

EXHIBIT B

BUSINESS ASSOCIATE AGREEMENT

This BUSINESS ASSOCIATE AGREEMENT (the “Agreement”) is effective as of this _____ day of _____, 20____, and is by and between _____ (the “Provider”) and Kenetic Aligners, LLC, a California limited liability company (the “Associate”).

RECITALS

A. Provider and Associate have entered into a certain Master Services Agreement dated of even date with this Agreement (the “MSA”). According to the terms of the MSA, Associate has agreed to retain copies of certain dental records, charts, files, patient information and related correspondence regarding patients that belong to patients of Provider.

B. Pursuant to the MSA, Provider and Associate must use and/or disclose certain information to each other, some of which may constitute Protected Health Information (“PHI”) or electronic Protected Health Information (“ePHI”) as defined in the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 (“HIPAA”) and its implementing regulations (the “HIPAA Regulations”). The term “PHI” as used herein shall include ePHI.

C. The federal Health Information Technology for Economic and clinical Health Act (the “HITECH Act”) imposes certain privacy and security obligations on Provider and Associate in addition to the obligations created by the HIPAA and the HIPPA Regulations.

D. Provider and Associate intend to protect the privacy of and provide for the security of the PHI disclosed to each other pursuant to the MSA, and in compliance with HIPAA, the HIPAA Regulations, the HITECH Act, and other applicable privacy and confidentiality laws.

E. As part of the HITECH Act, the HIPAA Regulations, the Privacy Rule and the Security Rule, Provider and Associate are required to obtain written assurances from each other, as set forth in this Agreement, that the parties will safeguard the PHI received from, or created or received on behalf of Associate or Provider.

NOW THEREFORE, in consideration of the mutual promises below, and the exchange of information pursuant to the Agreement, the parties agree as follows:

1. Definitions. Capitalized terms used, but not otherwise defined in this Agreement, shall have the meanings given those terms in the HIPAA Rules.

a. “Administrative Safeguards” shall mean administrative actions, policies and procedures to manage the selection, development, implementation and maintenance of security measures to protect PHI and to manage the conduct of the Associate’ workforce in relation to the protection of that information.

b. “MSA” shall mean the contract between Provider and Associate as described in the recitals above.

c. “Breach” shall have the same meaning as the term “breach” in 45 C.F.R. § 164.402.

d. **“Designated Record Set”** shall have the meaning given to such term under the Privacy Rule, including, but not limited to, 45 C.F.R. §164.501.

e. **“HIPAA Rules”** shall mean the Privacy, Security, Breach Notification, and Enforcement Rules found at 45 C.F.R. Part 160 and Part 164.

f. **“Individual”** shall have the same meaning as the “Individual” in 45 C.F.R. §160.103 and shall include a person who qualifies as a personal representative in accordance with 45 C.F.R. §164.502(g).

g. **“Individually Identifiable Health Information”** shall mean information that is a subset of health information, including genetic and demographic information collected from an individual, as defined in 45 C.F.R. § 160.103 of the Privacy Standards.

h. **“Physical Safeguards”** shall mean physical measures, policies and procedures to protect Provider’s electronic information systems and related buildings and equipment from natural and environmental hazards and unauthorized intrusion.

i. **“Privacy Standards”** shall mean the Standards for Privacy of Individually Identifiable Health Information codified at 45 C.F.R. Part 160 and Part 164.

j. **“Protected Health Information”** or **“PHI”** shall have the same meaning as the term “Protected Health Information” in 45 C.F.R. §160.103.

k. **“Secretary”** shall mean the Secretary of the Department of Health and Human Services or his designee.

l. **“Security Incident”** shall have the same meaning provided in 45 C.F.R. § 164.304.

m. **“Security Standards”** shall mean the Standards for Security of Electronic Protected Health Information codified at 45 C.F.R. Part 160 and Part 164.

n. **“Technical Safeguards”** shall mean the technology, and the policies and procedures for its use, which protects PHI and controls access to it.

o. **“Transaction Standards”** shall mean the Standards for Electronic Transactions at 45 C.F.R. Part 160 and Part 162.

p. **“Unsecured Protected Health Information”** shall mean PHI that is not rendered unusable, unreadable, or indecipherable to unauthorized persons through the use of a technology or methodology specified by the Secretary under Section 13402(h)(2) of Public Law 111-5.

2. **Obligations of Associate and Provider.**

a. *Permitted Uses.* As necessary to perform their obligations under the MSA and this Agreement, and consistent with the provisions of the HIPAA Rules, Associate and Provider shall receive and provide PHI from each other. Such information access shall be limited to the minimum

necessary for the respective party to perform the work required. Associate and Provider shall not, and shall ensure that their directors, officers, employees, contractors and agents do not, use PHI of the other party except for the purpose of performing their obligations under the MSA and this Agreement and as required or permitted under the MSA and this Agreement. In addition, Associate and Provider shall not use the PHI of each other in any manner that would constitute a violation of the HIPAA Rules.

b. *Permitted Disclosures.* The parties hereto shall not, and shall ensure that their directors, officers, employees, contractors and agents do not, disclose PHI of another party in any manner that would constitute a violation of the HIPAA Rules. The parties acknowledge and agree that each party shall receive prior written approval prior to disclosing the PHI of another party to any third party, except as otherwise expressly permitted herein or in the MSA. The parties further agree that, in the event prior approval is given to disclose PHI to a third party, the party must obtain, prior to making any such disclosure, (i) reasonable assurances in writing from such third party that the same restrictions and conditions that apply to Provider and Associate in this Agreement with respect to the PHI, will apply to said third party, and (ii) an agreement in writing from such third party to immediately notify Provider and Associate in writing of any Breaches, to the extent the third party has obtained knowledge of such Breach.

c. *Appropriate Safeguards.* Provider and Associate shall implement Administrative Safeguards, Physical Safeguards and Technical Safeguards that reasonably and appropriately protect the confidentiality, integrity and availability of any PHI that is created, received, maintained or transmitted on behalf of a party hereto.

d. *Reporting of Improper Use or Disclosure/Mitigation.* Each party hereto shall notify the other party in writing of any use or disclosure of PHI by such party, its directors, officers, employees, agents or contractors, in violation of this Agreement as soon as practicable but in no case more than five (5) days after becoming aware of such use or disclosure. The parties hereto further agree to mitigate, to the extent practicable, any harmful effect that is known to the party of a use or disclosure in violation of the requirements of this Agreement.

e. *Associate's Agents.* Each party hereto shall ensure that any agents, including subcontractors, to whom it provides PHI pursuant to this Agreement, agree in writing to the same restrictions and conditions that apply to the parties hereto with respect to the receipt, use and disclosure of PHI and PHI. Each party hereto shall implement and maintain sanctions against agents and subcontractors that violate such restrictions and conditions and shall take appropriate action to mitigate the effects of any such violation.

f. *Access to PHI.* Each party hereto agrees to make PHI maintained by it or its agents or subcontractors in Designated Record Sets available to the other party for inspection and copying as soon as practicable but in no case more than ten (10) days after receiving a request to enable the other party to fulfill its obligations under the HIPAA Rules.

g. *Amendment of PHI.* Within ten (10) days of receipt of a request from a party hereto for an amendment of PHI or a record about an individual contained in a Designated Record Set, the other party, or its agents or subcontractors, shall make such PHI available to the requesting party for amendment and incorporate any such amendment to enable the requesting party to fulfill its obligations under the HIPAA Rules. If any individual requests an amendment of PHI directly from a

party hereto or its agents or subcontractors, said party must notify the other party in writing within five (5) days of the request.

h. *Accounting Rights.* Within fifteen (15) days of notice by a party hereto of a request for an accounting of disclosures of PHI of said party, the other party and its agents or subcontractors shall make available to the requesting party the information required to provide an accounting of disclosures to enable the requesting party to fulfill its obligations under 45 C.F.R. Section 164.528, as amended by Section 13405(e) of the HITECH Act, and any related regulations or guidance issued by the Secretary. At a minimum, a party shall provide the other party with the following information: (1) the date of the disclosure; (2) the name of the entity or person who received the PHI, and if known, the address of such entity or person; (3) a brief description of the PHI disclosed; and (4) a brief statement of the purpose of such disclosure which includes an explanation of the basis for such disclosure.

i. *Government Access to Records.* Associate and Provider shall make their internal practices, books and records relating to the use and disclosure of PHI available to the Secretary of the U.S. Department of Health and Human Services (Secretary) for purposes of determining compliance with the Privacy Rule. Each party shall provide to the other party a copy of any of the other party's PHI that said party provides to the Secretary concurrently with providing such PHI to the Secretary.

j. *Minimum Necessary.* The parties hereto (and their agents and subcontractors, if any) shall only request, use and disclose the minimum amount of PHI necessary to accomplish the purpose of the request, use or disclosure.

k. *Data Ownership.* Each party acknowledges that they have no ownership rights with respect to PHI of the other party received pursuant to the MSA.

l. *Notification of Breach.* Each party agrees to notify the other party in writing of any Breach or Security Incident related to Unsecured PHI of which the notifying party (the "Notifying Party") becomes aware. Said notification shall be without unreasonable delay and in no event later than ten (10) days after discovery of a Breach or Security Incident. Discovery of a Breach or Security Incident shall be deemed to have occurred as of the first day on which such a Breach or Security Incident is known to a Notifying Party, or by exercising reasonable diligence, would have been known to the Notifying Party. Each party shall be deemed to have knowledge of a Breach or Security Incident if the Breach or Security incident is known, or, by exercising reasonable diligence would have been known, to such party or any person, other than the person committing the Breach or Security Incident, who is a workforce member or agent of the party. The notification shall include, to the extent known by the Notifying Party, the following: (1) the identification of each individual whose Unsecured PHI has been, or is reasonably believed by the Notifying Party to have been, accessed, acquired, used, or disclosed during the Breach or Security Incident; (2) a description of the nature of the unauthorized acquisition, access, use or disclosure, including the date of the Breach or Security Incident and the date of discovery of the Breach or Security Incident; (3) a description of the type of Unsecured PHI acquired, accessed, used or disclosed in the Breach or Security Incident; (4) a description of what Notifying Party is doing to investigate the Breach or Security Incident, to mitigate losses and to protect against further Breaches or Security Incidents; and (5) the contact information for the Notifying Party's representative(s) who are knowledgeable of the Breach or Security Incident. Each party agrees to implement reasonable systems for the discovery and prompt reporting of any breach of individually identifiable information (including but not limited to PHI and referred to hereinafter as "Individually

Identifiable Information") that, if misused, disclosed, lost or stolen, would trigger an obligation under one or more state's data breach notification laws (each a "**State Breach**") to notify the individuals who are the subject of the information. Each party agrees that in the event any Individually Identifiable Information is lost, stolen, used or disclosed in violation of one or more state's data breach notification laws, said party shall promptly: (i) cooperate and assist the other party with any investigation into any State Breach or alleged State Breach; (ii) cooperate and assist the other party with any investigation into any State Breach or alleged State Breach conducted by any state agency; (iii) comply with the other party's determination regarding the parties' obligations to mitigate to the extent practicable any potential harm to the individuals impacted by the State Breach; and (iv) assist with the implementation of any decision by a party or any state agency, to notify individuals impacted or potentially impacted by a State Breach.

3. **Obligation to Notify.** Each party hereto shall provide the other party with the notice of privacy practices that said party produces in accordance with 45 CFR 164.520, as well as any changes to such notice if requested. Each party shall also provide the other party with any changes in, or revocation of, permission by an individual to use or disclose PHI, if such changes affect a party's permitted or required uses and disclosures under this Agreement. In addition, each party shall notify the other party of any additional restriction agreed upon with an individual relating to the use or disclosure of PHI, in accordance with 45 CFR 164.522. For all uses and disclosures under this Agreement, the parties hereto shall be responsible for using appropriate safeguards to maintain and ensure the confidentiality, privacy and security of PHI transmitted to another party pursuant to the MSA or this Agreement, in accordance with the standards and requirements of the HIPAA Rules.

4. **Termination.**

a. *Material Breach.* A breach by either party of any material provision of this Agreement, as determined by the other party, shall constitute a material breach of the MSA and shall provide grounds for immediate termination of the MSA by the non-breaching party pursuant to the termination provisions of the MSA.

b. *Judicial or Administrative Proceedings.* Either party may terminate this Agreement, effective immediately, if (i) the other party is named as a defendant in a criminal proceeding for a violation of HIPAA, the HIPAA Regulations, the HITECH Act, or other security or privacy laws or (ii) a finding or stipulation that the other party has violated any standard or requirement of HIPAA, the HIPAA Regulations, the HITECH Act or other security or privacy laws is made in any administrative or civil proceeding in which the party has been joined.

c. *Effect of Termination of MSA.* Upon termination of the MSA for any reason, each party hereto shall return or destroy all PHI of the other party that said party or its agents or subcontractors still maintain in any form, and shall retain no copies of such PHI of the other party. Notwithstanding the foregoing, each party shall notify the other party and receive the other party's written consent prior to destroying any Protected Health Information created or received from the other party. If return or destruction is not feasible, the parties shall continue to extend the protections of this Agreement to such information, and limit further use of such PHI to those purposes that make the return or destruction of such PHI infeasible. If a party elects to destroy the PHI, said party shall certify in writing to the other party that such PHI has been destroyed within 30 days of termination of the Agreement.

5. **Indemnification.** Each party hereto agrees to and shall indemnify, defend, protect and hold harmless the other party and its officers, directors, members, employees, agents and representative from and against any actual or threatened claims, prosecutions, liabilities, debts, costs and expenses (including reasonable attorneys' fees) whatsoever arising from or in any way related to a party's use or disclosure of PHI of the other party under the MSA and/or this Agreement.

6. **Miscellaneous.**

a. ***Amendment.*** The parties acknowledge that state and federal laws relating to data security and privacy are rapidly evolving and that amendment of this Agreement may be required to provide for procedures to ensure compliance with such developments. The parties specifically agree to take such action as is necessary to implement the standards and requirements of the HIPAA Rules, and other applicable laws relating to the security or confidentiality of PHI. Upon the request of either party, the other party agrees to promptly enter into negotiations concerning the terms of an amendment to this Agreement embodying written assurances consistent with the standards and requirements of the HIPAA Rules or other applicable laws. Either party may terminate this Agreement upon thirty (30) days written notice in the event (i) the other party does not promptly enter into negotiations to amend this Agreement when requested pursuant to this Section, or (ii) the other party does not enter into an amendment to this Agreement providing assurances regarding the safeguarding of PHI that is sufficient to satisfy the standards and requirements of the HIPAA Rules.

b. ***Ineligible Persons.*** Each party represents and warrants to the other party that it (1) is not currently excluded, debarred, or otherwise ineligible to participate in any federal health care program as defined in 42 U.S.C. Section 1320a-7b(f) (the "Federal Healthcare Programs"); (2) has not been convicted of a criminal offense related to the provision of healthcare items or services and not yet been excluded, debarred, or otherwise declared ineligible to participate in the Federal Healthcare Programs, and (3) is not under investigation or otherwise aware of any circumstances which may result in the party being excluded from participation in the Federal Healthcare Programs. This shall be an ongoing representation and warranty during the term of this Agreement, and a party shall immediately notify the other party of any change in the status of the representations and warranty set forth in this Section.

c. ***No Third Party Beneficiaries.*** Nothing expressed or implied in the Agreement is intended to confer, nor shall anything herein confer, upon any person or organization other than Provider, Associate and their respective successors and assigns, any rights, remedies, obligations or liabilities whatsoever.

d. ***Interpretation.*** The Agreement shall be interpreted as broadly as necessary to implement and comply with the HIPAA Rules. The parties agree that any ambiguity in this Agreement shall be resolved in favor of a meaning that complies and is consistent with the HIPAA Rules.

e. ***Notices.*** All notices or communications required or permitted pursuant to the terms of this Agreement shall be in writing and will be delivered in person or by means of certified or registered mail, postage paid, return receipt requested, to such party at its address as set forth below, or such other person or address as such party may specify by similar notice to the other party hereto, or by telephone facsimile or email with a hard copy sent by mail by the next business day. All such notices will be deemed given upon delivery or delivered by hand, on the third business day after deposit with the U.S. Postal Service, and on the first business day after sending if by facsimile.

As to Associate: Name:
Address:
Email address:

As to Provider: **Kenetic Aligners, LLC**
Attn: Dr. Ken Smith
2807 Loma Vista Road, Ste 102
Ventura, California 93003
Email: drk@anacapaortho.com

IN WITNESS WHEREOF, the parties hereto have duly executed this Agreement as of the date first set forth above.

PROVIDER:

Kenetic Aligners, LLC

ASSOCIATE:

Print Name:

Sign: _____
Ken Smith, Manager

Sign: _____