

BUSINESS ASSOCIATE AND DATA USE AGREEMENT

THIS **BUSINESS ASSOCIATE AND DATA USE AGREEMENT** (“Agreement”) entered into by and between AMERICAN PODIATRIC MEDICAL ASSOCIATION (“APMA”) and _____ (“Participant”) shall be effective as of this ____ day of _____, 2017 (the “Effective Date”).

RECITALS

WHEREAS, APMA represents podiatrists in the United States and advances and advocates for the profession of podiatric medicine and surgery for the benefit of its members and the public;

WHEREAS, APMA has worked closely with Prometheus Research, LLC (“Prometheus”), to create a Clinical Data Registry to assist APMA as it aids its members in quality improvement, education, and advocacy initiatives, and to assist APMA in providing regulatory compliance assistance to APMA’s members;

WHEREAS, the Clinical Data Registry will be hosted and maintained by Prometheus and/or a subcontractor of Prometheus under license with APMA;

WHEREAS, Participant desires to provide to APMA the license and right to certain data in connection with the operation of the Clinical Data Registry for the purposes of designing and developing the information system infrastructure, the data analysis and reporting tools, and other capabilities necessary to render the Clinical Data Registry and its contents valuable and useful to participants in the Clinical Data Registry and other third parties;

WHEREAS, Participant further desires to provide PHI Participant Data to APMA for the creation of Limited Data Set Data for purposes of Research, health care operations and public health activities, the creation of De-Identified Data, and to permit APMA to Use and Disclose Limited Data Set Data and De-Identified Data for various purposes as set forth herein (as such capitalized terms are defined herein);

WHEREAS, Participant further desires to obtain and use Participant Data for its health care operations, Research and public health activities;

WHEREAS, Participant is subject to the Health Insurance Portability and Accountability Act of 1996 and regulations promulgated thereunder, including but not limited to, the Standards for Privacy of Individually Identifiable Health Information, 45 C.F.R. Parts 160 and 164, subparts A and E (“Privacy Regulations”) and the Security Standards for the Protection of Electronic Protected Health Information, 45 C.F.R. Parts 160 and 164, subparts A and C (“Security Regulations”) (collectively referred to herein as “HIPAA”);

WHEREAS, HIPAA requires Participant to enter into a Business Associate and Data Use Agreement with APMA to provide for the protection of the privacy and security of PHI Participant Data and Limited Data Set Data before APMA is permitted to create, receive, maintain, or transmit PHI Participant Data and Limited Data Set Data on behalf of Participant; and

WHEREAS, APMA has entered into a Subcontractor Business Associate and Data Use Agreement with Prometheus to permit the Disclosure of PHI Participant Data and Limited Data Set Data to Prometheus and the Use and Disclosure by Prometheus of PHI Participant Data and Limited Data Set Data to manage and operate the Clinical Data Registry.

NOW, THEREFORE, in consideration of the mutual promises and obligations contained herein, and for other good and valuable consideration, the receipt, adequacy, and efficiency of which is hereby expressly acknowledged, the parties hereto mutually agree as follows:

ARTICLE I DEFINITIONS

The following are key terms in this Agreement. The definitions of other terms not defined herein shall have the meaning set forth in HIPAA.

1.1. “Clinical Data Registry” or “Registry” means a medical information data registry containing Participant Data.

1.2. “De-Identified Data” means information that has been de-identified in accordance with 45 C.F.R. § 164.514(a)-(c).

1.3. “Derivative Work” means a derivative work as such term is defined in 17 U.S.C. § 101 *et seq.*, and any improvement, enhancement, modification or adaptation of or to Technology or Materials, including without limitation any improvement, enhancement, modification or adaptation to any databases, collections, compilations and/or aggregations of data or information.

1.4. “Disclose” and “Disclosure” means, with respect to PHI Participant Data, the release, transfer, provision of access to, or divulging in any other manner of PHI Participant Data outside of APMA.

1.5. “Limited Data Set Data” means any health information that includes indirect identifiers, such as dates related to an individual (including dates of admission, service and discharge, dates of birth and death), certain geographic information pertaining to an individual (five and nine digit zip codes and any other geographic subdivision, such as State, county, town, city, precinct and their equivalent geocodes) and any other information EXCEPT FOR the following direct identifiers of the individual or of relatives, employers, or household members of the individual: (i) name; (ii) postal address information (other than the postal address information listed above); (iii) telephone numbers; (iv) fax numbers; (v) electronic mail addresses; (vi) social security numbers; (vii) medical record numbers; (viii) health plan beneficiary numbers; (ix) account numbers; (x) certificate/license numbers; (xi) vehicle identifiers and serial numbers, including license plate numbers; (xii) device identifiers and serial numbers; (xiii) Web Universal Resource Locators (URLs); (xiv) Internet Protocol (IP) address numbers; (xv) biometric identifiers, including finger and voice prints; and (xvi) full face photographic images and any comparable images.

1.6. “Material” means any firmware, methodology or process, literary works or other works of authorship, including manuals, training materials, documentation or other material in whatever form, including any reports, any specification, project plan, business rules or requirements, user manuals, user guides, operations manuals, training materials and instructions, and any databases, collections, compilations and/or aggregations of data or information.

1.7. “Participant Data” means any and all data, which may or may not contain PHI, to be, or which has been, contributed to the Clinical Data Registry, including without limitation clinical, administrative, operational and financial data such as diagnosis, laboratory results, pharmaceutical protocol, application and result, patient outcome (including functional status and satisfaction), inpatient and outpatient claim data and procedures, clinical notes, transcribed comments, reports, images, and codes, etc. as further described in Section 3.2.

1.8. “PHI Participant Data” means Participant Data that comprises Protected Health Information as defined by HIPAA.

1.9. “Protected Health Information” and “PHI” has the same meaning as in 45 C.F.R. § 160.103 and generally means information, whether oral or recorded in any form or medium, that: (i) 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; (ii) identifies the individual (or for which there is a reasonable basis for believing that the information can be used to identify the individual); and (iii) is created, received, maintained, or transmitted by APMA for or on behalf of Participant.

1.10. “Required by Law” shall have the same meaning as the term “required by law” in 45 C.F.R. § 164.103.

1.11. “Research” means the systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

1.12. “Security Incident” means the attempted or successful unauthorized access, use, disclosure, modification, or destruction of information in, or interference with system operations in, an information system of APMA which contains Electronic Protected Health Information (as defined by HIPAA).

1.13. “Technology” shall mean inventions, discoveries, improvements, processes, data, formulations, algorithms, techniques, know-how, tools, requirements, software and documentation, whether or not patentable or copyrightable.

1.14. “Use” or “Uses” means, with respect to PHI Participant Data, the sharing, employment, application, utilization, examination or analysis of such PHI Participant Data within APMA’s internal operations.

ARTICLE II USES OF DATA; GRANT OF LICENSE

2.1. Uses and Disclosures of Data.

2.1.1 As more particularly described in Section 3.1, Participant shall provide Participant Data and PHI Participant Data to APMA and Prometheus for:

(i) The creation of Limited Data Set Data for Use and Disclosure by APMA and Prometheus for purposes of Research, health care operations and public health activities; and

(ii) The creation of De-Identified Data for Use and Disclosure by APMA and Prometheus for any purposes permitted under this Agreement and applicable law.

2.1.2 APMA will Use and Disclose PHI Participant Data (i.e., data other than Limited Data Set Data and De-Identified Data) for Research, health care operations, and public health activities only with written approval from Participant and in accordance with applicable law.

2.2. Grant of License.

2.2.1 License to Participant Data, PHI Participant Data and Limited Data Set Data. Participant hereby grants to APMA a non-exclusive, world-wide, perpetual, irrevocable, royalty-free, fully paid-up license, with the express right to sublicense, to: (a) Use, Disclose, collect, compile, store, validate, integrate, normalize, aggregate, sort, manipulate, analyze and create Derivative Works of Participant Data, PHI Participant Data and Limited Data Set Data; and (b) transfer, license or otherwise distribute in any format, either in whole or in part, such Participant Data, PHI Participant Data and Limited Data Set Data and Derivative Works thereof as permitted under this Agreement.

2.2.2 License to De-Identified Data. Participant hereby grants to APMA a non-exclusive, world-wide, unlimited, unrestricted, perpetual, irrevocable, royalty-free, fully paid-up license, with the express right to sublicense, to: (a) Use, Disclose, collect, compile, store, validate, integrate, normalize, aggregate, sort, manipulate, analyze and create Derivative Works of De-Identified Data; and (b) transfer, license or otherwise distribute in any format, either in whole or in part, such De-Identified Data and Derivative Works thereof for any purposes permitted by law.

2.2.3 Right to Redistribute. The foregoing license to APMA expressly includes the right to redistribute to Prometheus and third parties and have redistributed by Prometheus and third parties De-Identified Data and Derivative Works thereof, in both cases in whole or in part.

2.2.4 APMA's Ownership Rights. As between APMA and Participant, APMA shall own all De-Identified Data and Derivative Works created from such De-Identified Data.

2.2.5 Participant's Rights. Participant shall: (i) retain its rights of ownership in its own Participant Data; and (ii) retain all rights to use, release or disclose its own Participant Data as it may deem necessary or desirable, as permitted by applicable federal

and state law, and subject to any additional restrictions as may be set forth in the Participation Agreement as defined in Section 3.1 (Participation Agreement) below.

ARTICLE III PARTICIPANT COVENANTS

3.1. Submission of Data. APMA, through Prometheus and/or a subcontractor of Prometheus, is seeking an extraction of Participant Data from Participant that represents a collection of all administrative, financial and medical information based on parameters agreed to by APMA and Participant, as such may be revised by APMA from time to time. Participant agrees to provide to APMA, or Prometheus on behalf of APMA, the following types of data as such data may be available to Participant: administrative, financial and medical information including but not limited to data required to be in compliance with the government's quality payment program or similar programs.

3.2. Participant Guidelines. Participant shall comply with standardized procedures, requirements and restrictions regarding the Clinical Data Registry, for example the manner and time frame of data delivery, (the "Participant Guidelines") as may be established from time to time by APMA or by Prometheus on behalf of APMA.

3.3. Privacy Practices. Participant will notify APMA of any limitation(s) in its notice of privacy practices in accordance with 45 C.F.R. § 164.520, to the extent that such limitation may affect APMA's use or disclosure of PHI. Participant will provide such written notice no later than fifteen (15) days prior to the effective date of the limitation.

3.4. Notice of Changes Regarding Individual Permission. Participant will obtain any consent or authorization that may be required by the Privacy Regulations, or applicable state law, prior to furnishing APMA with PHI. Participant will notify APMA in writing of any changes in, or revocation of, permission by an individual to Use or Disclose PHI, to the extent that such changes may affect APMA's Use or Disclosure of PHI. Participant will provide such written notice no later than fifteen (15) days prior to the effective date of the change.

3.5. Notice of Restrictions to Use or Disclosure of PHI. Participant will notify APMA in writing of any restriction to the Use or Disclosure of PHI that Participant has agreed to in accordance with 45 C.F.R. § 164.522, to the extent that such restriction may affect APMA's Use or Disclosure of PHI. Participant will provide such written notice no later than fifteen (15) days prior to the effective date of the restriction. If APMA reasonably believes that any restriction agreed to by Participant pursuant to this Section may materially impair APMA's ability to perform its obligations, the parties will mutually agree upon any necessary modification of APMA's obligations.

3.6. Permissible Requests by Participant. Participant shall not request APMA to Use or Disclose PHI in any manner that would not be permissible under HIPAA if done by Participant, except that APMA may Use or Disclose PHI as set forth herein.

3.7. Safeguards. Participant shall use appropriate safeguards to maintain the confidentiality, privacy, and security of PHI in transmitting PHI to APMA pursuant to this Agreement.

ARTICLE IV APMA COVENANTS

4.1. Permitted Uses and Disclosures of PHI Participant Data. APMA shall Use and Disclose PHI Participant Data solely as necessary to perform functions, activities or services for, or on behalf of, Participant, provided that such Use or Disclosure would not violate the Privacy Regulations if done by Participant. In addition, APMA may:

4.1.1 Use or Disclose PHI Participant Data for the proper management and administration of APMA and to carry out its legal responsibilities; provided that with respect to any such Disclosure either: (a) the Disclosure is Required by Law; or (b) APMA obtains reasonable assurances from the person to whom the PHI Participant Data is to be Disclosed that such person will hold the PHI Participant Data in confidence and will not use or further disclose such PHI Participant Data except as Required by Law and for the purpose(s) for which it was Disclosed by APMA to such person, and that such person will notify APMA of any instances of which it is aware in which the confidentiality of the PHI Participant Data has been breached;

4.1.2 Use PHI Participant Data to aggregate data from multiple participants and/or create Limited Data Set Data and De-Identified Data in accordance with the Privacy Regulations; and

4.1.3 Use or Disclose PHI Participant Data to report violations of law to appropriate federal and state authorities in accordance with the Privacy Regulations.

4.2. Safeguards. APMA shall use appropriate safeguards to prevent Use or Disclosure of PHI Participant Data other than as provided for by this Agreement and comply with the Security Regulations with respect to Electronic PHI.

4.3. Reporting Non-permitted Use or Disclosure, Breach, and/or Security Incident. APMA shall report to Participant each Use or Disclosure of PHI Participant Data that is made by APMA that is not specifically permitted by this Agreement, including any Breach of Unsecured PHI in accordance with 45 C.F.R. § 164.410. In addition, APMA shall report to Participant each Security Incident which it becomes aware has occurred to APMA; however, this Agreement serves as APMA's notice to Participant that attempted but unsuccessful Security Incidents, such as pings and other broadcast attacks on APMA's firewall, port scans, unsuccessful log-on attempts, denials of service and any combination of the above, regularly occur and that no further notice will be made by APMA unless there has been a successful Security Incident.

4.4. Use of Subcontractors. APMA shall ensure that any subcontractors, including Prometheus, that receive PHI Participant Data from APMA agree to substantively the same restrictions and conditions that apply to APMA with respect to such PHI Participant Data.

4.5. Access and Amendment. APMA shall, to the extent APMA possesses any PHI Participant Data that constitutes a "designated record set" under the Privacy Regulations: (a) make the designated record set specified by Participant available to Participant to provide an individual access to, and copies of, the designated record set; and (b) make any amendments to a designated record set that are requested by Participant. APMA is not required to provide such

access or make any amendments where the PHI Participant Data contained in a designated record set is duplicative of the PHI Participant Data contained in a designated record set possessed by Participant.

4.6. Accounting. APMA shall, upon Participant's written request, provide to Participant an accounting of each Disclosure of any PHI Participant Data contributed by such Participant made by APMA in accordance with the Privacy Regulations.

4.7. Availability of Internal Practices, Books and Records to Secretary. APMA shall make its internal practices, books and records relating to the Use and Disclosure of PHI Participant Data available to the Secretary of the U.S. Department of Health and Human Services ("Secretary"), in a time and manner designated by the Secretary, for purposes of determining Participant's compliance with the Privacy Regulations.

4.8. Re-Identification. APMA and Prometheus shall not re-identify the Limited Data Set Data or De-Identified Data and will not contact the individuals to whom the Limited Data Set Data or De-Identified pertains.

4.9. Compliance with Law. To the extent APMA is expressly obligated to carry out one or more of Participant's obligation(s) under the Privacy Regulations, APMA shall comply with the requirements of the Privacy Regulations that apply to APMA in the performance of such obligation(s).

ARTICLE V TERM AND TERMINATION

5.1. Term and Termination. This Agreement shall be effective upon the Effective Date and shall remain in effect until all of the PHI Participant Data provided by Participant to APMA, or created or received by APMA on behalf of Participant, is destroyed or returned to Participant, or, if it is infeasible to return or destroy PHI Participant Data, protections are extended to such information, in accordance with Section 5.3 (Disposition of PHI Participant Data Upon Termination).

5.2. Material Breach. Upon either party's knowledge of a material breach of this Agreement by the other Party, the non-breaching party must provide an opportunity for the breaching party to cure the breach or end the violation opportunity to cure the breach within thirty (30) business days, and if the breaching party does not cure the breach or end the violation within thirty (30) business days, the non-breaching party may terminate this Agreement.

5.3. Disposition of PHI Participant Data Upon Termination. Upon termination of this Agreement for any reason, APMA shall either return or destroy, in accordance with any instructions by Participant, all PHI Participant Data in the possession or control of APMA. However, if APMA determines that neither return nor destruction of PHI Participant Data is feasible, APMA may retain PHI Participant Data, provided that it: (a) continues to comply with the provisions of this Agreement for as long as it retains PHI Participant Data, and (b) further limits Uses and Disclosures of PHI Participant Data to those purposes that make the return or destruction of PHI Participant Data infeasible. The requirements set forth in this Section do not

apply to De-Identified Data and Limited Data Set Data. This Section shall survive the expiration or termination of this Agreement.

ARTICLE VI MISCELLANEOUS

6.1. Warranties and Disclaimers. Each party represents and warrants that it has the full right and authority to enter into this Agreement and to perform its obligations under this Agreement. Participant warrants that any and all data will be provided in a form that does not violate any applicable Federal or state law or regulation, including, but not limited to, HIPAA or any similar law or regulation. **ALL DATA TO BE CREATED AND PROVIDED UNDER THIS AGREEMENT IS FOR THE PURPOSES OF POPULATING THE CLINICAL DATA REGISTRY AND IS NOT INTENDED TO BE USED FOR PURPOSES OTHER THAN DATA ANALYSIS, RESEARCH, PUBLIC HEALTH AND HEALTH CARE OPERATIONS, EXCEPT AS SET FORTH IN THIS AGREEMENT. EXCEPT AS EXPRESSLY SET FORTH ABOVE IN THIS SECTION 6.1, APMA EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, WHETHER WRITTEN OR ORAL, EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY, INTEROPERABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, QUIET ENJOYMENT OR THOSE ARISING FROM TRADE USAGE OR COURSE OF DEALING. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, IN NO EVENT SHALL APMA AND/OR PROMETHEUS HAVE ANY OBLIGATION OR LIABILITY TO PARTICIPANT NOR ANY THIRD PARTY AS A RESULT OF PARTICIPANT'S OR SUCH THIRD PARTY'S PARTICIPATION IN OR USE OF THE CLINICAL DATA REGISTRY.**

6.2. Limitation of Liability.

6.2.1 EXCLUDED DAMAGES. IN NO EVENT SHALL APMA AND/OR PROMETHEUS BE LIABLE FOR ANY INDIRECT, INCIDENTAL, DELAY, SPECIAL, PUNITIVE OR CONSEQUENTIAL DAMAGES, (INCLUDING WITHOUT LIMITATION DAMAGES FOR LOST OPPORTUNITIES, LOST PROFITS, BUSINESS INTERRUPTION OR LOST SAVINGS).

6.2.2 LIMITATION OF DAMAGES. IN NO EVENT SHALL APMA BE LIABLE FOR ANY AMOUNT IN EXCESS OF THE AMOUNTS PAID BY PARTICIPANT TO APMA AND/OR PROMETHEUS FOR THE PRODUCT OR SERVICE THAT GAVE RISE TO THE CLAIM IN THE SIX (6) MONTH PERIOD PRECEDING THE CLAIM.

6.2.3 APPLICABILITY. THE LIMITATIONS AND EXCLUSIONS OF LIABILITY SET FORTH ABOVE SHALL APPLY TO ANY AND ALL CLAIMS OR DAMAGES ARISING OUT OF OR IN ANY WAY CONNECTED WITH THIS AGREEMENT, REGARDLESS OF THE FORM OF ACTION, WHETHER IN CONTRACT, TORT OR OTHERWISE, EVEN IF APMA AND/OR PROMETHEUS HAVE BEEN ADVISED OF THE POSSIBILITY OF SUCH

CLAIMS OR DAMAGES AND EVEN IF SUCH CLAIMS OR DAMAGES WERE FORESEEABLE. THE PARTIES ACKNOWLEDGE THAT APMA AND/OR PROMETHEUS HAVE SET THEIR PRICES AND ENTERED INTO THIS AGREEMENT IN RELIANCE UPON THE LIMITATIONS AND EXCLUSIONS OF LIABILITY AND DISCLAIMERS OF WARRANTIES SET FORTH IN THIS AGREEMENT, AND THAT THE SAME FORM AN ESSENTIAL BASIS OF THE BARGAIN BETWEEN THE PARTIES. THE PARTIES AGREE THAT THE LIMITATIONS, EXCLUSIONS AND DISCLAIMERS IN THIS AGREEMENT SHALL SURVIVE AND APPLY EVEN IF FOUND TO HAVE FAILED OF THEIR ESSENTIAL PURPOSE.

6.2.4 Practice of Medicine. Notwithstanding anything to the contrary contained herein, Participant acknowledges that APMA and Prometheus are not authorized or qualified to engage in any activity which may be construed or deemed to constitute the practice of medicine, and that Participant shall retain the authority to direct all medical decisions regarding the care and treatment of its patients, and shall assume full responsibility for any clinical decisions made by Participant as a result of data, directly, or indirectly, generated by APMA and/or Prometheus. Participant represents that it shall have full responsibility for the care and well-being of its patients, and any reliance by Participant upon the data shall not diminish that responsibility. Participant agrees to defend, indemnify, and hold APMA and Prometheus harmless from and against any damages caused by Participant's use of the data provided hereunder.

6.3. Force Majeure. Neither party will be in default or otherwise liable for any delay in failure of its performance under this Agreement if such delay or failure arises by any reason beyond the party's reasonable control. Such causes may include, but are not limited to, fire, flood, accident, strike, riot, civil unrest, an act of God, war or other hostilities, or other cause beyond a party's reasonable control (including, without limitation, any mechanical, electronic, or other communications failure, but excluding failure caused by a party's financial condition). If either party becomes aware of any such factor that would cause a delay or failure in performance, it must immediately notify the other party in writing of the existence of such factor and, as applicable, the expected length of such delay.

6.4. Notice. All notices required or permitted by this Agreement shall be sufficiently served by mailing the same by certified or registered mail, return receipt requested, to the parties at their respective addresses, as follows:

To Participant:

To APMA:

James R. Christina, DPM
Executive Director/CEO
9312 Old Georgetown Road
Bethesda, MD 20814

6.5. Independent Contractors. APMA, in furnishing services to Participant, is acting as an independent contractor, and APMA has the sole right and obligation to supervise, manage, contract, direct, procure, perform, or cause to be performed, all work to be performed by APMA under this Agreement. APMA is not an agent of Participant, and has no authority to represent Participant as to any matters, except as expressly authorized in this Agreement.

6.6. Waiver. Failure by either party to enforce any rights under this Agreement shall not be construed as a waiver of such rights, nor shall a waiver by either party in one or more instances be construed as constituting a continuing waiver or as a waiver in any other instance.

6.7. No Third Party Beneficiaries. Nothing express or implied in this Agreement is intended to confer, nor shall anything herein confer, upon any person other than Participant or APMA any rights, remedies, obligations, or liabilities whatsoever.

6.8. Relationship to Other Agreement Provisions. In the event that a provision of this Agreement is contrary to a provision of another agreement under which Participant discloses PHI Participant Data to APMA, the provision of this Agreement shall control. Otherwise, this Agreement shall be construed under, and in accordance with, the terms of such agreement between the parties.

6.9. Controlling Law. This Agreement shall be governed by and construed in accordance with the laws of the State of Maryland, without reference to its conflicts of law provisions.

6.10. Severability. If any provision of this Agreement is determined by a court of competent jurisdiction or to be invalid or unenforceable, such determination shall not affect the validity or enforceability of any other part or provision of this Agreement.

6.11. Integration. This Agreement constitutes the entire understanding of the parties, revokes and supersedes all prior agreements between the parties, and is intended as a final expression of their Agreement. This Agreement may be executed in counterparts, each of which shall be deemed an original, but both of which shall constitute one and the same document.

[signature page follows]

IN WITNESS WHEREOF, this Agreement is duly executed and effective as of the Effective Date.

(“Participant”)

**AMERICAN PODIATRIC MEDICAL
ASSOCIATION (“APMA”)**

By: _____

By: _____

Title: _____

Title: Executive Director/CEO

Date: _____

Date: _____