

**MERIDIAN ACCOUNTABLE CARE ORGANIZATION, LLC
PARTICIPATING PRACTICE AGREEMENT**

THIS PARTICIPATING PRACTICE AGREEMENT (the “**Agreement**”) is made as of the ___ day of _____, 201_ and shall be effective as of January 1, 2017 (the “**Effective Date**”) by and among Meridian Accountable Care Organization, LLC (“**ACO**”) and the practice identified on the signature page hereof (the “**Practice**”) and physician(s) (“**Physician**” or “**Participating Physician**”) identified on **Exhibit A**. ACO, the Practice and the Participating Physician are the “**Parties,**” and each is a “**Party.**”

Introduction

The ACO has entered into an agreement (“**MSSP Agreement**”), with the Centers for Medicare & Medicaid Services (“**CMS**”) to participate in the Medicare Shared Savings Program (“**MSSP**”) to provide services to Medicare fee-for-service beneficiaries (“**MSSP Enrollees**”) assigned to the ACO. This Agreement allows Participating Physicians and other licensed health care providers employed by, or contracted with, the Practice and who bill for items and services furnished to Medicare fee-for-service beneficiaries under the Medicare billing number assigned to the tax identification number (“**TIN**”) of the Practice (each, a “**Provider**”) to participate in the ACO’s network of providers (“**Network**”) with respect to the MSSP Agreement. The Practice wishes for its Participating Physicians and other Providers to provide and arrange for Covered Services to MSSP Enrollees in accordance with the terms and conditions set forth in this Agreement and the terms of the MSSP Agreement and the provisions of **Exhibit B**, attached hereto and incorporated herein (“**MSSP Requirements**”).

Article 1 - Definitions

- 1.1 “**Covered Services**” means those medical, surgical and related health care services which Practice and Participating Physicians provide to, or arrange for, MSSP Enrollees pursuant to the MSSP Agreement and this Agreement.
- 1.2 “**Excluded Individuals**” means those individuals or entities that are excluded under the U.S. Department of Health and Human Services (“**HHS**”) Office of Inspector General’s (“**OIG**”) List of Excluded Individuals/Entities, the U.S. General Services Administration’s Excluded Parties List System, or otherwise excluded from participation in Medicare or other Federal Health Care Programs, or are debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded by any federal or state department or agency.
- 1.3 “**HIPAA**” means the Federal Health Insurance Portability and Accountability Act of 1996, 42 USC § 201 et seq., and the HIPAA Privacy and Security Regulations at Parts 160, 162 and 164 of Title 45 of the Code of Federal Regulations, as amended by the Health Information Technology for Economic and Clinical Health (“**HITECH**”) Act enacted as a part of the American Recovery and Reinvestment Act of 2009.

- 1.4 **“Policies and Procedures”** means any and all of ACO’s standards, policies, protocols, programs, regulations and procedures as adopted by the ACO’s governing board (“Board”) and set forth in writing and made available to Practice and Participating Physicians during the term of this Agreement, including, but not limited to, any case management, care coordination, referral guidelines, quality assurance, quality improvement, medical records, and clinical integration policies and programs, including those processes adopted by ACO to promote evidence-based patient-centeredness medicine; promote patient engagement; enable Practice to provide feedback on quality and cost metrics; and coordinate care among PCPs, specialists, and acute and post-acute providers.
- 1.5 **“PCP”** means a primary care physician, which is a physician who has a primary specialty designation of internal medicine, general practice, family practice, or geriatric medicine.
- 1.6 **“Protected Health Information”** shall have the same meaning given to that term in 45 C.F.R. § 160.103.

Article 2 - Practice Representations and Obligations

- 2.1 **General.** Practice, on behalf of it and its Providers, and the Participating Physicians hereby agree to participate in the MSSP through ACO’s Network as contemplated in, and subject to the terms and conditions of, this Agreement. Practice and the Participating Physicians agree to abide by the ACO’s Policies and Procedures. ACO may amend the Policies and Procedures at any time, but will use reasonable efforts to provide notice of such amendments at least thirty (30) days prior to their effective date. The Parties agree that any Policies and Procedures necessary to comply with laws and regulations do not require thirty (30) days prior notice and shall be effective as stated in such notice. Participating Physicians shall and Practice shall, and shall ensure that its Providers, abide by the determinations of ACO’s Board in all matters related to Participating Physicians’, Practice’s and its Providers’ compliance with the Policies and Procedures and this Agreement.
- 2.2 **MSSP Requirements.** Practice, on behalf of it and its Providers, and Participating Physicians hereby agree to comply with all MSSP Requirements, attached as **Exhibit B**. In the event of a conflict or inconsistency between this Agreement and/or the ACO’s Policies and Procedures and Exhibit B, Exhibit B shall control.
- 2.3 **Practice Representations.** The Practice and the Participating Physicians represent and warrant that, at all times during the Term of this Agreement:
- a. The Practice is authorized to act on behalf of its Participating Physicians and other Providers;
 - b. The Practice, each of its Participating Physicians, and each of its Providers are currently, and for the duration of this Agreement shall remain, participants in the Medicare fee-for-service program;

- c. Neither the Practice, nor any Participating Physician, nor any Provider is an Excluded Individual and Practice does not employ, obtain services from or contract with any Excluded Individuals; and
- d. Each Participating Physician has medical staff privileges in good standing on the medical staff of a New Jersey hospital that is accredited by an accrediting body recognized by CMS (unless the Clinical Performance and Credentials Committee has approved an exemption from this requirement and such exemption is approved by the Board and consistent with the MSSP Requirements).

If, during the term of the Agreement, any of the representations above are determined to be untrue or shall become untrue, Practice will immediately notify ACO in writing and ACO will have the right to terminate this Agreement immediately upon written notice.

2.4 **Notice of Disciplinary Actions.** Subject to any limitations or restrictions imposed by law, Practice shall notify ACO within five (5) business days of Practice's actual knowledge of any of the following matters:

- a. any action taken by any governmental authority to restrict, suspend or revoke any Participating Physician's or Provider's license, certification or other approvals necessary to provide the Covered Services contemplated by this Agreement;
- b. any disciplinary action involving Practice, any Participating Physician, or any Provider by any administrative agency or accreditation body which directly relates to the provision of Covered Services;
- c. the permanent suspension, revocation, or involuntary modification, restriction, or reduction of the medical staff privileges of a Participating Physician at any hospital or other institutional health care provider;
- d. a determination made that Practice, any Participating Physician, or any Provider, has committed fraud;
- e. the imposition of any final sanctions against Practice, any Participating Physician, or any Provider under the Medicare or Medicaid program or any other governmental health benefit program;
- f. any criminal action against a Participating Physician or Provider relating to the individual's professional practice; or
- g. any other act, occurrence, condition or situation which might materially affect any Participating Physician's or Provider's ability to provide Covered Services under this Agreement.

2.5 **Notice of Changes.** Practice shall notify ACO within thirty (30) days of any change:

- a. of Practice’s address(es), phone number(s), business hours, or TIN;
 - b. in Practice’s roster of Participating Physicians or Providers participating in the ACO, including the termination or retirement of any Participating Physician or Provider; or
 - c. of Practice’s, any Participating Physician’s, or any Provider’s national provider identifier.
- 2.6 **Referrals.** Practice and its Participating Physicians shall use best efforts to make referrals of MSSP Enrollees to other ACO Network providers and suppliers in accordance with the voluntary referral policies established by ACO; provided, ACO, Practice, and Providers are prohibited from:
- a. conditioning the participation of Network providers or suppliers, or other individuals or entities performing functions or services related to ACO activities on referrals of federal health care program business that the ACO, Practice, Providers, Network providers or suppliers, or other individuals or entities performing functions or services related to ACO activities know or should know is being (or would be) provided to Medicare fee-for-service beneficiaries who are not assigned to the ACO; and
 - b. except as permitted by 42 C.F.R. 425.304(c)(2), requiring that MSSP Enrollees be referred only to any ACO participant or Network provider or supplier.
- 2.7 **Financial Incentive Plans.** If Practice or a Participating Physician receives from ACO a “**financial incentive**” (as defined under applicable law or Policies and Procedures) related to the performance of Practice’s, or any Participating Physician’s, duties under this Agreement, Practice agrees that no payments shall be made directly or indirectly to Practice or any Participating Physician as an inducement to reduce or limit medically necessary services. The ACO will adopt specific Policies and Procedures regarding the requirements Practice and Participating Physicians must meet to be eligible to receive financial incentives. The Practice understands that such financial incentives may include the opportunity to receive shared savings or other payments intended to encourage Practice and the Participating Physicians to adhere to the ACO’s quality assurance and improvement program, CMS reporting requirements, and evidence-based clinical guidelines.
- 2.8 **Exclusive Contracting Requirements.** As required by CMS regulations, if any Participating Physicians are PCPs, Practice and the Participating Physicians agree to participate in the MSSP exclusively through ACO. If none of Practice’s Participating Physicians are PCPs, Practice understands that it may still be required to participate in the MSSP exclusively through ACO if CMS assigns to ACO one or more MSSP Enrollees who have received a primary care service from a Participating Physician. In the latter event, ACO will notify Practice that,

pursuant to the MSSP Requirements, Practice may not participate in any other accountable care organization participating in the MSSP.

- 2.9 **Joinder Agreement.** The Practice acknowledges and agrees that ACO shall require from each Participating Physician a signature on the form attached hereto as **Exhibit A**.
- 2.10 **Billing and Collecting Fees for Professional Services.** Practice, or each Participating Physician, shall be solely responsible for the billing and collection of professional fees for services rendered to MSSP Enrollees in connection with the Practice's and Participating Physicians' participation in the MSSP through the Network.
- 2.11 **Medicare Enrollment.** Practice shall maintain accurate enrollment information for Practice and Participating Physicians with its Medicare Contractor using the Provider Enrollment, Chain and Ownership System ("PECOS") on a timely basis in accordance with Medicare program requirements and such maintenance includes but is not be limited to, the addition or deletion of Participating Physicians that are billing through the Practice's tax identification number ("TIN"). Notwithstanding the foregoing, Practice shall advise ACO in writing within thirty (30) days of any addition or deletion of a Participating Physician.

Article 3 – ACO Obligations

- 3.1 **Quality Performance Activities.** As part of its MSSP obligations, ACO will define processes to promote evidence-based medicine and administer quality improvement activities, including development and implementation of quality and efficiency performance initiatives, performance measures, and monitoring Practice's and Participating Physicians' compliance. Practice and Participating Physicians agree to comply with and implement such processes and participate in all such activities.
- 3.2 **Patient Relationship.** As part of its MSSP obligations, ACO will define processes to promote MSSP Enrollee engagement, which Practice and each Participating Physician will adopt. Practice and Participating Physicians acknowledge, however, that nothing in this Agreement shall be construed to materially alter or adversely affect any Provider's relationship with his or her patients. The final decision to provide, or withhold, Covered Services is to be made by each Provider with the active and informed participation of his or her patient and/or the patient's family or appointed medical-decision representative.
- 3.3 **Business Associate Relationship.** To ensure ACO has sufficient data and information related to patient care to achieve success in the MSSP, Practice agrees that ACO, acting in its capacity as Practice's and Participating Physicians' business associate under the Business Associate Agreement attached hereto as **Exhibit C**, may request and receive clinical and administrative data from CMS and other data sources pertaining to services a Participating Physician provided,

or requested, on behalf of a MSSP Enrollee. Such data may be compiled into reports and used by ACO to monitor Covered Services provided to MSSP Enrollees and each Participating Physician's performance in relation to ACO's and CMS's quality and efficiency standards. Each Party to this Agreement shall ensure that it and all personnel maintain confidentiality of all patient records, charts and other Protected Health Information in accordance with HIPAA and other state and federal laws.

- 3.4 **Periodic Reports.** Practice will receive regular reports of group and individual Participating Physician performance relative to the ACO's performance initiatives and on the CMS performance standards, which Practice shall distribute to Participating Physicians. It is the intention of ACO to provide electronic reports to Practice and the Participating Physicians via the Internet.
- 3.5 **Audits and Fraud, Waste, and Abuse.** Consistent with federal regulations, Practice and the Participating Physicians shall fully cooperate with ACO's initiatives, policies, procedures, processes, and programs relating to: (a) ACO's auditing and oversight obligations; and (b) the identification of and remediation of identified instances or patterns of fraud, waste, and abuse (collectively "**FWA Program**"). Practice and the Participating Physicians acknowledge and agree that ACO's FWA Program may include any process, procedure, or program that has been adopted by or contemplated by CMS or its designees.

Article 4 – Term and Termination

- 4.1 **Term.** The term of the Agreement shall commence on the date first noted above and continue until December 31, 2018 unless otherwise terminated in accordance with Section 4.2 below. Upon expiration of the initial term, this Agreement shall automatically renew for successive three-year terms unless otherwise terminated as provided in this Agreement.
- 4.2 **Termination.**
- a. **Without Cause.** Either Party may terminate this Agreement without cause upon written notice to the other Party at least ninety (90) days prior to the end of each calendar year. Said termination shall be effective as of the last day of that calendar year.
 - b. **Insolvency.** Either ACO or Practice may terminate this Agreement immediately if a Party commits an act of bankruptcy within the meaning of the bankruptcy, receivership, insolvency, reorganization, dissolution, liquidation or other similar proceedings under either state or federal laws.
 - c. **Termination for Breach.** Either ACO or Practice may terminate this Agreement immediately upon written notice in the event the other Party materially breaches any of the provisions contained herein; provided, however, the breaching Party shall have been given written notice of such breach and has failed to cure such breach within thirty (30) days of receipt of such notice. The written notice shall set forth the nature and details of the

breach with sufficient specificity as to fully describe the nature of the alleged breach.

- d. **Termination of MSSP Agreement.** This Agreement shall automatically terminate if ACO's MSSP Agreement with CMS terminates.
- e. **Effect of Termination.** In the event of termination or expiration of this Agreement and consistent with the requirements of Exhibit B, Section 13, Practice shall furnish to ACO any and all data necessary for ACO to satisfy its obligations as set forth in the MSSP Agreement or ACO law, rule or regulation which includes, but is not limited to the completion of the annual assessment of ACO's quality of care and other relevant matters. Practice shall provide and shall cause Participating Physicians to provide any and all data in accordance with ACO's reasonable request and shall provide such data to ACO within the timeframe designated by ACO and if no timeframe is provided within twenty (20) business days of such ACO request.

Article 5 – General

- 5.1 **Notice.** All notices that may be or are required to be given, served or sent by any Party to any other Party pursuant to this Agreement shall be in writing and shall be sent by overnight courier service; mailed by certified mail, return receipt requested, postage prepaid; or transmitted by facsimile, addressed to the address set forth on the signature page. Each notice or communication shall be deemed received at the time shown on the delivery receipt, if delivered by courier service; three days after being mailed if sent by certified mail; or upon successful transmission, if sent by facsimile.
- 5.2 **Dispute Resolution.** In the event of any dispute under this Agreement, the Parties agree that they will initially attempt to resolve the dispute informally by meeting as often as necessary during a thirty (30) day period in an attempt to resolve the dispute. In the event a good faith effort to resolve the dispute has not produced a mutually agreeable resolution during the thirty (30) day period, the Parties may mutually agree to extend the time period in which to settle their dispute, and, if no such extension is agreed upon, either Party may pursue its rights in a judicial proceeding.
- 5.3 **Assignment.** No assignment of rights or delegation of obligations hereunder shall be valid without the specific written consent of the Parties hereto. Notwithstanding the foregoing, ACO may assign any of its rights and delegate any of its obligations under this Agreement to Meridian Health System, Inc. (“**Meridian Health**”) or an affiliated entity (corporation or limited liability company) on the same terms provided in this Agreement upon written notice to Practice and Participating Physician.
- 5.4 **Amendment.** This Agreement may be amended or modified in writing as mutually agreed upon by the Parties. Notwithstanding the foregoing, amendments necessary to effect compliance with laws, regulations, or MSSP requirements, do

not require the consent of Practice or Participating Physicians and shall be effective as stated in ACO's notice of amendment.

- 5.5 **Confidentiality.** This Agreement is confidential between the Parties, and the Parties hereto shall not release information concerning this Agreement, the MSSP Agreement, or any activities undertaken in compliance therewith (collectively, "**Confidential Information**"), to any person without the consent of the other Party. Notwithstanding the foregoing, each party may disclose Confidential Information (a) to its directors, managers, officers, employees, consultants, advisors, affiliates, counsel, and accountants on an as-needed basis to the extent such party agrees to keep such information confidential, and (b) as required by applicable law. In addition, ACO may release information concerning this Agreement to Meridian Health's governing board and those agencies having jurisdiction over the operations of Meridian Health and its affiliates.
- 5.6 **Third Party Beneficiaries.** This Agreement is entered into by and between ACO and Practice and the Participating Physicians for their benefit. Except as specifically provided herein, no third party shall have any right to enforce any right or enjoy any benefit created or established under this Agreement. The Parties acknowledge that, with respect to ACO's participation in the MSSP, CMS shall be deemed to be a third party beneficiary to this Agreement.
- 5.7 **Waiver.** No waiver may be deemed to have been made unless made expressly in writing and signed by the waiving Party. The waiver by either Party of a breach or violation of any provision of this Agreement shall not operate as, or be construed to be, a waiver of any subsequent breach of the same or other provision hereof. No failure by either Party to insist upon the strict performance of any provision of this Agreement may be construed as depriving that Party of the right to insist on strict performance of that provision or of any other provision in the future.
- 5.8 **Independent Contractor Relationship.** This Agreement is not intended to create nor shall be construed to create any relationship between ACO and Practice other than that of independent entities contracting for the purpose of effecting provisions of this Agreement.
- 5.9 **Entire Agreement.** This Agreement, including all exhibits and attachments hereto, constitutes the entire agreement of the Parties hereto with respect to the subject matter hereof and supersedes any prior or contemporaneous oral and written understandings or agreements.
- 5.10 **Jurisdiction.** This Agreement and any claim of any kind under any theory of law will be governed by and construed in accordance with the laws of the State of New Jersey, including all matters of construction, validity, performance and enforcement and without giving effect to contrary principles of conflict of laws.
- 5.11 **Counterparts.** This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, but all of which shall constitute one

and the same instrument. Signatures to this Agreement that are distributed to the Parties via facsimile or other electronic means (including PDF) shall have the same effect as if distributed in original form to all Parties.

5.12 **Severability.** Each provision of this Agreement is intended to be severable. If any term or provision is illegal or invalid for any reason whatsoever, such illegality or invalidity shall not affect the validity of the remainder of this Agreement.

5.13 **Liability.** ACO shall not exercise control over any Participating Physician's exercise of medical judgment and shall not, by entering into and performing its obligations under this Agreement, become liable for any of the liabilities, claims, actions or losses of Practice or any Participating Physician including, without limitation, any and all liability, claims, and causes of action arising out of or related to any loss, damage, or injury claimed by a MSSP Enrollee or other third party in connection with the delivery of Covered Services. ACO shall have no liability whatsoever for damages suffered on account of the acts or omissions of any employee, agent or independent contractor of Practice or Participating Physician.

The Practice and ACO have executed this Agreement as of the Effective Date below and each Participating Physician in the Practice has executed the Joinder Agreement attached hereto as of the Effective Date.

PRACTICE:

By: _____

Name: _____

Title: _____

Tax Identification No.: _____

Address for Notices:

ACO:

MERIDIAN ACCOUNTABLE CARE ORGANIZATION, LLC

By: _____

Name: JAMES CLARKE, MD

Title: EXECUTIVE DIRECTOR

Address for Notices:

1350 Campus Parkway

Neptune, New Jersey 07753

Fax: (732) 751-7545

Attn: Executive Director, ACO

**EXHIBIT A
JOINDER AGREEMENT**

Each undersigned Participating Physician hereby acknowledges, agrees and confirms that, by execution of this Joinder Agreement, the undersigned will be deemed to be a Party to the Participating Practice Agreement for participation in the MSSP through ACO, and agrees that all notices shall be delivered to him/her at the address set forth for the Practice.

PARTICIPATING PRACTICE (please print):
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PARTICIPATING PHYSICIAN

Print Name: _____

National Provider Identifier: _____

PARTICIPATING PHYSICIAN

Print Name: _____

National Provider Identifier: _____

PARTICIPATING PHYSICIAN

Print Name: _____

National Provider Identifier: _____

PARTICIPATING PHYSICIAN

Print Name: _____

National Provider Identifier: _____

EXHIBIT B CMS REQUIREMENTS FOR MSSP PROGRAM

As part of Practice's and Participating Physicians' obligations under this Agreement, Practice and Participating Physicians agree to comply with the requirements set forth in this **Exhibit B** with respect to the provision of Covered Services to MSSP Enrollees under this Agreement and pursuant to the terms of the MSSP Agreement.

1. **ACO Mission.** Participating Physicians and Practice agree, and shall ensure its Providers agree, to use commercially reasonable efforts to assist ACO in fulfilling its purpose (the "**ACO Mission**") under the MSSP. The ACO Mission includes, but is not limited to, the promotion of evidence-based medicine, the promotion of patient engagement, and the development of an infrastructure for Network providers to internally report on quality and cost metrics that enables the ACO to monitor, provide feedback, and evaluate its Network providers' performance and to use these results to provide better care for individuals, improved health for populations and lower per capita growth in expenditures for MSSP Enrollees.
2. **Compliance with Law.** Participating Physicians and Practice shall comply, and Practice shall contractually require its employees and its Providers providing services hereunder to comply, with any and all applicable federal and state laws, regulations and rules, CMS instructions and guidance, including, without limitation, (a) federal criminal law; (b) the False Claims Act (31 USC 3729 et seq.); (c) the anti-kickback statute (42 USC 1320a-7b(b)); (d) the civil monetary penalties law (42 USC 1320a-7a); (e) the physician self-referral law (42 USC 1395nn); (f) the MSSP regulations (42 CFR Part 425); and (g) those requirements specified in the MSSP Agreement (collectively the "**Applicable Requirements**").
3. **Other ACO Participation.** Neither Practice, nor any Participating Physician, nor any Provider shall participate in the MSSP under this Agreement if Practice, any Participating Physician, or an individual Provider participates in the (i) independence at home medical practice pilot program under Section 1866E of the Act; (ii) Medicare Health Care Quality Demonstration Programs; (iii) Multipayer Advance Primary Care Practice Demonstration with a shared savings arrangement; (iv) Care Management for High-Cost Beneficiaries Demonstration; (v) Physician Group Practice Transition Demonstration; (vi) Pioneer ACO Demonstration; (vii) a model tested or expanded under Section 1115A of the Act that involves shared savings; (viii) the Comprehensive Primary Care Initiative; or (ix) any other Medicare initiative that involves shared savings. Accordingly, Practice and each Participating Physician represent, warrant, and covenant, and shall attest upon written request, that neither Practice nor any Participating Physician for which MSSP Enrollees are assigned to ACO under the MSSP is currently or will subsequently participate in the MSSP under the same or a different name, or is related to or has an affiliation with another MSSP ACO.
4. **Previous ACO Participation.** If Practice or a Participating Physician was previously terminated from the MSSP, such previously terminated Practice or Participating Physician shall notify ACO of the cause of termination and what safeguards are now in place to enable Practice or the Participating Physician to participate in the MSSP for the full term of the MSSP Agreement.

5. **MSSP Enrollee Inducements.** Practice, Participating Physicians, Providers, and Suppliers are prohibited from:
 - a. providing gifts or other remuneration to MSSP Enrollees as inducements for receiving items or services from, or remaining in, the ACO or with Practice, a Participating Physician, or the ACO's Network providers, or receiving items or services from Practice, a Participating Physician, or Network providers; provided, Practice or a Participating Physician may provide in-kind items or services to MSSP Enrollees if there is a reasonable connection between the items and services and the medical care of the MSSP Enrollee and the items or services are preventive care items or services or advance a clinical goal for the MSSP Enrollee, including adherence to a treatment regime, adherence to a drug regime, adherence to a follow-up care plan, or management of a chronic disease or condition.
 - b. conditioning the participation of Practice, a Participating Physician or Network providers or suppliers on referrals of Federal health care program business that the individual knows or should know is being (or would be) provided to Medicare fee-for-service beneficiaries who are not assigned to the ACO.
 - c. except as permitted by 42 C.F.R. 425.304(c)(2), requiring that MSSP Enrollees be referred only to Practice, a Participating Physician, Network providers or other providers or suppliers.

6. **Marketing.** Participating Physicians and Practice agree to:
 - a. notify MSSP Enrollees at the point of care that Practice, Participating Physicians, and Providers are participating in the MSSP;
 - b. post signs in its facilities to notify MSSP Enrollees that Practice, Participating Physicians, and Providers are participating in the MSSP;
 - c. make available to MSSP Enrollees the standardized written notices regarding participation in an ACO and data opt-out. Such written notices must be provided by Practice or Participating Physicians, as applicable, in settings in which MSSP Enrollees receive primary care services;
 - d. use the standardized written notice developed by ACO or CMS;
 - e. only market involvement in the MSSP utilizing materials approved by ACO; and
 - f. discontinue use of any marketing materials or activities disapproved by ACO or CMS.

7. **Confidentiality of Records and Enrollment Information.** Participating Physicians and Practice shall comply, and Practice shall contractually require each Provider and Supplier to comply, with HIPAA and all other state and federal laws and regulations regarding health care privacy and security and the use and disclosure of Protected Health Information, any medical records or other information Practice, Participating Physicians, Providers, or Suppliers maintain with respect to MSSP Enrollees. Nothing herein shall be construed to limit or restrict appropriate sharing of Protected Health Information and medical record data with the ACO, Network providers, or other Medicare fee-for-service

providers and suppliers outside the ACO if such sharing is done in accordance with HIPAA and other federal and state health care privacy and security laws and regulations.

8. **Screening and Related Requirements.** Practice shall:
 - a. review the OIG List of Excluded Individuals/Entities and the U.S. General Services Administration's Excluded Parties List System prior to the initial hiring of any employee or the engagement of any Provider to furnish Covered Services, and monthly thereafter, to ensure compliance with this Section 8;
 - b. provide documentation, upon written request by ACO, of such screening;
 - c. immediately notify ACO upon discovering that it, or any of its employees (a) has furnished Covered Services under this Agreement as, or through, an Excluded Individual; (b) has been subject to any conviction or adverse action that subjects the individual to federal health care program exclusion under 42 U.S.C. § 1320a-7; or (c) has a history of health care program integrity, including any history of Medicare program exclusions or other sanctions and affiliations with individuals or entities that have a history of program integrity issues; and
 - d. immediately remove an Excluded Individual from any work related, directly or indirectly, to services furnished under this Agreement and take other appropriate corrective action requested by ACO based on the above notification.

9. **MSSP Enrollees Hold Harmless.** Neither Practice, nor Participating Physicians, nor Providers shall, in any event, including, without limitation, insolvency of ACO or breach of this Agreement, bill, charge, collect a deposit from, seek compensation or remuneration or reimbursement from, hold responsible, or otherwise have any recourse against any MSSP Enrollee or any other person acting on behalf of any MSSP Enrollee other than for Enrollee Costs or non-Covered Services. Practice agrees that neither Practice, nor any Participating Physician or Provider shall maintain any action at law or equity against an MSSP Enrollee to collect sums owed to Practice or any Participating Physician or Provider pursuant to this Agreement other than for Enrollee Costs or non-Covered Services. This Section 9 shall (a) survive the termination or expiration of the Agreement regardless of the cause giving rise to such termination and shall be construed to be for the benefit of MSSP Enrollees; and (b) supersede any oral or written contrary agreement now existing or hereafter entered into between Practice or any Participating Physician or Provider and an MSSP Enrollee or a person acting on an MSSP Enrollee's behalf.

10. **Maintenance of Records and Audits.**
 - a. Participating Physicians and Practice shall, and Practice shall contractually require its Providers to, maintain in an accurate and timely manner, operational, financial, administrative and medical records, contracts, books, files and other documents (including data related to Medicare utilization and costs, quality performance measures, shared savings distributions, and other financial arrangements related to ACO activities) ("Records") in connection with Covered Services performed under this Agreement. Such Records shall, at a minimum, be prepared, maintained and retained in accordance with generally accepted medical practices and applicable state and federal laws and regulations, ACO's policies, and the MSSP Agreement, and shall be sufficient to allow ACO to determine

whether Practice, Participating Physicians and Providers are performing their obligations under this Agreement consistent with the terms hereof and in accordance with Applicable Requirements.

- b. Upon request, Practice or a Participating Physician shall give HHS, the Comptroller General of the United States, CMS, ACO and/or their designees the right to access, audit, investigate, evaluate, and inspect any Records of Practice or any Participating Physician or Provider that pertain to: (1) Practice's, any Participating Physician's or any Provider's compliance with the MSSP Requirements; (2) the quality of services performed and determination of amount due to or from CMS under the MSSP Agreement; (3) data related to Medicare utilization and costs; and (4) the ability of the ACO to bear the risk of potential losses and to repay any losses to CMS.
 - c. Practice shall furnish copies of Records at no additional cost to ACO, and ACO will provide such Records directly to the applicable regulatory agency unless ACO, in its discretion, directs Practice to furnish copies directly to the applicable regulatory agency.
 - d. Practice shall permit CMS, HHS, the Comptroller General and ACO or their respective designees to conduct on-site evaluations of Practice, Participating Physicians, Providers, and physical premises, facilities and equipment to assess and audit Practice's, Participating Physicians' and Providers' performance under this Agreement and compliance with Applicable Requirements.
 - e. The terms of this Section 10, including the provisions with respect to maintenance of Records by Practice, Participating Physicians and Providers, shall remain in effect for a period of the longer of (a) ten (10) years from the final date of the MSSP Agreement period; or (b) completion of any audit, evaluation, or inspection; unless (i) CMS determines there is a special need to retain a particular Record or group of Records for a longer period and notifies ACO or Practice at least thirty (30) days before the normal disposition date; or (ii) there has been a termination, dispute, or allegation of fraud or similar fault against ACO, Practice, a Participating Physician, a Provider, ACO's Network providers or other individuals or entities performing functions or services related to ACO's activities under the MSSP Agreement, in which case Practice shall retain Records for an additional six (6) years from the date of any resulting final resolution of the termination, dispute, or allegation of fraud or similar fault.
11. **Monitoring.** Practice acknowledges and understands that ACO has a contractual obligation to CMS to comply with the Applicable Requirements relating to the MSSP and that ACO is ultimately responsible and accountable to CMS for compliance with all terms and conditions of the MSSP Agreement. Practice shall permit ACO, directly or through its representatives, to monitor the services furnished under this Agreement on an on-going basis, in any reasonable manner that ACO or CMS deems appropriate for compliance with ACO's obligations to CMS.

12. **Non-compliance.** When necessary, ACO will take steps to address non-compliance by Practice and/or individual Participating Physicians with the requirements of this Agreement, including adherence to the quality assurance and improvement program and evidence-based clinical guidelines. Such steps may include program implementation assistance, education, and mentoring to the Practice and/or Participating Physician. Practice and the Participating Physicians agree to work in good faith with ACO to improve performance and correct any areas of non-compliance with the requirements of this Agreement. Practice understands, however, that, if any Participating Physician fails to adhere to the quality assurance and improvement program, the evidence-based clinical guidelines, or the patient-centeredness processes, or is deficient in meeting the CMS quality performance standards, ACO may use progressive remedial processes and sanctions to improve compliance and performance. Such measures may include adoption and implementation of corrective action plans, the assessment of sanctions, the loss of the ability to receive shared savings, and the potential for expulsion. The ACO Board will adopt specific Policies and Procedures regarding non-compliance issues. To the extent the Practice has a contract with an ACO provider/supplier, as such is defined by 42 CFR Part 425.20, Practice shall take the necessary steps, as set forth in this section, to address ACO provider/supplier non-compliance with the requirements of this Agreement and when necessary Practice may use remedial processes and sanctions, also set forth in this section, to improve compliance and performance.

13. **Reporting and Disclosure; Submission of Encounter and Other Data.**

- a. Practice and Participating Physicians shall promptly submit (and Practice shall require Providers to submit) to ACO, or to CMS as directed by ACO, encounter data with respect to Practice's, the Participating Providers' and the Providers' participation under this Agreement and such other information required to be submitted in connection with ACO's reporting obligations under the MSSP Agreement. Such data and information includes, but is not limited to, data relating to the nature, outcome, quality of and payment for healthcare provided by Providers and other Network providers. Such data and information shall be submitted by Practice and its Providers in compliance with the Applicable Requirements.
- b. Prior to any data submission to CMS and at any time thereafter, ACO shall have the right to review and audit the data that will be submitted by Practice so that ACO can certify that the data being submitted is, to the best of its knowledge and belief, accurate, complete and truthful in accordance with Applicable Requirements.
- c. This Section 12 shall survive termination of this Agreement, regardless of the cause giving rise to termination.

14. **Compliance Program and Anti-Fraud Initiatives.** ACO shall develop and maintain an effective compliance program to detect, correct and prevent incidences of non-compliance with Applicable Requirements and incidences of fraud, waste and abuse relating to the MSSP and the federal healthcare program generally. Practice and Participating Physicians shall, and Practice shall contractually require its Providers to, comply with all requirements of ACO's compliance program. ACO's compliance program shall be appropriate to ACO's operations, shall be in compliance with, and be updated periodically to reflect changes in, law and regulations, and shall include at least the following elements:

- a. a designated compliance official or individual who is not legal counsel to the ACO and reports directly to the ACO's governing body;
- b. mechanisms for identifying and addressing compliance problems related to the ACO's operations and performance;
- c. a method for Participating Physicians, employees or contractors of the Practice including Providers, and other Network providers to anonymously report suspected problems related to the ACO to the compliance officer;
- d. compliance training for Practice, Participating Physicians, Providers and other Network providers; and
- e. a requirement that ACO, Practice Participating Physicians, and Providers report probable violations of law to an appropriate law enforcement agency.

15. **Certifications/Attestation**. Upon ACO's request, Practice and/or a Participating Physician shall certify and attest, and/or Practice shall provide certifications and attestations from Providers, that:

- a. Practice, Participating Physicians, and Providers, pursuant to Section 1 of this Exhibit B, (a) agree to become accountable for the quality, cost, and overall care of the MSSP Enrollees assigned to ACO under the MSSP; (b) will comply with and implement ACO's processes to promote evidence-based medicine and patient engagements, as required by 42 C.F.R. 425.112; and (c) shall be held accountable for meeting ACO's performance standards for each required process as required under this Agreement;
- b. Practice, Participating Physicians, and Providers are, to the best of Practice's knowledge, information and belief, in compliance with the MSSP Requirements and act consistent with the ACO Mission; and
- c. All data and information that is generated or submitted by Practice, Participating Physicians, and Providers, including any quality data or other information or data relied upon by CMS in determining ACO's eligibility for, and the amount of a shared savings payment or the amount of shared losses or other monies owed to CMS is, to the best of Practice's knowledge, information and belief, accurate, complete, and truthful.

EXHIBIT C
BUSINESS ASSOCIATE ADDENDUM

THIS BUSINESS ASSOCIATE ADDENDUM (the “**Agreement**” or “**BAA**”) supplements and is made a part of the Participating Practice Agreement (“**Underlying Agreement**”) by and between Practice (“**Covered Entity**”) and Meridian Accountable Care Organization, LLC (“**Business Associate**”) and is effective as of the effective date of the Underlying Agreement (the “**Effective Date**”). Covered Entity and Business Associate are sometimes referred to herein as the “Parties,” or individually as a “Party.”

RECITALS

WHEREAS, Business Associate has contracted with physician practice groups, including Covered Entity, that employ physicians and other licensed health care providers who have agreed to participate in Business Associate’s Network for purposes of Business Associate’s agreement with CMS for participation in the Medicare Shared Savings Program (“**MSSP**”); and

WHEREAS, if and only to the extent that Business Associate uses and/or discloses protected health information (“**PHI**”) in connection with the Underlying Agreement, or otherwise performs a function that is subject to protection under Health Insurance Portability and Accountability Act of 1996 (“**HIPAA**”) and the Health Information Technology for Economic and Clinical Health (“**HITECH**”) Act; Business Associate will comply with the responsibilities set forth herein;

NOW THEREFORE, in consideration of the mutual promises and covenants herein, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

ARTICLE 1 - DEFINITIONS

Terms used herein, but not otherwise defined, shall have meaning ascribed by the Underlying Agreement or by 45 C.F.R. parts 160, 162, and 164. Should any term set forth in the Underlying Agreement or in 45 C.F.R. Parts 160, 162 or 164 conflict with any defined term herein, the definition found in the Underlying Agreement or 45 C.F.R. Parts 160, 162 and 164 shall prevail, with the regulatory definition controlling.

ARTICLE 2 - BUSINESS ASSOCIATE OBLIGATIONS

Business Associate agrees to comply with applicable federal confidentiality and security laws, specifically the provisions of the HIPAA Rules and the HITECH Act applicable to business associates, including:

2.1 **Use and Disclosure of PHI.** Except as otherwise permitted by this Agreement, the HIPAA Rules, or applicable law, Business Associate shall not make any uses or disclosures of PHI except as necessary to provide services to, or on behalf of, Covered Entity as described in the Underlying Agreement, and shall not use or disclose PHI that would violate the HIPAA Rules or HITECH Act if used or disclosed by Covered Entity; provided, however, Business Associate may use and disclose PHI as necessary for the proper management and administration of Business Associate, or to carry out its legal responsibilities, consistent with Covered Entity’s minimum necessary policies and

procedures. Business Associate may not use or disclose PHI which it creates, receives, maintains or transmits for or on behalf of the Covered Entity for any purpose except as otherwise provided by the Agreement and this BAA. Business Associate agrees to review and understand any state privacy and security laws to the extent that such laws are not preempted by HIPAA, as may be amended from time to time. Business Associate acknowledges that it shall comply specifically with the HIPAA Security Rule, and, to the extent that Business Associate is to carry out one or more of Covered Entity's obligations under the Privacy Rule, it shall comply with the requirements of the Privacy Rule which apply to Covered Entity in the performance of such obligation(s). Business Associate shall in such cases:

2.1.1 provide information to members of its workforce using or disclosing PHI regarding the confidentiality requirements in the HIPAA Rules and this Agreement;

2.1.2 obtain reasonable assurances, in writing from the person or entity to whom the PHI is disclosed that: (i) the PHI will be held in confidence and further used and disclosed only as required by law or for the purpose for which it was disclosed to the person or entity; and (ii) the person or entity will notify Business Associate of any instances of which it is aware in which confidentiality of the PHI has been breached; and

2.1.3 agree to notify the Privacy Officer of Covered Entity of any instances of which it is aware in which the PHI is used or disclosed for a purpose that is not otherwise provided for in this Agreement or for a purpose not expressly permitted by the HIPAA Rules or HITECH Act.

2.2 **Marketing; Sale of PHI.** Business Associate may not use or disclose PHI for marketing purposes. Marketing includes any communication which would encourage the recipient to use or purchase a product or service. Business Associate may not use or disclose PHI where it has directly or indirectly received remuneration, financial or otherwise, from or on behalf of the recipient of the PHI in exchange for the PHI. "Sale" is not limited to circumstances where a transfer of ownership occurs, and would include access, license or lease agreements.

2.3 **Disclosure to Agents and Subcontractors.** If Business Associate discloses PHI received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity to Agent, or another subcontractor, Business Associate shall contractually require Agent, or the subcontractor, to agree to the same restrictions and conditions as apply to Business Associate under this Agreement. Business Associate shall contractually require that Agent, or any subcontractor, agrees to implement reasonable and appropriate safeguards to protect the confidentiality, integrity, and availability of the electronic PHI that it creates, receives, maintains, or transmits on behalf of Covered Entity. Business Associate shall be liable to Covered Entity for any acts, failures or omissions of a subcontractor in providing the services as if they were Business Associate's own acts, failures or omissions, to the extent permitted by law. Business Associate further expressly warrants that its agents or subcontractors which will have access to Covered Entity's PHI will be specifically advised of, and will comply in all respects with, the applicable terms of this Agreement.

2.4 **Safeguards.** Business Associate agrees to maintain appropriate safeguards to ensure that PHI is not used or disclosed other than as provided by this Agreement or as required by law. Business Associate shall comply with Subpart C of 45 CFR Part 164 of HIPAA. Business Associate shall implement, and shall contractually require that Agent and other subcontractors implement administrative, physical and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of any electronic PHI it creates, receives, maintains, or transmits on behalf of Covered Entity.

2.5 **Individual Rights Regarding Designated Record Sets.** If Business Associate maintains a Designated Record Set on behalf of Covered Entity, Business Associate agrees as follows:

2.6 **Individual Right to Copy or Inspection.** Business Associate agrees that if it maintains a Designated Record Set for Covered Entity that is not maintained by Covered Entity, it will permit an Individual to inspect or copy PHI about the Individual in that set as directed by Covered Entity to meet the requirements of 45 C.F.R. § 164.524. Under the HIPAA Rules, Covered Entities are required to take action on such requests as soon as possible, but not later than 30 days following receipt of the request. Business Associate agrees to make reasonable efforts to assist Covered Entity in meeting this deadline. The information shall be provided in the form or format requested if it is readily producible in such form or format; or in summary, if the Individual has agreed in advance to accept the information in summary form. If Covered Entity maintains the requested records, it, rather than Business Associate, shall permit access according to its policies and procedures implementing the HIPAA Rules.

2.7 **Individual Right to Amendment.** Business Associate agrees, if it maintains PHI in a Designated Record Set, to make amendments to PHI at the request and direction of Covered Entity pursuant to 45 C.F.R. 164.526. If Business Associate maintains a record in a Designated Record Set that is not also maintained by Covered Entity, Business Associate agrees that it will accommodate an Individual's request to amend PHI only in conjunction with a determination by Covered Entity that the amendment is appropriate according to 45 C.F.R. § 164.526.

2.8 **Accounting of Disclosures.** Business Associate agrees to maintain documentation of the information required to provide an accounting of disclosures of PHI in accordance with 45 C.F.R. § 164.528, and to make this information available to Covered Entity upon Covered Entity's request, in order to allow Covered Entity to respond to an Individual's request for accounting of disclosures. Such accounting is limited to disclosures that were made in the six (6) years prior to the request unless required by HITECH (not including disclosures prior to the compliance date of the HIPAA Rules) and shall be provided for as long as Business Associate maintains the PHI.

2.9 **Internal Practices, Policies, and Procedures.** Except as otherwise specified herein, Business Associate shall make its internal practices, books, records, policies and procedures and service, related to the use and disclosure of PHI received from or on behalf of Covered Entity available to the Secretary of the Department of Health and Human Services, or its agents or subcontractors, for the determination of the Business Associate's compliance with HIPAA. To the extent permitted by law, the Business Associate shall provide a copy of information provided to the Secretary to the Covered Entity.

2.10 **Minimum Necessary.** Whenever required by HITECH, Business Associate shall attempt to ensure that all uses and disclosures of PHI are subject to the principle of "minimum necessary use and disclosure," *i.e.*, that only PHI that is the minimum necessary to accomplish the intended purpose of the use, disclosure, or request is used or disclosed.

2.11 **Notice of Privacy Practices.** Business Associate shall abide by the limitations of Covered Entity's Notice of which it has knowledge. Any use or disclosure permitted by this Agreement may be amended by changes to Covered Entity's Notice; provided, however, that the amended Notice shall not affect permitted uses and disclosures on which Business Associate relied prior to receiving notice of such amended Notice.

2.12 **Security Incident/Unauthorized Disclosure of PHI.** Business Associate shall report to Covered Entity, pursuant to the HITECH Act, any instances, including Security Incidents, of which it is aware in which PHI is used or disclosed for a purpose that is not otherwise provided for in this Agreement or for a purpose not expressly permitted by the HIPAA Rules. Business Associate shall be considered aware of a Breach or Security Incident as of the first day on which such Breach or Security Incident is known to Business Associate; this shall include notification to Business Associate by a Subcontractor of a Breach or Security Incident. In the event that Business Associate knows of any breach of Unsecured PHI (i.e., PHI was inappropriately used, disclosed, released, or obtained), Business Associate shall notify Covered Entity in writing within five (5) calendar days of such breach. Notification shall include, to the extent known, detailed information about the breach, including, but not limited to, the nature and circumstances of such breach, the means by which PHI was or may have been breached (e.g., stolen laptop; breach of security protocols; unauthorized access to computer systems, etc.), the names and contact information of all individuals whose PHI was used, disclosed, released, or obtained in violation of this Agreement, and such other information as Covered Entity may reasonably request. Any delay in notification must include evidence demonstrating the necessity of the delay. Business Associate shall not be required to report an immaterial incident consisting solely of trivial incidents that occur on a daily basis, such as scans, "pings," or an unsuccessful attempt to improperly access PHI that is stored in an information system under its control; provided, however, Business Associate shall maintain logs of such incidents and make such logs available to Covered Entity upon written request. The party responsible for the breach shall bear the cost of any required notifications and corrective actions (e.g. credit monitoring services).

In accordance with 45 CFR § 164.402, any acquisition, access, use or disclosure of PHI in a manner not permitted by the Privacy Rule is presumed to be a Breach unless it can be demonstrated that a low probability exists that the PHI has been compromised. Covered Entity shall have the final and exclusive right to make determinations as to whether a Breach has occurred requiring notification under the Breach Rule. In no case shall any reporting be delayed pending Business Associate's internal risk assessment of whether an unauthorized use or disclosure resulted in a low probability that the PHI has been compromised.

2.13 **HIPAA Security Rule.** With regard to its use and/or disclosure of PHI, Business Associate shall, at its own expense:

2.13.1 implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the PHI that Business Associate creates, receives, maintains, or transmits on behalf of Covered Entity or its affiliates and at a minimum comply with those applicable safeguards in 45 CFR Section 164;

2.13.2 ensure that Agent and any and all of Business Associate's other subcontractors or agents to whom the Business Associate provides PHI agree in writing to implement reasonable and appropriate safeguards consistent with the requirements of 2.12.1, above, to protect such PHI; and

2.13.3 report promptly to Covered Entity any Security Incident (as defined in 45 CFR Section 164.304) relating to PHI created, received, maintained or transmitted in regards to

Covered Entity, of which Business Associate becomes aware, subject to the limitations in Section 2.11 above.

2.14 **Data Aggregation.** As may be applicable, Business Associate is permitted to use and disclose PHI for data aggregation purposes for or on behalf of the Covered Entity, however, only in order to analyze data for permitted health care operations, and only to the extent that such use is permitted under HIPAA and the underlying Agreement.

2.15 **De-identified Information.** Business Associate may use and disclose de-identified health information if (i) the intended use is disclosed to and permitted in writing by the Covered Entity, and (ii) the de-identification is in compliance with 45 C.F.R. §164.502(d) and meets the standard and implementation specifications for de-identification under 45 C.F.R. §164.514(a) and (b) and guidance issued thereafter by HHS.

ARTICLE 3 - COVERED ENTITY OBLIGATIONS

3.1 If deemed applicable by Covered Entity, Covered Entity shall:

3.1.1 provide Business Associate a copy of its Notice of Privacy Practices (“**Notice**”) in accordance with 45 C.F.R. 164.520 (“**Notice of Privacy Practices**”) as well as any changes to such Notice;

3.1.2 provide Business Associate with any changes in, or revocation of, authorizations by Individuals relating to the use and/or disclosure of PHI, if such changes affect Business Associate’s permitted or required uses and/or disclosures;

3.1.3 notify Business Associate of any restriction to the use and/or disclosure of PHI to which Covered Entity has agreed in accordance with 45 C.F.R. 164.522, to the extent that such restriction may affect Business Associate’s use or disclosure of protected health information;

3.1.4 notify Business Associate of any amendment to PHI to which Covered Entity has agreed that affects a Designated Record Set maintained by Business Associate; and

3.1.5 if Business Associate maintains a Designated Record Set, provide Business Associate with a copy of Covered Entity’s policies and procedures related to an Individual’s right to: access PHI; request an amendment to PHI; request confidential communications of PHI; or request an accounting of disclosures of PHI.

ARTICLE 4 - TERM AND TERMINATION

4.1 **Term.** The term of this BAA shall begin on the Effective Date and shall terminate when all of the PHI provided by Covered Entity to Business Associate, or created or received by Business Associate on behalf of Covered Entity, is destroyed or returned to the Covered Entity, or, if it is not feasible to return or destroy PHI, protections are extended to such PHI, in accordance with the provisions in Section 4.3.

4.2 **Termination for Cause.** Upon Covered Entity’s knowledge of a material breach of this Agreement by Business Associate, Covered Entity shall provide an opportunity for Business Associate to cure the breach or end the violation. If Business Associate does not cure the breach or end the violation within the time specified by Covered Entity, Covered Entity shall terminate:

(A) this Agreement; and (B) all of the provisions of the Underlying Agreement that involve the use or disclosure of Protected Health Information.

4.3 **Effect of Termination.** Upon termination of this Agreement for any reason, Business Associate agrees to return or destroy all PHI received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity, and which may be maintained by Business Associate or any Subcontractor of Business Associate in any form or format. Where Business Associate is unable to return PHI to the Covered Entity, Business Associate shall certify to the Covered Entity in writing that such PHI has been appropriately destroyed as required by the Security Rule. If Business Associate determines that the return or destruction of PHI is not feasible, Business Associate shall inform Covered Entity in writing of the reason thereof, and shall agree to extend the protections of this Agreement to such PHI and limit further uses and disclosures of the PHI to those purposes that make the return or destruction of the PHI not feasible for so long as Business Associate retains the PHI and limitations of this BAA in accordance with Subpart C of 45 CFR Part 164.

ARTICLE 5 – MISCELLANEOUS

5.1 **Mitigation.** If Business Associate violates this Agreement or the HIPAA Rules, Business Associate agrees to mitigate any damage caused by such breach.

5.2 **Interpretation.** Any ambiguity in this Agreement shall be resolved in favor of a meaning that permits Covered Entity to comply with the HIPAA Rules. The provisions of this Agreement shall prevail over the provisions of any other agreement, including the Underlying Agreement that exists between the Parties that may conflict with, or appear inconsistent with, any provision of this Agreement or the HIPAA Rules.

5.3 **Amendment.** Except as provided in this Section 6.3, no supplement, modification, or amendment of any term, provision, or condition of this Agreement will be binding or enforceable unless executed in writing by the Parties. Notwithstanding the foregoing, the Parties acknowledge that the HITECH Act imposes new requirements on business associates and their Subcontractors and agents with respect to the privacy and security of PHI and notification of breaches involving Unsecured PHI and contemplates that such requirements shall be implemented by regulations to be adopted by HHS. Those provisions of the HITECH Act and the final regulations implementing the HITECH Act that are applicable to business associates and their Subcontractors and agents are collectively referred to herein as the “HITECH BA Provisions”. Business Associate hereby acknowledges and agrees to comply with HITECH BA Provisions applicable to a business associate as mandated by HIPAA and the HITECH BA Provisions commencing on the applicable effective date of each such provision. Covered Entity and Business Associate each further agree that the provisions of HIPAA and HITECH, including the HITECH BA Provisions, that apply to business associates, and that are required to be incorporated into a business associate agreement, are hereby incorporated into this Agreement as if set forth in this Agreement in their entirety and are effective as of the applicable effective date.