



BUSINESS ASSOCIATE AGREEMENT

1. DEFINITIONS:

1.1 Undefined Terms:

Terms used, but not otherwise defined, in this Agreement shall have the same meaning as those terms defined by the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), in the Privacy Rule, 45 CFR 160.103 and 164.501 or the Security Rule, 45 CFR 164.304 .

1.2 Specific Definitions:

- a. Business Associate. “Business Associate” shall have the same meaning as the term “ business associate” in 45 CFR 160.103 and assists in the performance of: A function or activity involving the use or disclosure of individually identifiable health information, including claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, billing, benefit management, practice management, and repricing; or provides legal, actuarial, accounting, consulting, data aggregation (as defined in § 164.501) management, administrative, accreditation, or financial services to or for a covered entity where the provision of the service involves the disclosure of individually identifiable health information from such covered entity or from another business associate of such covered entity.
This term will apply to:
- b. Covered Entity. “Covered Entity” shall have the same meaning as the term “covered entity” and is a health care provider who transmits any health information in electronic form in connection with a transaction covered by this Rule. This term will apply to BIOTECH X-RAY, INC.
- c. Individual. “Individual” shall have the same meaning as the term “individual” in 45 CFR 164.501 and shall include a person who qualifies as a personal representative in accordance with 45 CFR 164.502(g).
- d. Privacy Rule. “Privacy Rule” shall mean the Standards for Privacy of Individually Identifiable Health Information at 45 CFR Part 160 and Part 164, Subparts A and E.
- e. Protected Health Information. “Protected Health Information” (PHI) shall have the same meaning as the term “protected health information” in 45 CFR 164.501, limited to the information created or received by Business Associate from or on behalf of Covered Entity.
- f. Required By Law. “Required By Law” shall have the same meaning as the term “required by law” in 45 CFR 164.501
- g. Secretary. “Secretary” shall mean the Secretary of the Department of Health and Human Services or his designee.
- h. Security Rule. “Security Rule” shall mean the Security Standards for the Protection of Electronic Protected Health Information at 45 CFR Part 164, Subpart C, and Amendments thereto.

2. DUTIES

2.1 Business Associate's Duties:

- a. 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.
- b. Business Associate agrees to use appropriate safeguards to prevent use or disclosure of the Protected Health Information other than as provided for by this Agreement.
- c. Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of Protected Health Information by Business Associate in violation of the requirements of this Agreement.
- d. Business Associate agrees to promptly report to Covered Entity any use or disclosure of the Protected Health Information not provided for by this Agreement of which it becomes aware.
- e. Business Associate agrees to ensure that any agent, including a subcontractor, to whom it provides Protected Health Information received from, or created or received by Business Associate on behalf of Covered Entity, agrees to the same restrictions and conditions that apply through this Agreement to Business Associate with respect to such information.
- f. Business Associate agrees to make internal practices, books, and records 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 at the request of the Covered Entity to the Secretary, for purposes of the Secretary determining Covered Entity's compliance with the Privacy Rule and Security Rule.
- g. Business Associate agrees to document such disclosures of Protected Health Information and information related to such disclosures 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.
- h. Business Associate agrees to provide to Covered Entity or an Individual, in time and manner designated by Covered Entity, information collected in accordance with Section g. above 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 164.528.

2.2 Covered Entity's Duties:

- a. Covered Entity shall provide Business Associate with the notice of privacy practices that Covered Entity produces in accordance with 45 CFR 164.520, to the extent that such information may affect Business Associate's use or disclosure of Protected Health Information, as well as any changes to such notice.
- b. Covered Entity shall notify Business Associate of any changes in, or revocation of, permission by Individual to use or disclose Protected Health Information, to the extent that such changes may affect Business Associate's permitted or required use or disclosure of Protected Health Information.
- c. Covered Entity shall notify Business Associate of any restriction to the use or disclosure of Protected Health Information that Covered Entity has agreed to in accordance with 45 CFR

164.522, to the extent that such restriction may affect Business Associate's use or disclosure of Protected Health Information.

- d. Covered Entity shall not request Business Associate to use or disclose Protected Health Information in any manner that would not be permissible under the Privacy Rule or Security Rule if done by Covered Entity.

3. CONFIDENTIALITY

3.1 Specific Use and Disclosure Provisions

- a. Except as otherwise limited in this Agreement, Business Associate may use or disclose Protected Health Information for the proper management and administration of the Business Associate, provided that these uses or disclosures are required by law, or Business Associate obtains reasonable assurances from the person to whom the information is used or disclosed that it will remain confidential and used or further disclosed only as required by law or for the purpose for which it was disclosed to the person, and the person notifies the Business Associate of any instances of which it is aware in which the confidentiality of the information has been breached.
- b. Except as otherwise limited in the Agreement, Business Associate may use Protected Health Information to provide Data Aggregation services to Covered Entity as permitted by 42 CFR 164.504 (e)(2)(i)(B).

4. TERM AND TERMINATION

4.1 Term. The Term of this Agreement shall be effective as of {April 14, 2003 or service commencement date, if later}, and shall terminate when all of the Protected Health Information provided by Covered Entity to Business Associate, or created or received by Business Associate on behalf of Covered Entity, is destroyed or returned to Covered Entity, or if it is not feasible to return or destroy Protected Health Information, protections are extended to such information, in accordance with the termination provisions in this Section.

4.2 Termination for Cause. Upon Covered Entity's knowledge of a material breach by Business Associate, Covered Entity shall either:

- a. Provide an opportunity for Business Associate to cure the breach or end the violation and terminate this Agreement if Business Associate does not cure the breach or end the violation within the time specified by Covered Entity;
- b. Immediately terminate this Agreement if Business Associate has breached a material term of this Agreement and cure is not possible; or
- c. If neither termination nor cure is feasible, Covered Entity shall report the violation to the Secretary.

4.3 Effect of Termination

- a. Except as provided in paragraph (2) of this section, upon termination of this Agreement, for any reason, Business Associate shall return or destroy all Protected Health Information received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity. This provision shall apply to Protected Health Information that is in the possession of subcontractors

or agents of Business Associate. Business Associate shall retain no copies of the Protected Health Information.

- b. In the event that Business Associate determines that returning or destroying the Protected Health Information is not feasible, Business Associate shall provide to Covered Entity notification of the conditions that make return or destruction not feasible. Upon mutual agreement of the Parties that return or destruction of Protected Health Information is not feasible, Business Associate shall extend the protections of this Agreement to such Protected Health Information and limit further uses and disclosures of such Protected Health Information to those purposes that make the return or destruction not feasible, for so long as Business Associate maintains such Protected Health Information.

5. SECURITY RULE

5.1 Security Requirements. In order to create, receive, maintain or transmit Electronic Protected Health Information (EPHI) on covered Entity's behalf, Business Associate, upon the Security Rule's April 20, 2005 compliance date, will:

- a. Implement administrative, physical and technical safeguards that will reasonably and appropriately protect the confidentiality, integrity and availability of EPHI that it creates, receives, maintains, or transmits on behalf of Covered Entity.
- b. Ensure that its agents, including subcontractors, to whom it provides EPHI, agree to implement reasonable and appropriate safeguards to protect such EPHI.
- c. Report to covered Entity any security incident of which it becomes aware.
- d. Make its Security Rule policies and procedures and documentation available to the Secretary for purposes of determining the Covered Entity's compliance with the Security Rule.

5.2 Termination. Business Associate authorizes, just as in Section 4 of this agreement, termination of the agreement by Covered Entity if Covered Entity determines that Business Associate has violated a material term of the agreement.

6. MISCELLANEOUS

6.1 Regulatory References. A reference in this Agreement to a section in the Privacy Rule or Security Rule means the section as in effect or as amended, and for which compliance is required.

6.2 Amendment. The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for Covered Entity to comply with the requirements of the Privacy Rule and the Security Rule and the Health Insurance Portability and Accountability Act of 1996, Public Law No. 104-191.

6.3 Survival. The respective rights and obligations of Business Associate under Section 4.3 above of this Agreement shall survive the termination of this Agreement.

6.4 Interpretation. Any ambiguity in this Agreement shall be resolved in favor of a meaning that permits Covered Entity to comply with the Privacy Rule and the Security Rule.

6.5 Governing Law. This agreement has been executed and delivered in, and shall be construed and enforced in accordance with the laws of the State of MO.

6.6 Execution. This agreement and any amendments hereto shall be executed in duplicate copies (i) on behalf of Business Associate and (ii) on behalf of Covered Entity. Each duplicate copy shall be deemed an original but both duplicate originals shall together constitute one and the same instrument.

**AMENDMENT OF AGREEMENT BETWEEN BUSINESS ASSOCIATES AND
BIOTECH X-RAY, INC.**

THIS AMENDMENT is entered into as the _____ day of _____, 2013, by and between the Business Associate and BIOTECH X-RAY, INC. (Covered Entity).

BACKGROUND

The parties may or may not have entered into a Business Associate agreement previously and by this Amendment desire to amend the Agreement or enter into a Business Associate agreement to address changes required by the passage of the Health Information Technology for Economic and Clinical Health provisions of the American Recovery and Reinvestment Act of 2009, (the ‘HITECH Act’), as set forth below.

In consideration of the foregoing, Business Associate and BIOTECH X-RAY, INC. agree as follows:

TERMS

1. HIPAA COMPLIANCE. Effective as of February 17, 2010, in accordance with the requirements set forth in the HITECH Act (Sections 13400 et seq.), the Privacy and Security Regulations of HIPAA, as they may be amended from time to time, apply directly to the Business Associate of BIOTECH X-RAY, INC.

2. NOTIFICATION IN CASE OF BREACH.

a. In the case of the unauthorized acquisition, access, use or disclosure of PHI, constituting a “breach” (per Section 13400 of the HITECH Act, and as further defined in the Privacy Regulations at 45 CFR 164.400 et seq. a “breach” means the acquisition, access, use, or disclosure of PHI in a manner not permitted under the HIPAA Privacy Regulations, which compromises the security or privacy of such information, posing a significant risk of financial, reputational, or other harm to the individual patient,) and following the discovery of any such breach the Business Associate shall promptly (no later than 10 days after determining that a breach has occurred) notify the Corporate Compliance Officer that a breach has occurred. Such notifications shall be sent via email to compliance@biotechxray.com and in writing to BIOTECH X-RAY, INC., 1065 Executive Parkway, St. Louis, MO 63141-6367, Attention: Corporate Compliance Officer. The initial notification shall identify the nature of the breach, as required by the Privacy Regulations, including without limitation: a description of what happened; the date of the breach; and specific elements of PHI that were subject to the breach.

b. The Business Associate shall work with BIOTECH X-RAY, INC., promptly and as reasonably required by BIOTECH X-RAY, INC., and identify all individuals whose PHI has been breached; ensure that the cause giving rise to the breach has been remediated; and gather any other information reasonably required to comply with the Privacy Regulations and to address the breach.

c. For breaches arising out of the acts or omissions of the Business Associate, all of the direct costs reasonably associated with sending out notifications of the breach to patients, clients and regulatory authorities shall be the responsibility of the Business Associate. In addition, to the extent such breach warrants the provision of credit monitoring for patients, Business Associate shall be responsible for the costs of providing one year’s worth of credit monitoring. In the event that a patient experiences identity theft arising from the Business Associate’s breach, the Business Associate shall be responsible for the costs incurred by BIOTECH X-RAY, INC. in providing the patient with services reasonably required to remediate the consequences of such identity theft.

All other terms of the Agreement remain in full force and effect. In the event of any conflict between the terms of this Amendment and the Agreement, the terms of this Amendment shall prevail.

AGREED:

AGREED:

By: _____

By: **BIOTECH X-RAY, INC.**

Name: _____
Please Print

Name: _____
Please Print

Title: _____
Please Print

Title: _____
Please Print

Signature: _____

Signature: _____

Date: _____

Date: _____