



HIPAA HITECH POLICY

Effective March 1, 2010

OVERVIEW OF THE HIPAA HITECH ACT OF 2009

The Health Information Technology for Economic and Clinical Health Act (the HITECH Act) amends HIPAA. Prior to passage of the HITECH Act, only Covered Entities (a health care provider, health plan or clearinghouse) were directly regulated under HIPAA. Covered Entities were required to have written agreements with their Business Associates specifying that the Associates would treat protected health information in a manner consistent with HIPAA (Health Insurance Portability and Accountability Act) regulations—but there was no regulatory obligation for Associates to implement the detailed requirements of the HIPAA privacy and security rules. In the event of a breach of its contractual obligations, the Business Associate faced only a contract claim from the Covered Entity.

The HITECH Act changes all that. It applies many of the HIPAA privacy standards directly to Business Associates, and requires Associates to directly report security breaches.

Generally, HIPAA is concerned with an individual's Protected Health Information ("PHI"). PHI is any information created or received by or on behalf of a Covered Entity 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. Examples of PHI include anything included in a patient's medical records, e.g. names, dates, birth date, admission date, discharge date, age, phone numbers, fax numbers, electronic mail addresses, social security numbers, medical record numbers, health plan beneficiary numbers, and account numbers. You should assume that any information that you receive from a provider about a patient or patients will be considered PHI and will be subject to HIPAA, unless you have received prior written guidance to the contrary from the Advanced BioHealing Compliance Officer.

HIPAA HITECH ACT – PENALTIES FOR VIOLATIONS

The HITECH Act calls for increased enforcement activities through: (1) additional public education; (2) increased audits; (3) newly authorized state attorneys general civil actions; and, in the future, (4) an avenue for affected patients to share in monetary penalties collected. HHS gets to retain all collected penalties for future enforcement activities.

Civil penalties can be substantial. They range from \$100 to \$250,000 per violation, with a maximum annual penalty of \$1,500,000 for all violations of an "identical requirement or prohibition" during a calendar year.

The HITECH act "clarifies" that criminal penalties may be imposed under HIPAA on any individual or entity that wrongly obtains or discloses PHI. Criminal penalties range from a fine of up to \$50,000 and imprisonment for up to one year to \$250,000 and imprisonment for up to ten years.

ADVANCED BIOHEALING HIPAA HITECH POLICY

Advanced BioHealing has adopted the following policy to ensure compliance with HIPAA and the HITECH Act.

You are required to comply with this policy, and failure to comply may result in discipline up to and including termination.

WE MUST ENTER INTO A BUSINESS ASSOCIATE AGREEMENT WITH THE CUSTOMER

Unless you have confirmed that Advanced BioHealing already has a signed BAA on file, you must provide your customer with a copy of the enclosed BAA that follows, to proactively request that the agreement be completed and signed by the customer.

If your customer would rather use their BAA, please provide a copy to Advanced BioHealing's in-house counsel for approval and signature of the BAA. Luke Albrecht, in-house counsel, can be reached at 203.682.7224 or at the following address:

Luke Albrecht, Senior Counsel
Advanced BioHealing, Inc.
36 Church Lane
Westport, CT. 06880

An electronic copy can also be sent to: lalbrecht@abh.com

Questions? Contact your Reimbursement Specialist for reimbursement support for you or your customer regarding Dermagraft® Benefit Verifications.

Concerns about compliance? Contact the Advanced BioHealing Compliance Officer.

HIPAA HITECH ACT: DERMAGRAFT® BENEFIT VERIFICATIONS

SPECIFICALLY--

There must be a signed Business Associate Agreement [BAA] with the facility on file with the Advanced BioHealing General Counsel, for you to have access to any PHI for any patient. (See above for the process for initiating a BAA.) After a BAA is in place, you must conduct yourself in accordance with its terms.

You may only look at PHI, (e.g., charts and patient lists), with the agreement of, and at the direction of, a provider-affiliated managerial health care professional. Although no formal written direction is required, it is very important that you establish that the provider wants you to look at the PHI for the purpose of obtaining benefit information from the Hotline. You may not rely on clerical personnel for this consent, unless they are relaying a message from a health care provider or member of the management.

You may only obtain the minimum necessary information to complete the task requested of you. This means that specific to the Benefit Verification Form (“BVF”), you may only take and complete the information in the highlighted fields (see the attached example). Provider personnel must complete the other fields, e.g. diagnoses. By having them complete this information, we underscore that the provider wants us to begin the Benefit Verification Process, which the provider is responsible for ensuring that protected health information or data is correct, and we avoid misunderstandings regarding the provider-assigned diagnoses.

Providers may ask you questions related to completing the BV form. It is critical that only accurate reimbursement information is provided to customers. When you answer questions, you may only use information provided to you by the Advanced BioHealing Reimbursement Department or a copy of the local LCD coverage. You may never recommend off-label application of the product. Reimbursement questions not addressed in the materials provided by the Reimbursement Department should be referred to the reimbursement staff.

You must keep any patient information that you obtain from the customer safe and secure and may not take it from provider’s premises. To assist in sending the BVF to the hotline you may:

- Fax a completed BVF from the provider’s premises to the hotline at: 866-866-7713.
- Suggest the provider fax completed forms directly to the hotline at: 866-866-7713.

You may not offer the provider an option to fax completed forms to you at another fax number. This includes a personal fax machine, a Blackberry, or other mobile device. The Dermagraft Reimbursement Hotline will only work with clinic or physician office fax numbers, but you will be provided with information sufficient for you to assist with the Benefit Verification Process.

You may never make or dictate any entries into any patient medical record/chart. You may not place any stickers inside the chart. You may place a sticker outside the chart with the following verbiage: “Preliminary Coverage Established.” The company will supply you with pre-printed stickers.

You may not indicate that a benefit verification, once received by the treating facility or provider, is a “guarantee” of coverage, nor may you indicate “approved” on the BVF or patient file. The benefit verification process does not establish medical necessity. On the BVF, customers are made aware of the potential that even where a preliminary judgment is made that coverage exists and there is the potential for rejection of the claim.



HIPAA BUSINESS ASSOCIATE AGREEMENT

This **HIPAA Business Associate Agreement** (the “**Agreement**”), is made and is effective as of this day of _____, 2010 (“**Effective Date**”), between Advanced BioHealing, Inc., a Delaware corporation (“**Business Associate**”), and _____, a _____ corporation (“**Covered Entity**”) (each a “**Party**” and collectively the “**Parties**”).

BACKGROUND

The Parties are committed to complying with the Privacy Rule (defined below) and the Security Standards for electronic Protected Health Information (“**ePHI**”) under the Health Insurance Portability and Accountability Act of 1996 (“**HIPAA**”) and ARRA (defined below), as each is amended from time to time. This Agreement sets forth the terms and conditions pursuant to which the Business Associate and Covered Entity will handle Protected Health Information that is created, received, maintained or transmitted by the Business Associate from or on behalf of Covered Entity.

1. **DEFINITIONS.** Terms used, but not otherwise defined, in this Agreement shall have the same meaning as those terms are defined in HIPAA or ARRA, as amended.

1.1. “**ARRA**” means Subtitle D of the Health Information Technology for Economic and Clinical Health Act provisions of the American Recovery and Reinvestment Act of 2009, 42 U.S.C. §17921-17954.

1.2. “**Breach**” means the acquisition, access, use or disclosure of PHI (defined below) in a manner not permitted by the Privacy Rule that compromises the security or privacy of the PHI.

1.3. “**Individual**” has 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).

1.4. “**Privacy Rule**” means the Standards for Privacy of Individually Identifiable Health Information at 45 CFR part 160 and part 164, subparts A and E.

1.5. “**Protected Health Information**” or “**PHI**” has the meaning as set out in its definition at 45 CFR §164.501, limited to the information created, received, maintained or transmitted by Business Associate from or on behalf of the Covered Entity.

1.6. “**Required By Law**” has the same meaning as the term “required by law” in 45 CFR §164.501.

1.7. “**Secretary**” means the Secretary of the Department of Health and Human Services or his/her designee.

1.8. “**Security Incident**” means the attempted or successful unauthorized access, use, disclosure, modification or destruction of information or interference with system operations in an information system in which PHI is created, received, maintained or transmitted.

1.9. “**Security Standards**” means the Security Standards for the Protection of Electronic Protected Health Information at 45 CFR Part 164, Subpart C.

2. **PERMITTED USES AND DISCLOSURES BY BUSINESS ASSOCIATE.**

Except as otherwise limited in this Agreement:

2.1. Business Associate may make any and all uses of PHI necessary to perform its obligations under this Agreement and under its other agreements with Covered Entity.

2.2. Business Associate may use Protected Health Information for the proper management and administration of Business Associate or to carry out the legal responsibilities of Business Associate.

2.3. Business Associate may disclose Protected Health Information for the proper management and administration of Business Associate, provided that disclosures are required by law, or Business Associate obtains reasonable assurances from the person to whom the information is 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.

2.4. 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).

3. OBLIGATIONS AND ACTIVITIES OF BUSINESS ASSOCIATE.

3.1. Business Associate will not use or further disclose Protected Health Information other than as permitted or required by the Agreement or as Required By Law.

3.2. Business Associate will implement and use appropriate administrative, physical and technical safeguards to (i) prevent use or disclosure of PHI other than as permitted or required by this Agreement; (ii) reasonably and appropriately protect the confidentiality, integrity, and availability of the ePHI that Business Associate creates, receives, maintains, or transmits on behalf of the Covered Entity; and (iii) comply with the Security Standards.

3.3. Business Associate will 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.

3.4. Business Associate will report to Covered Entity any use or disclosure of the Protected Health Information not provided for by this Agreement. With respect to any use or disclosure of Unsecured PHI not permitted by the Privacy Rule that is caused solely by Business Associate's failure to comply with one or more of its obligations under this Agreement, Business Associate will determine when any such incident is a Breach and will provide all legally required notifications to Individuals, HHS and the media, as applicable, and shall pay for the reasonable and actual costs associated with such notifications. As soon as reasonably possible, and in any event prior to Business Associate's notification to Individuals, Business Associate shall provide Covered Entity with written notification that includes a description of the Breach, a list of Individuals and a copy of the template notification letter to be sent to Individuals.

3.5. Business Associate will require that any third party, including a subcontractor, to whom it provides Protected Health Information created, received, maintained or transmitted 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.

3.6. Business Associate will provide access, at the request of Covered Entity, and in the time and manner agreed upon by Covered Entity and Business Associate, 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 under 45 CFR §164.524.

3.7. Business Associate will make any amendment(s) to Protected Health Information in a Designated Record Set that 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 agreed upon by Covered Entity and Business Associate.

3.8. Business Associate will make internal practices, books, and records relating to the use and disclosure of Protected Health Information created, received, maintained or transmitted by Business Associate on behalf of Covered Entity available to the Secretary, in a time and manner designated by the Secretary, for purposes of the Secretary determining Covered Entity's compliance with the Privacy Rule and the Security Standards.

3.9. Business Associate will document such disclosures of Protected Health Information and information related to such disclosures in order to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR §164.528.

3.10. Business Associate will provide to Covered Entity or an Individual, in a time and manner agreed upon by Covered Entity and Business Associate, information collected in accordance with this Agreement, to respond to a request by Covered Entity or an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR §164.528.

3.11. Business Associate will not directly or indirectly receive remuneration in exchange for any PHI as prohibited by 42 U.S.C. § 17935(d) as of its Compliance Date.

3.12. Business Associate will not make or cause to be made any communication about a product or service that is prohibited by 42 U.S.C. § 17936(a) as of its Compliance Date.

3.13. Business Associate will not make or cause to be made any written fundraising communication that is prohibited by 42 U.S.C. § 17936(b) as of its Compliance Date.

3.14. Business Associate will accommodate reasonable requests by Individuals for confidential communications in accordance with 45 C.F.R. § 164.522(b).

4. COMPLIANCE WITH SECURITY STANDARDS.

4.1. Business Associate shall implement administrative, physical and technical safeguards consistent with the Security Standards that reasonably and appropriately protect the confidentiality, integrity and availability of the ePHI that it creates, receives, maintains or transmits on behalf of Covered Entity.

4.2. Business Associate shall promptly report to Covered Entity any Security Incident.

5. TERM AND TERMINATION.

5.1. This Agreement shall become effective on the Effective Date and shall continue in effect until all obligations of the Parties have been met, unless terminated as provided in this Agreement.

5.2. Covered Entity may terminate this Agreement if Covered Entity reasonably determines that Business Associate has breached any provision of this Agreement or otherwise violated the Privacy Standards or the Security Standards. Covered Entity shall provide written notice to Business Associate and an opportunity for Business Associate to cure the breach or end the violation within thirty (30) calendar days of such written notice, unless cure is not possible. If Business Associate fails to cure the breach or end the violation within the specified time period or cure is not possible, Covered Entity shall immediately terminate this Agreement, unless termination is infeasible. Business Associate acknowledges that if cure is not possible and termination of this Agreement is infeasible, as determined in the sole discretion of the Covered Entity, Covered Entity shall have the right to report the violation to the Secretary.

5.3. If Business Associate reasonably believes that Covered Entity has breached a material term of this Agreement, Business Associate shall provide thirty (30) days notice of its intention to terminate this Agreement. Business Associate will cooperate with Covered Entity to find a mutually satisfactory resolution to the matter prior to terminating.

5.4. Upon the event of termination, Business Associate will return or destroy all Protected Health Information pursuant to 45 C.F.R. §164.504(e)(2)(I), if it is feasible to do so. Prior to doing so, Business Associate will recover any Protected Health Information in the possession of its subcontractors or agents. If it is not feasible for Business Associate to return or destroy the Protected Health Information, Business Associate will notify Covered Entity in writing. Business Associate will extend any and all protections, limitations and restrictions contained in this Agreement to Business Associate's use and/or disclosure of any Protected Health Information retained after the termination of this Agreement, and to limit any further uses and/or disclosures to the purposes that make the return or destruction of the Protected Health Information infeasible. If it is infeasible for the Business Associate to obtain from a subcontractor or agent any Protected Health Information in the possession of the subcontractor or agent,

Business Associate will require the subcontractors and agents to agree to extend any and all protections, limitations and restrictions contained in this Agreement to the subcontractors' and/or agents' use and/or disclosure of any Protected Health Information retained after the termination of this Agreement, and to limit any further uses and/or disclosures to the purposes that make the return or destruction of the Protected Health Information infeasible.

6. MISCELLANEOUS.

6.1. The respective rights and obligations of Covered Entity and Business Associate under any section that, by its terms, should survive, shall survive termination of this Agreement indefinitely.

6.2. This instrument sets forth the entire understanding and agreement of the Parties as to the subject matter of this Agreement. This Agreement may be changed or modified only by an agreement in writing signed by both Parties. Any waiver of any term of this Agreement or the breach of any of its provisions shall not operate or be construed as a waiver of any other or subsequent failure of strict performance. This Agreement may be executed in counterparts and by original, electronic or facsimile signatures, each of which shall be an original, but all of which together shall constitute one and the same agreement.

6.3. Nothing express or implied in this Agreement is intended to confer, nor shall anything herein confer, upon any person other than the Parties and the respective successors or assigns of the Parties, any rights, remedies, obligations, or liabilities whatsoever.

6.4. All notices required under this Agreement shall be in writing, addressed to the other Party at the address indicated below, (or at such other address as either Party may designate by proper written notice to the other Party). Notices may be delivered by hand or sent by facsimile transmission (delivery confirmed) or overnight carrier. Notices shall be effective upon receipt.

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

* * * * *

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date first written above.

ADVANCED BIOHEALING, INC.
(BUSINESS ASSOCIATE)

(COVERED ENTITY)

By:



By: _____

Print Name: Luke J. Albrecht

Print Name: _____

Print Title: Senior Counsel

Print Title: _____

Address: 36 Church Lane, Westport, CT 06880

Address: _____

Dermagraft® Benefit Verification Request Form
The Sales Representative may complete only the highlighted areas.

Phone: 866-866-7731 Fax: 866-866-7713
 Program Hours are 8:00am – 5:00 pm EST

Patient Information

Patient Name: _____ Social Security # _____ Male
 Female
 Address: _____ City, State, ZIP: _____
 Daytime Phone #: _____ Date of Birth: _____

Patient Insurance Information

Primary Insurance Information (including Medicaid or Medicare)	Secondary Insurance Information
Participating Status (check one): In Network Out of Network	Participating Status (check one): In Network Out of Network
Payer Name: _____	Payer Name: _____
Policy #: _____ Group #: _____	Policy #: _____ Group #: _____
Payer Phone #: _____	Payer Phone #: _____
Subscriber Name: _____	Subscriber Name: _____
Subscriber Date of Birth: _____	Subscriber Date of Birth: _____
Employer: _____	Employer: _____
Payer Specific Provider ID #: _____	Payer Specific Provider ID #: _____
Payer Specific Facility ID #: _____	Payer Specific Facility ID #: _____

Physician Information

Physician Name: _____ Physician Specialty: _____ PTAN # (Medicare): _____
 Physician Site Name: _____ NPI #: _____ Tax ID #: _____
 Practice Address: _____ City, State, ZIP: _____
 Contact Name: _____ Phone #: _____ Fax #: _____

Facility Information

Facility Name: _____ Fiscal Intermediary: _____
 NPI #: _____ Tax ID #: _____ PTAN # (Medicare): _____
 Practice Address: _____ City, State, ZIP: _____
 Contact Name: _____ Phone #: _____ Fax #: _____

Treatment Information Dermagraft®

Dermagraft is not payable in a Skilled Nursing Facility: Is this patient currently residing in a SNF or Nursing Home? Yes No

Select One: Physician Office Hospital Outpatient Free Standing ASC Hospital-based ASC Skilled Nursing Facility Other

Diagnosis (please follow the 5 digit format within the ICD-9-CM coding system): Medicare claims require 1 ICD-9 code from each category.

<u>Diabetes Codes</u>	<u>Ulcer Codes</u>	<u>Other Codes</u>
<input type="checkbox"/> 250.____ Diabetes Mellitus	<input type="checkbox"/> 707.14 Ulcer of the heel and midfoot	<input type="checkbox"/> _____ Other (Please specify)
<input type="checkbox"/> 249.____ Secondary Diabetes	<input type="checkbox"/> 707.15 Ulcer of other part of foot	<input type="checkbox"/> _____ Other (Please specify)
<input type="checkbox"/> _____ Other (Please specify)	<input type="checkbox"/> _____ Other (Please specify)	
<input type="checkbox"/> No diabetes		

Check here if the patient is a home health referral Physician Declaration

By signing below, I certify that, to the best of my knowledge, the above information is accurate and I direct Advanced BioHealing, Inc. and its agents or contractors including the Lash Group, to use the information supplied herein for the purpose of seeking preliminary verification of coverage and claims support through the Dermagraft Reimbursement Hotline.] Further, I acknowledge that neither Lash nor Advanced BioHealing guarantees the payment of any claim. I understand that the insurance verification process establishes generally whether coverage is available for the particular patient for the stated diagnosis. However, coverage or reimbursement may ultimately be denied for a variety of reasons.

Physician Signature _____ Date _____
 Doc# 31710032



ACKNOWLEDGMENT OF RECEIPT OF HIPAA HITECH POLICY

I certify that I have received a copy of the Advanced BioHealing, Inc. HIPAA HITECH POLICY (the "Policy"). I understand that it is my responsibility to read the attached Policy and seek clarification on questions I may have. I agree to follow the guidelines and procedures contained within the Policy to the best of my ability. I understand that the purpose of the Policy is to provide me with information that I need to know during the course of my employment with Advanced BioHealing.

Advanced BioHealing employees are expected to comply with all state and federal laws and regulations governing the Company and the products and services that we provide.

I further agree that it is my responsibility to report any suspected violation of the Policy consistent with the procedures contained within as outlined in the Customer Interaction Policy and protocol specific to the Company compliance policy.

Signature

Printed Name

Department

Date