement shall control.

Protected Health Information – The term “Protected Health Information” (abbreviated as “PHI”) means individually identifiable health information including, without limitation, all information, data, documentation, and materials, including without limitation, demographic, medical and financial information, that relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and that identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

Covered Entity – The term “Covered Entity” (abbreviated as “CE”) means;

- 1) a health plan;
- 2) a health care clearinghouse;
- 3) a health care provider who transmits any health information in an electronic form in connection with a transaction covered by this subchapter.

Business Associate – The term “Business Associate” means, with respect to a Covered Entity, a person who:

1) On behalf of such Covered Entity or of an organized health care arrangement (as defined in this section) in which the Covered Entity participates, but other than in the capacity of a member of the workforce of such Covered Entity or arrangement, creates, receives, maintains, or transmits protected health information for a function or activity regulated by this subchapter, including claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, patient safety activities listed at 42 CFR 3.20, billing, benefit management, practice management, and repricing; or,

2) Provides, other than in the capacity of a member of the workforce of such Covered Entity, legal, actuarial, accounting, consulting, data aggregation (as defined in 45 CFR Part § 164.501 of this subchapter), management, administrative, accreditation, or financial services to or for such Covered Entity or to or for an organized health care arrangement in which the Covered Entity participates, where the provision of the service involves the disclosure of protected health information from such Covered Entity or arrangement, or from another Business associate of such Covered Entity or arrangement, to the person.

Business Associates, under the 2013 HIPAA Final Rule amendments, include the following:

- Subcontractors.
- Patient Safety Organizations.
- HIOs – Health Information Organizations, including Health Information Exchanges (HIEs) and regional Health Information Organizations.
- E-Prescribing gateways.
- PHRs – Personal Health Record vendors that provide services on behalf of a Covered Entity. PHR vendors that do not offer PHRs on behalf of Covered Entities are not Business Associates.
- Other firms or persons who “facilitate data transmission” that requires routine access to PHI.

HIPAA RULES – The term “HIPAA Rules” means the HIPAA Privacy, Security, Breach Notification, and Enforcement Rules at 45 CFR Part 160 and Part 164.

II. COVERED INFORMATION

BUSINESS ASSOCIATE ACKNOWLEDGES AND AGREES that all Protected Health Information that is created or received by Covered Entity and disclosed or made available in any form, including paper record, oral communication, audio recording, and electronic media by Covered Entity or its operating units to Business Associate or is created or received by Business Associate on Covered Entity’s behalf shall be subject to this Agreement.

III. CONFIDENTIALITY REQUIREMENTS

(A) Business Associate agrees:

(i) to use or disclose any Protected Health Information solely: (1) for meeting its obligations as set forth in any agreements between the Parties evidencing their business relationship, or (2) as required by applicable law, rule or regulation, or by accrediting or credentialing organization to whom Covered Entity is required to disclose such information or as otherwise permitted under this Agreement, or the HIPAA Privacy Rule or Security Rule;

(ii) at termination of this Agreement, or any similar documentation of the business relationship of the Parties, or upon request of the Covered Entity, whichever occurs first, if feasible, Business Associate shall return or destroy all Protected Health Information received from, or created, or received by Business Associate on behalf of Covered Entity that Business Associate still maintains in any form and retains no copies of such information, or if such return or destruction is not feasible, Business Associate shall extend the protections of this Agreement to make the information protected in perpetuity, or until such time as its return or destruction becomes feasible, and limit further uses and disclosure to those purposes to make the return or destruction of the information not feasible; and

(iii) to ensure that its agents, including a subcontractor, to whom it provides Protected Health Information received from, or created by Business Associate on behalf of Covered Entity, agrees to the same restrictions and conditions that apply to Business Associate with respect to such information. In addition, Business Associate agrees to take reasonable steps to ensure that its employees' actions or omissions do not cause Business Associate to breach the terms of this Agreement or the mandatory requirements of the HIPAA Privacy Rule and Security Rule that may apply to Business Associate.

(B) Notwithstanding the prohibitions set forth in this Agreement, Business Associate may use and disclose Protected Health Information as follows:

(i) If necessary, for the proper management and administration of Business Associate or to carry out the legal responsibilities of Business Associate, provided that as to any such disclosure, the following requirements are met:

(a) The disclosure is required by law, not merely permitted by law; or

(b) Business Associate obtains reasonable written assurances from the person or party to whom the information is disclosed that it shall be held confidentially and used or further disclosed only as required by law or for the purpose for which it was disclosed to the person or party, and the person or party notifies Business Associate of any instances of which it is aware in which the confidentiality of the information has been breached;

(ii) for data aggregation services, if to be provided by Business Associate for the health care operations of Covered Entity pursuant to any agreements between the Parties evidencing their business relationship. For the purpose of this Agreement, data aggregation services means the combining of PHI by Business Associate with the PHI received by Business Associate in its capacity as a Business Associate of another Covered Entity, to permit data analyses that relate to the health care operations of the respective covered entities.

(iii) Business Associate will implement appropriate safeguards to prevent use or disclosure of Protected Health Information other than as permitted in this Agreement. The Secretary of Health and Human Services (HHS) shall have the right to audit Business Associate's records and practices related to uses and disclosures of Protected Health Information to ensure Covered Entity's compliance with the terms of the HIPAA Privacy Rule and Security Rule. Business Associate shall timely report to Covered Entity any use

or disclosure of Protected Health Information which is not in compliance with the terms of this Agreement of which it becomes aware.

IV. ADDITIONAL OBLIGATIONS AND ACTIVITIES OF BUSINESS ASSOCIATE

- (A) Business Associate agrees that it is required under the amended HIPAA regulations to comply with, and shall comply with, the HIPAA Security Rule, including the Security Rule's Administrative, Physical, and Technical safeguard requirements.
- (B) Business Associate agrees that it is required under the amended HIPAA regulations to comply with, and shall comply with, the use and disclosure provisions of the HIPAA Privacy Rule.
- (C) Business Associate agrees to not use or disclose Protected Health Information other than as permitted or required by the Agreement or as required by law.
- (D) Business Associate agrees that it may not use or disclose PHI in a manner that would violate Subpart E of 45 CFR Part 164 if done by Covered Entity.
- (E) Business Associate agrees to use appropriate safeguards, and comply with Subpart C of 45 CFR Part 164 with respect to electronic PHI ("ePHI"), to prevent use or disclosure of PHI other than as provided for by this Agreement.
- (F) Breach Disclosures to Covered Entity: Business Associate agrees to immediately report to Covered Entity any use or disclosure of PHI not provided for, by this Agreement of which it becomes aware; and any security incident of which it becomes aware. Further, Business Associate agrees to notify the Covered Entity of any individual who's PHI has been inappropriately or unlawfully released, accessed, or obtained. Business Associate agrees that such notification shall meet the requirements of 45 CFR § 164.410 of the amended HIPAA regulations.

Specifically, the following shall apply:

- (i) A breach is considered discovered on the first day the Business Associate knows or should have known about it.
 - (ii) In no case, shall the Business Associate notify the Covered Entity of any breach later than 48 hours after a breach is discovered.
 - (iii) Business Associate shall notify the Covered Entity of any and all breaches of Protected Health Information, and provide detailed information to the Covered Entity about the breach, along with the names and contact information of all individuals whose Protected Health Information was involved.
- (G) Business Associate agrees, in accordance with 45 CFR 164.502(e)(1)(ii) and 164.308(b)(2), if applicable, to ensure that any subcontractors that create, receive, maintain, or transmit Protected Health Information on behalf of the Business Associate agree to the same restrictions, conditions, and requirements that apply to the Business Associate with respect to such information;
 - (H) Business Associate agrees to apply HIPAA's Minimum Necessary Standard to all uses, disclosures, and requests for Protected Health Information, and to make reasonable efforts to limit the Protected Health Information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.
 - (I) Business Associate agrees to provide access, at the request of Covered Entity, and in the time and manner of 5 business days after receiving a written request, to Protected Health Information in a Designated Record Set, to Covered Entity or, as directed by Covered Entity, to an Individual in order to meet the requirements of 45 CFR § 164.524.

- (J) Business Associate agrees to make any amendment(s) to Protected Health Information in a Designated Record Set that the Covered Entity directs or agrees to pursuant to 45 CFR § 164.526 at the request of Covered Entity or an Individual, and in the time and manner of 5 business days after receiving a written request.
- (K) Business Associate agrees to make internal practices, books and records, including policies and procedures and Protected Health Information, relating to the use and disclosure of Protected Health Information received from, or created, or received by Business Associate on behalf of, Covered Entity available to the Covered Entity or to the Secretary, in a time and manner of 5 business days after receiving a written request, or designated by the Secretary, for purposes of the Secretary determining Covered Entity's compliance with the HIPAA Privacy Rule and Security Rule.
- (L) Business Associate agrees to document such disclosure of Protected Health Information and information related to such disclosure as would be required for Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR § 164.528.
- (M) Business Associate agrees to provide to Covered Entity or an Individual, in time and manner of 5 business days after receiving a written request, information collected in accordance with Section V(C) of this Agreement, to permit Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR § 164.258.

V. AVAILABILITY OF PHI

- (A) Business Associate agrees to make available Protected Health Information to the extent and in the manner required by Section 164.524 of the HIPAA Privacy Rule.
- (B) Business Associate agrees to make Protected Health Information available for amendment and incorporate any amendments to Protected Health Information in accordance with the requirements of Section 164.526 of the HIPAA Privacy Rule.
- (C) In addition, Business Associate agrees to make PHI available for purposes of accounting of disclosures, as required by Section 164.528 of the HIPAA Privacy Rule.

VI. TERMINATION

Notwithstanding anything in this Agreement to the contrary, Covered Entity shall have the right to terminate this Agreement immediately if Covered Entity determines that Business Associate has violated any material term of this Agreement. If Covered Entity reasonably believes that Business Associate will violate a material term of this Agreement and, where practicable, Covered Entity gives written notice to Business Associate of such belief within a reasonable time after forming such belief, and Business Associate fails to provide adequate written assurances to Covered Entity that it will not breach the cited term of this Agreement within a reasonable period of time given the specific circumstances, but in any event, before the threatened breach is to occur, then Covered Entity shall have the right to terminate this Agreement immediately.

Upon termination of this Agreement for any reason, Business Associate agrees to return to Covered Entity, or destroy, all Protected Health Information received from Covered Entity, or created, maintained, or received by Business Associate on behalf of Covered Entity, that the Business Associate still maintains in any form. Business associate shall retain no copies of the Protected Health Information in any form or medium. The return or destruction of Protected Health Information received from the Covered Entity will be done according to the "Termination Procedure".

Termination Procedure – Upon notification and authorization of Account Termination, the SDD Site Administrator will send an email to the Customer/Owner of the account; stating that their account access will be disabled 30 days after the termination date. The account owner can use this time to offload/download their data during that 30-day window. At 30 days, the SDD Site Administrator will send an email notice to the account owner; stating that their

account has been disabled. If the account owner has not offloaded/downloaded their data prior to this date, they will now need to contact the SDD Site Administrator to set up a date and time for the account owner to retrieve their data. A warning will be included stating that the account data will be purged within 90 days from the date of termination. At 90 days from the termination date, the data will be purged from the account and Customer will no longer have access, nor will SDD have the ability to retrieve or provide any Customer data (however, it may not be purged from site backups until an additional 365 days has elapsed), subject to the following limited exception: PHI directly related to Customer support requests previously submitted to SDD support may not be purged for up to five years from Account Termination. As such, (i) SDD will extend the protections of this Agreement to such PHI and limit further uses and disclosures of such PHI to those purposes that make the return or destruction infeasible, for so long as SDD maintains such PHI; and (ii) Customer will comply with its obligations under this Agreement with respect to any PHI retained by SDD after the termination or expiration of this Agreement. This section will survive any termination or expiration of this Agreement.

VII. INDEMNIFICATION.

Each party (the “Indemnifying Party”) shall indemnify and hold the other party and its officers, directors, employees and agents (each an “Indemnified Party”) harmless from and against any claim, cause of action, liability, damage, cost or expense (“Liabilities”) to which the Indemnified Party becomes subject to as a result of third party claims (including reasonable attorneys' fees and court or proceeding costs) brought against the Indemnified Party, which arise as a result of: (i) the material breach of this Agreement by the Indemnifying Party; or (ii) the gross negligence or willful misconduct of the Indemnifying Party, except to the extent such Liabilities were caused by the Indemnified Party. A party entitled to indemnification under this Section shall give prompt written notification to the Indemnifying Party of the commencement of any action, suit or proceeding relating to a third party claim for which indemnification is sought, subject to applicable confidentiality constraints. The Indemnifying Party shall be entitled to assume control of the defense of such action, suit, proceeding or claim with competent counsel of its choosing. Indemnification shall not be required if any claim is settled without the Indemnifying Party’s consent, which such consent shall not be unreasonably withheld. NOTWITHSTANDING THE FOREGOING PROVISIONS OF THIS SECTION, IN NO EVENT WILL AN INDEMNIFYING PARTY BE LIABLE TO AN INDEMNIFIED PARTY UNDER CONTRACT, TORT, OR ANY OTHER LEGAL THEORY FOR INCIDENTAL, CONSEQUENTIAL, INDIRECT, PUNITIVE, OR SPECIAL LOSSES OR DAMAGES OF ANY KIND.

VIII. LIMITATION OF LIABILITY

In no event shall Business Associate (or any director, officer or employee or any entity controlling, controlled by or under common control with business associate) be liable to Covered Entity or to any third party for any special, consequential, incidental, or indirect damages, however caused and under any theory of liability arising out of this Agreement, which shall include data breach, corruption, and loss, whether or not advised of the possibility of such damages, and notwithstanding any failure of essential purpose of any limited remedy. In the event that Business Associate is held liable arising out of or relating to this Agreement or the obligations of Business Associate under this Agreement, Business Associate’s aggregate liability under any legal theory, including tort claims, shall not exceed the fees paid and to be paid by covered entity pursuant to the services agreement within the twelve month period prior to such event occurring that gives rise to such liability.

IX. MISCELLANEOUS

Except as expressly stated herein or in the HIPAA Rules, the parties to this Agreement do not intend to create any rights in any third parties. The obligations of Business Associate under this Section shall survive the expiration, termination, or cancellation of this Agreement and/or the business relationship of the parties, and shall continue to bind Business Associate, its agents, employees, contractors, successors, and assigns as set forth herein.

This Agreement may be amended or modified only in writing signed by the Parties. No Party may assign its respective rights and obligations under this Agreement without the prior written consent of the other Party. None of the provisions of this Agreement are intended to create, nor shall they be deemed to create any relationship between

the Parties other than that of independent parties contracting with each other solely for the purposes of effecting the provisions of this Agreement and any other agreements between the Parties evidencing their business relationship. This Agreement shall be governed by the laws of the State of Minnesota. No change, waiver or discharge of any liability or obligation hereunder on any one or more occasions shall be deemed a waiver of performance of any continuing or other obligation, or shall prohibit enforcement of any obligation, on any other occasion. The parties agree that; in the event that any documentation of the arrangement pursuant to which Business Associate provides services to Covered Entity contains provisions relating to the use or disclosure of Protected Health Information which are more restrictive than the provisions of this Agreement, the provisions of the more restrictive documentation shall control. The provisions of this Agreement are intended to establish the minimum requirements regarding Business Associate's use and disclosure of Protected Health Information.

In the event that any provision of this Agreement is held, by a court of competent jurisdiction, to be invalid or unenforceable; the remainder of the provisions of this Agreement shall remain in full force and effect. In addition, in the event a party believes in good faith that any provision of this Agreement fails to comply with the then-current requirements of the HIPAA Privacy Rule or Security Rule, such party shall notify the other party in writing. For a period of UP TO 30 days, the parties shall address in good faith such concern and amend the terms of this Agreement, if necessary to bring it into compliance. If, after such 30-day period, the Agreement fails to comply with the requirements of the HIPAA Privacy Rule and Security Rule, then either party has the right to terminate upon written notice to the other party.