



Medtronic

Dear Provider:

Attached is Medtronic Neuromodulation's business associate (BA) agreement, which we provide to cover the services of Medtronic Neuromodulation Health Economic Managers who from time to time review specific medical insurance claims to offer advice on appropriate coding for Medtronic Neuromodulation therapies.

Please note that the agreement only covers Medtronic Neuromodulation's receipt and use of patient personal health information (PHI) in the context when we are providing services as a business associate. Specifically, this includes review of claims containing PHI in order to provide reimbursement and coding advice on our therapies. In other contexts, Medtronic Neuromodulation's receipt of PHI may be covered under exceptions to HIPAA that do not require us to have a BA agreement (e.g., information we receive in providing technical support to patient treatment, and information in connection with our FDA reporting obligations). This BA agreement does not apply to PHI we receive under such exceptions.

This BA agreement is consistent with, and includes all the required elements for, BA agreements under the HIPAA regulations.

Please note also that your signature on the business associate agreement is not required. You are deemed to have accepted the agreement by providing PHI to Medtronic Neuromodulation for our services in advising you on coding and reimbursement for our therapies after the date when we sign and provide you with the agreement. We adopted this approach to make it easy to enter into this agreement as necessary. Since Medtronic bears the obligation to protect the PHI, we considered this easy approach to be most Provider-friendly. This method of acceptance legally binds us to protect the PHI the same as if both parties signed the agreement.

The Medtronic Economic Solutions and Reimbursement personnel are authorized to sign this agreement on behalf of Medtronic. They will leave an original with you and keep a photocopy for our records.

Sincerely,

Medtronic, Inc., Neuromodulation
Legal Department

Medtronic Neuromodulation Business Associate Agreement

This Business Associate Agreement (this "BA Agreement") is entered into by and between Medtronic, Inc. Neuromodulation ("Medtronic") and _____ ("Provider") with an address of _____ (each a "Party" and collectively the "Parties"). The purpose of this agreement is for both Parties to meet their obligations under federal Privacy and Security Rules issued pursuant to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") as a result of Provider providing Medtronic PHI (as defined below) so that Medtronic can provide services and/or products by Medtronic's Health Economic Managers such as review of specific medical insurance claims or coding of Medtronic therapies to Provider, now or in the future ("Services").

1. DEFINITIONS.

1.1 Unless otherwise specified in this BA Agreement, all capitalized terms used in this BA Agreement not otherwise defined have the meaning established for purposes of Title 45 parts 160 and 164 of the United States Code of Federal Regulations, as amended from time to time.

1.2 "Electronic PHI" means Electronic Protected Health Information, as defined in 45 CFR § 160.103, limited to the information received from or created or received on behalf of Provider by Medtronic in its capacity as a Business Associate of Provider.

1.3 "PHI" means Protected Health Information, as defined in 45 CFR § 160.103, limited to the information received from or created or received on behalf of Provider by Medtronic in its capacity as a Business Associate of Provider solely in connection with providing the Services.

1.4 "Privacy Rule" means the federal standards for privacy of individually identifiable health information codified at 45 CFR 160 and 164 subparts (a) and (e).

1.5 "Security Rule" means the federal security standard regulations codified at 45 CFR 160 and 164 subparts (a) and (c).

2. MEDTRONIC'S BUSINESS ASSOCIATE RESPONSIBILITIES.

2.1 Medtronic agrees to:

- (a) Use and/or Disclose PHI only as permitted or required by this BA Agreement or required by law;
- (b) use appropriate safeguards to prevent Use or Disclosure of PHI other than as permitted or required by this BA Agreement;
- (c) (i) implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the Electronic PHI that it creates, receives, maintains or transmits on behalf of Provider; and (ii) make its policies and procedures, and documentation required by the Security Rule relating to such safeguards, available to the Secretary of the

Department of Health and Human Services ("HHS") for purposes of determining Provider's compliance with the Security Rule;

(d) report to Provider any Use or Disclosure of PHI of which it becomes aware that is not permitted by this BA Agreement;

(e) report to Provider any Security Incident with respect to Electronic PHI of which it becomes aware;

(f) require all its subcontractors and agents that create, receive, Use, Disclose or have access to PHI to perform Services for Provider to agree, in writing, to the same restrictions and conditions on the Use and/or Disclosure of PHI that apply to Medtronic;

(g) ensure that all of its subcontractors and agents to whom it provides Electronic PHI agree to implement reasonable and appropriate safeguards to protect such Electronic PHI;

(h) Use and Disclose PHI consistent with the minimum necessary requirements of the Privacy Rule;

(i) make available its internal practices, books, and records relating to the Use and Disclosure of PHI to the HHS for purposes of determining Provider's compliance with the Privacy Rule;

(j) document such Disclosures of PHI and information related to such Disclosures as would be required by Provider to respond to a request for an accounting of Disclosures of PHI about an individual;

(k) within 30 days of receiving a written request from Provider, make available information necessary for Provider to make an accounting of Disclosures of PHI about an individual; and

(l) mitigate to the extent practicable, any harmful effect that is known to Medtronic of a Use or Disclosure of PHI by Medtronic in violation of the requirements of this BA Agreement.

2.2 If any PHI in Medtronic's possession constitutes a Designated Record Set, Medtronic agrees as follows with regard to such PHI:

(a) within 15 days of receiving a written request from Provider, to make available the PHI necessary for Provider to respond to individuals' requests for access to PHI about them; and

(b) within 30 days of receiving a written request from Provider, to incorporate any amendments or corrections to the PHI in accordance with the Privacy Rule.

3. PERMITTED USES AND DISCLOSURES OF PHI.

Unless otherwise limited herein, in addition to any other Uses and/or Disclosures permitted or required by this BA Agreement or required by law, Medtronic may:

(a) make any and all Uses and Disclosures of PHI necessary to provide the Services to Provider;

(b) Use the PHI in its possession for its proper management and administration and to fulfill any legal responsibilities of Medtronic;

(c) Disclose the PHI in its possession to a third party for the purpose of Medtronic's proper management and administration or to fulfill any legal responsibilities of Medtronic; provided, however, that the Disclosures are required by law or Medtronic has received from the third party written assurances that (i) the information will be held confidentially and Used or further Disclosed only as required by law or for the purpose for which it was Disclosed to the third party; and (ii) the third party will notify Medtronic of any instances of which it becomes aware in which the confidentiality of the information has been breached.

4. TERM AND TERMINATION.

4.1 Term. This BA Agreement shall be effective on the date it is signed on behalf of Medtronic (the "BAA Effective Date"), and shall continue in effect until terminated in accordance with the provisions of this Section 4.

4.2 Termination.

(a) This BA Agreement shall terminate immediately upon completion of the Services.

(b) This BA Agreement may be terminated immediately by either party upon written notice to the other party.

(c) Upon Provider's determination of a breach of a material term of this BA Agreement by Medtronic, Provider shall provide Medtronic written notice of that breach in sufficient detail to enable Medtronic to understand the specific nature of that breach and afford Medtronic an opportunity to cure the breach; provided, however, that if Medtronic fails to cure the breach within 30 days, Provider may terminate this BA Agreement. If Provider terminates this BA

Agreement, Medtronic shall have no continuing obligation to provide any Services.

4.3 Effect of Termination or Expiration. Except as provided below, upon termination of this BA Agreement for any reason Medtronic shall return or destroy all PHI received from Provider, or created or received by Medtronic, on Provider's behalf if so requested by Provider in writing. This provision shall apply to PHI that is in the possession of Medtronic's subcontractors or agents. Medtronic shall retain no copies of the PHI. In the event that Medtronic determines that returning or destroying the PHI is infeasible, Medtronic shall notify Provider of the conditions that make return or destruction infeasible. In such event, Medtronic shall extend the protections of this BA 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 Medtronic maintains such PHI. This Section 4.3 shall survive any termination or expiration of this BA Agreement.

5. ACCEPTANCE BY PROVIDER. Execution of this BA Agreement by Provider is not required. Provider shall be deemed to have accepted this BA Agreement in all respects by providing PHI to Medtronic for performance of Services by Medtronic as a Business Associate after the BAA Effective Date.

MEDTRONIC, INC., NEUROMODULATION

By _____

Title _____

Date _____