

**MEDICARE SHARED SAVINGS PROGRAM**  
**ACO AFFILIATION AGREEMENT**

This ACO Affiliation Agreement ("Agreement") is entered into as of the \_\_\_\_ day of \_\_\_\_\_, 2014 (the "Effective Date") by and between Quality Health Alliance-ACO,LLC, a Pennsylvania limited liability company ("Company"), and the entity or individual identified on the signature page hereof ("Participant"), on behalf of itself and its Contract Providers (as hereinafter defined).

**Recitals**

**WHEREAS**, Company intends to submit an application for participation as an Accountable Care Organization ("ACO") in the Medicare Shared Savings Program ("MSSP") with a goal to participate in the Track 1 Option (the one-sided option) and to commence its participation on [\_\_\_\_\_] or such date thereafter as its application is accepted by the Centers for Medicare and Medicaid Services ("CMS"); and

**WHEREAS**, Company is desirous of having Participant participate, through an affiliation, in its ACO if Company's application is accepted by CMS; and

**WHEREAS**, Participant is a Specialist Physician, as more fully defined herein, duly licensed to practice medicine or is an entity that employs and/or contracts with Specialist Physicians, and other licensed professionals duly licensed to practice medicine ("Physicians") or other licensed activities, who will be furnishing Medicare Part A or Part B services to Medicare beneficiaries who are members of the ACO; and

**WHEREAS**, the parties desire Participant and its Eligible Professionals (as hereinafter defined) to be Contract Providers in the ACO, and Participant is willing to participate in the Company's ACO in the MSSP on the terms and conditions in this Agreement, which defines agreements and the terms and conditions of the Participant's affiliation with the ACO.

**NOW, THEREFORE**, in consideration of the mutual promises herein set forth and other good and valuable consideration, it is agreed as follows:

**SECTION 1 – PURPOSE, AFFILIATION WITH THE ACO**

Participant agrees that it is entering into an affiliation with ACO and that Company will not include or list Participant as an ACO Participant in its application for participation in the MSSP. Participant further agrees that, not being an ACO Participant, it (i) will not qualify for the Physician Quality Reporting System ("PQRS") incentives or avoid PQRS adjustments through ACO quality reporting, and (ii) will not be included in determining beneficiary assignment to the ACO. Participant acknowledges and agrees that Participant may not be entitled to receive any distribution of shared savings paid to the Company and ACO under the MSSP. In the event Participant desires to become an ACO Participant, Participant will be required to, and will agree to, execute the Company's standard MSSP ACO Participation Agreement ("Participation Agreement").

## **SECTION 2 – DEFINITIONS**

The following definitions apply to this Agreement. Capitalized terms not otherwise defined will have the meaning as utilized in the regulations at 42 C.F.R. Part 425 (Section 425.10 et seq.), and particularly the definitions at 42 C.F.R. § 425.20 (collectively the “MSSP Regulations”).

2.1 ACO. ACO means the accountable care organization to be established and operated by Company, and that shall apply to participate in the MSSP.

2.2 ACO Participant. ACO Participant means an individual or group of ACO providers/suppliers that is identified by a Medicare-enrolled TIN, that alone or together with one or more other ACO participants comprise(s) an ACO, and that is included on the list of ACO participants that is required under the MSSP Regulations.

2.3 Contract Providers. Contract Providers means Participant’s Eligible Professionals, and/or employees or contractors of Participant, (i) who have agreed to provide services to beneficiaries and who bill for items and services furnished to Medicare fee-for-service beneficiaries under the Medicare billing number assigned to the TIN of Participant, and (ii) who are participating in this ACO via the Participant’s execution of this Agreement.

2.4 Eligible Professional. Eligible Professional means any of the following who are employed by, or under contract with, the Participant: a Specialist Physician; a physical or occupational therapist or a qualified speech-language pathologist; a qualified audiologist; and/or a Practitioner.

2.5 Governing Body. Governing Body means the Management Board of the ACO (the “Board”). The Board has been, and shall be structured in accordance with the organizational and governance requirements of the MSSP Regulations and serves as the governing body in accordance with the MSSP Regulations.

2.6 Marketing Materials and Activities. Marketing Materials and Activities means, but is not limited to, general audience materials such as brochures, advertisements, outreach events, letters to beneficiaries, Web pages, data sharing opt out letters, mailings, social media, or other activities conducted by or on behalf of the ACO, or by the Participant, Contract Providers, ACO Participants, or ACO providers/suppliers participating in the ACO, when used to educate, solicit, notify, or contact Medicare beneficiaries or providers and suppliers regarding the MSSP.

2.7 Personnel. Personnel means Participant’s Eligible Professionals, employees, contractors, agents and representatives.

2.8 Policies. Policies means any and all of the Company’s standards, policies, protocols, programs, regulations and procedures as adopted by the Company’s Governing Body and set forth in writing during the Term of this Agreement, including, but not limited to, any case management, care coordination, referral guidelines, quality assurance, quality improvement, medical records, credentialing, peer review and clinical integration policies and programs, including those processes adopted by the ACO, which address participation in the ACO, or the

delivery of care to ACO beneficiaries or members, including policies which enable Contract Providers to provide feedback on quality and cost metrics; and coordinate care among Primary Care Physicians, Specialist Physicians, and acute and post-acute providers.

2.9 Practitioner. Practitioner means any of the following: a physician assistant, nurse practitioner, or clinical nurse specialist; a certified registered nurse anesthetist; a certified nurse-midwife; a clinical social worker; a clinical psychologist; and/or a registered dietitian or nutrition professional.

2.10 Primary Care Services. Primary Care Services means the set of services identified by the following HCPCS codes:

- i. HCPCS codes 99201 through 99215;
- ii. HCPCS codes 99304 through 99340, and 99341 through 99350, G0402, G0438 and G0439;
- iii. Revenue Center codes 0521, 0522, 0524, 0525.

2.11 Specialist Physician. Specialist Physician means a Physician, other than a Primary Care Physician, who provides specialist services.

### **SECTION 3 – AGREEMENTS OF PARTICIPANT**

The MSSP Regulations require ACO Participants and ACO Providers/Suppliers to make a number of agreements and commitments with respect to their participation in the ACO and MSSP. Participant hereby makes and agrees to the commitments, representations and warranties set forth below and herein.

3.1 Organizational Authority. Participant represents and warrants to the Company that:

- i. if Participant is an entity, it is duly organized, and validly existing under the laws of the Commonwealth of Pennsylvania;
- ii. it, on its behalf and on behalf of its Contract Providers, has the requisite power and authority to enter into this Agreement, has the power and ability to bind the Contract Providers to this Agreement by executing it on their behalf, and has taken all corporate action necessary to enter into this Agreement;
- iii. it, and its Contract Providers are participating providers in the Medicare program, billing Medicare fee-for-service beneficiaries under a Medicare billing number assigned to the Participant and billing under identified tax identification number(s) (“TINs”) of the Participant;
- iv. its Personnel are not subject to any suspension or exclusion from participation in any federal or state funded health care program;

v. if Participant elects to change its participation status and become a full participating member of the ACO it, and its employed or contracted providers, will utilize the TINs and NPIs listed on Exhibit A in all of their services billed to the Medicare program, and none of such TINs that are utilized to bill any Primary Care Services as described in the MSSP Regulations, shall be utilized as part of another ACO from the date the Company's MSSP participation agreement with CMS is made effective, until the termination of this Agreement; Participant agrees to update such list of NPIs and TINs within twenty (20) days of any modification by written notice to the President of the ACO (such notice to be provided in accordance with Section 8 herein);

vi. it holds all licenses, approvals, and certifications necessary to provide the services it provides and has provided, and to participate in the Medicare program;

vii. it possesses and shall maintain all insurance as required by Section 4.7 herein;

viii. if Participant engages any other person to assist in performing services under this Agreement, Participant represents and warrants that such person (i) is either employed by or under the direct supervision and control of Participant, (ii) is appropriately licensed/certified and has all other qualifications necessary to assist Participant, and (iii) does not appear on the list of excluded individuals and entities who are excluded from participation in the Medicare or Medicaid program; and

ix. all of its Contract Providers (a) are duly licensed in the Commonwealth of Pennsylvania and in good standing to provide the services they provide; (b) have a current controlled substance registration from the Drug Enforcement Agency and any state agency as necessary to prescribe a full range of pharmaceuticals without restriction; (c) shall perform medical and professional services in accordance with applicable standards of care, and within the scope of each individual's license, training and experience; and, (d) are not a party to any agreement that shall preclude participation as part of the ACO.

Participant shall promptly notify the Company if any claim, trial, investigation, demand, suit or proceeding ("Claim") is instituted against any Contract Provider by a plaintiff, government agency, hospital, professional society or peer review organization involving any allegation of substandard care, professional misconduct, violations of any federal or state health care program statute or regulation, or any other matter that is likely to affect the continuing accuracy of the representations or warranties in this Section 3.1, except to the extent that the confidentiality of any such proceedings is protected by applicable law.

3.2 Maintenance/Accuracy of Representations and Warranties. Participant represents that the representations and warranties set forth in Section 3.1 shall remain true and correct at all times during the Term of this Agreement. In the event any of the representations and warranties contained in Section 3.1 (and throughout this Agreement) cease to be true and/or

accurate (an “Inaccuracy”), Participant shall immediately provide notice of any such Inaccuracy to Company (such notice shall be provided in accordance with Section 8 herein) and such Inaccuracy shall be deemed a breach, thus triggering Company’s termination rights under Section 7.2 herein.

3.3 Non-Contravention. Participant represents and warrants that neither the execution and entering into of this Agreement, nor the performance of the obligations, representations and duties herein shall (i) conflict with or result in a breach or a default under any agreement or other arrangement by which the Participant is bound, or (ii) result in the violation by the Participant of any law, rule, regulation, or judicial or governmental restriction.

3.4 Support and Commitment to ACO Mission. Participant agrees for itself and its Contract Providers that it shall cooperate with the Company in its operation of the ACO and shall at all times comply with all regulatory and contractual agreements required for participation in the MSSP as part of the ACO, including, without limitation, the MSSP Regulations and the agreement between the Company and CMS for participation in the MSSP.

3.5 Compliance With and Implementation of Process. As required by 42 C.F.R. § 425.108(d), Participant agrees that it is committed to the mission of the ACO, shall help ensure the ACO’s success through its compliance with the terms and conditions of this Agreement, and agrees comply with and implement the ACO’s Policies (all of which are incorporated herein by reference), and the ACO’s processes required by 42 C.F.R. § 425.112, and shall be held accountable for meeting the ACO’s performance standards for each required process. The Policies may be amended by the Governing Body from time to time, however the ACO shall use reasonable efforts to provide Participant of notice of any such amendments thirty (30) days prior to the effective date of the amendment. Such required processes include: promotion of evidence-based medicine; promotion of patient engagement, including compliance with the patient experience of care survey requirements, compliance with beneficiary representative requirements, process for evaluating the health needs of the ACO’s population; communication of clinical knowledge/evidence-based medicine to beneficiaries in an understandable way; beneficiary engagement, and written standards for beneficiary access and communication; development of an infrastructure to internally report on quality and cost metrics; and coordination of care across and among physicians and other providers. As the ACO develops Policies and such processes in more detail, it shall inform Participant of the terms thereof. The foregoing are described in more detail in 42 C.F.R. § 425.112. Participant further agrees that it shall reasonably (i) participate in, and cooperate with the ACO, with respect to any marketing and promotional activities undertaken by the ACO, (ii) consider participation in and service as members of committees, through its Physicians, if requested, appointed or elected to such committees by the Governing Body or the officers of the ACO, and (iii) assist the Company in addressing and responding to, upon the request of the Company, any Claims brought against the Company.

3.6 Required Disclosures. Participant understands it is required to disclose any prior or other participation in the MSSP under the same name or another name, or is related to or has an affiliation with another Shared Savings Program Accountable Care Organization. Participant understands and acknowledges that the Company must make submissions of information to CMS concerning Participant. Such information includes the list of Participant and

its Contract Providers, including TINs and provider identifiers (NPIs) with an indication of who is a “primary care physician,” as defined in the MSSP Regulations. Participant represents that the information on Exhibit A is a true and correct reflection of such information.

3.7 Compliance with Laws. Participant agrees that it and its Personnel shall at all times comply with all applicable laws, including but not limited to:

- Federal criminal law;
- The False Claims Act (31 U.S.C. § 3729 *et seq.*);
- The anti-kickback statute (42 U.S.C. § 1320a-7b(b));
- The civil monetary penalties law (42 U.S.C. § 1320a-7a); and
- The physician self-referral law (42 U.S.C. § 1395nn).

3.8 Conflict of Interest Policy and Compliance Plan. Participant agrees for itself Personnel that it and they shall comply with any Conflict of Interest Policy adopted by the Governing Body of the Company, or any Conflict of Interest Policy required by any governmental agency.

Participant further agrees for itself and its Personnel to comply with any reasonable Compliance Plan and/or Program (“Compliance Plan”) adopted by the Governing Body of the Company and in connection therewith to reasonably cooperate with the designated compliance official for the ACO in identifying and addressing compliance problems related to ACO’s operations and methods. Without limitation, Participant and its Personnel agree to participate in compliance training as developed by the ACO and Participant understands that it and its Personnel are required to report to the Company (which is obligated to report to an appropriate law enforcement agency) any probable violations of law related to the ACO. Participant shall include such reporting obligation in its employment and independent contractor agreements with its Personnel who provide services hereunder. It is understood the Company’s Compliance Plan shall be updated from time to time to reflect changes in law and regulations.

3.9 Data Submission Requirements, Certifications and Reporting.

- a. Submissions. If Participant elects to change its participation status and become a full participating member of the ACO, Participant, for itself and its Personnel, agrees to submit all data and information, including data on all measures required by CMS under 42 C.F.R. 425.500 *et seq.*, in a form and manner specified by CMS. Such data shall be submitted with a certification from an individual with authority to bind Participant and each individual or entity submitting such data or information, as to the accuracy, completeness and truthfulness of the data and information, to the best of the information and belief of the certifying individual.

- b. Annual Certification. Annually, the Participant and other individuals or entities performing functions or services related to the ACO and behalf of Participant shall make a similar certification concerning their compliance with MSSP requirements and the MSSP Regulations.
- c. Quality Reporting. Participant acknowledges that the MSSP requires quality reporting by the ACO, which is part of the determination of the shared savings to which ACO may be entitled. Participant agrees to participate in all quality reporting requirements, to report all required data in a timely and accurate manner, and to cooperate fully with all quality reporting requirements, including doing so in the manner specified by CMS. Participant understands that, not being an ACO Participant, it cannot earn a PQRS incentive.

3.10 Beneficiary Inducements. Participant understands and agrees that in performing services for the ACO:

- a. it and its Contract Providers are prohibited from providing gifts or other remuneration to beneficiaries as inducements for receiving items or services from or remaining in the ACO or with ACO Providers/Suppliers in the ACO or receiving items or services from ACO Participants or ACO Providers/Suppliers (unless expressly permitted by applicable law);
- b. it and its Contract Providers are subject to review during the application process and periodically thereafter with regard to their program integrity history, including any Medicare programs exclusions or other sanctions and affiliations with individuals and entities that have a history of program integrity issues; and if the screening reveals a history of integrity issues or affiliations with a history of integrity issues it, he, she or they may be subject to denial from participation or the imposition of other safeguards or assurances;
- c. it and its Contract Providers, and others performing functions or services related to ACO activities may not condition their participation in the ACO on referrals of federal health care program business that they may know or should know is being (or would be) provided to beneficiaries not assigned to the ACO;

3.11 Public Reporting; Transparency. Participant understands that the ACO is required to publicly report certain information as specified by CMS. Participant shall cooperate to allow ACO to meet its reporting obligations.

3.12 Marketing. Any Marketing Materials and Activities (which include, but are not limited to, communications to and materials disseminated to the public and beneficiaries) (i) must be developed in collaboration with the Company and/or approved by the Governing Body in advance of use, (ii) must be filed with CMS, and (iii) are subject to CMS disapproval

before such materials and activities may be utilized. All such Marketing Materials and Activities must use template language developed by CMS, if available; not be used in a discriminatory manner; comply with the limits on beneficiary inducements; and not be materially inaccurate or misleading. In addition, Participant shall cooperate with the Company, upon request of the Company, in providing up-to-date information regarding the address, credentials and qualifications of the Participant and its Contract Providers for use in rosters, directories, and promotional materials of the Company and/or the ACO.

### 3.13 Monitoring.

a. CMS Monitoring. Participant acknowledges that the operation of the ACO is subject to ongoing monitoring by CMS. Participant shall promptly comply with any CMS requests for documentation and with any directives, including any corrective action plan required by CMS. Participant shall immediately provide the Company with notice and copies of any and all such CMS requests. The Company shall promptly notify the Participant of any CMS requests for information applicable to the Participant and changes in applicable requirements.

b. ACO Monitoring and Evaluation Activities. Participant shall, and shall require its Contract Providers to, participate in, and cooperate with the Company and the ACO's programs, policies, including the Policies, and procedures for monitoring and evaluating the quality, cost effectiveness and medical necessity of services provided to beneficiaries, including, but not limited to, those relating to adoption and use of electronic health information technology, adoption and compliance with clinical protocols and pathways, utilization management, pre-registration or prior authorization, quality assurance reviews, cost effectiveness programs (including programs designed to reduce the cost of supplies, pharmaceuticals and equipment), clinical efficacy of treatment, and/or credentialing or grievance procedures. Such cooperation may include service on committees and work groups, review and response to reports on provider's performance or the performance of peers or other clinicians, collection of any data required to measure performance regarding utilization management and clinical quality, including adherence to clinical protocols and pathways and achievement of patient satisfaction goals; and compliance with recommendations to improve utilization or quality performance or patient satisfaction.

3.14 Notice to Beneficiaries. The MSSP requires that beneficiaries receive certain notices concerning the ACO, and Participant agrees to comply with such requirements. Participant agrees to collaborate with the Company to ensure the beneficiary notice requirements are complied with and appropriate notices given, such collaboration may include use of forms or documents provided to Participant by the Company for such purposes. In connection therewith, Participant agrees:

- a. to notify Medicare fee-for-service beneficiaries at the point of care that Participant and its Contract Providers is/are participating in the MSSP;



- b. to post signs in Participant's facilities that Participant, its Contract Providers and its providers/suppliers are participating in the MSSP; and
- c. to make available standardized written notices regarding participation in the ACO and data sharing opt-out, and to ensure the availability of such notices at all locations where Primary Care Services are provided (including distributing a form describing the right to decline data sharing to beneficiaries at their first primary care visit, as and to the extent required by 42 C.F.R. § 425.708.

#### **SECTION 4 – OTHER REQUIREMENTS**

4.1 Provision of Services. Participant shall provide the full range of services to Medicare fee-for-service beneficiaries that it is qualified to provide, and provides in the ordinary course and scope of its practice, and to accept all Medicare fee-for-service beneficiaries for such services.

4.2 Care Coordination. As part of its MSSP obligations, the ACO shall 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 Participant's compliance. Participant agrees to comply with and implement such processes and participate in all such activities. Participant shall cooperate with all care coordination, utilization, management, case management and similar activities as the ACO implements or utilizes.

4.3 Credentialing and Peer Review. Participant shall, and shall cause its Contract Providers (as applicable) participate in, and comply with, any credentialing program and peer review processes established by ACO from time to time. Participant shall cause each Contract Provider to authorize each hospital or other health care facility at which such Contract Provider has privileges and to release to ACO the Eligible Professional's credentialing files and other information with respect to the Contract Providers' professional credentials.

4.4 Non-Discrimination. Neither Participant nor its Contract Providers shall differentiate or discriminate in any manner in accepting, or providing services, to Medicare fee-for-service beneficiaries on the basis of race, age, color, sex, sexual orientation, ethnicity, nationality, religion, disability, place of residence, health or economic status or source of payment.

4.5 Physician-Patient Relationship. As part of its MSSP obligations, the ACO shall define processes to promote MSSP enrollee engagement, which Participant shall adopt. Participant acknowledges, however, that each Contract Provider shall maintain an independent doctor-patient relationship with all Medicare fee-for-service beneficiaries who are their patients and shall exercise independent professional judgment consistent with accepted standards of medical care in rendering treatment of such beneficiaries. Participant acknowledges that Participant and each Contract Provider are solely responsible to such patients for all treatment decisions made by them, including any decision not to treat, and that actions by ACO pursuant to utilization management, case management, referral management or other programs do not

absolve Participant and its Contract Providers of their responsibility to provide appropriate medical care to Medicare fee-for-service beneficiaries, regardless of whether the care is covered and/or reimbursable.

4.6 Claims and Disciplinary Actions. Participant shall notify ACO promptly of any formally initiated Claim or written allegation of malpractice, professional misconduct, or grounds for licensure or clinical privilege disciplinary action raised against any Contract Provider by any governmental agency, professional organization, health care facility, health care practice or plaintiff, and any modification, suspension, reduction or revocation of any license, membership, privileges or registration of a Contract Provider, except to the extent that the confidentiality of any such claims or proceedings is protected by applicable law. Participant shall provide full details of the nature, circumstances and disposition of such claims upon request by ACO, except to the extent that the confidentiality of any such claims or proceedings is protected by applicable law. If any Contract Provider is the subject of any final disciplinary action by any governmental agency, professional organization, health care facility or practice, ACO may, in its discretion, terminate such Contract Provider's participation under this Agreement. When necessary, the ACO shall take steps to address non-compliance by Participant or any Contract Provider with the requirements of this Agreement, including adherence to the Compliance Plan and evidence-based clinical guidelines. Such steps may include program implementation assistance, education, and mentoring to the Participant and/or the applicable Contract Provider. Participant agrees to work in good faith with the ACO to improve performance and correct any areas of noncompliance with the requirements of this Agreement. Participant understands, however, that, if Participant or any Contract Provider fails to adhere to the Compliance Plan, the evidence-based clinical guidelines, or the patient-centeredness processes, or is deficient in meeting the CMS quality performance standards, the 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 Governing Body shall adopt specific policies and procedures regarding non-compliance issues.

4.7 Professional Liability Insurance. Participant and its Eligible Professionals shall obtain and maintain professional liability (malpractice) insurance from an insurer licensed to provide malpractice insurance in the Commonwealth of Pennsylvania in no less than the minimum amount required under state law. Participant shall obtain any required tail coverage to insure coverage for claims made after the performance period for not less than the applicable statute of limitations.

4.8 Compliance with Law. The Company hereby represents and warrants that it shall operate substantially in accordance with applicable laws, including, without limitation, the laws referenced in Section 3.8. Neither Company nor Participant shall employ or contract with any individual or entity that is excluded from participation in the Medicare or any Medicaid program. The Company shall promptly notify Participant of any Claim, action or proceeding initiated against the Company alleging a violation of any applicable law, and Participant shall, if requested by Company, provide assistance to Company in addressing or responding to same. In addition, in performing their obligations under this Agreement, the Participant and its Personnel shall comply with all applicable statutes, rules and regulations, and the Policies in effect from time to time. Both parties represent and warrant that they shall conduct themselves in a manner

that complies with federal and state antitrust and unfair competition laws, and that they shall not engage in unlawful price fixing or any unlawful collective refusal to deal.

4.9 Exclusion Reporting. Neither Participant, nor any owner or Personnel of Participant is or has been (i) excluded, debarred, suspended or sanctioned by Medicare, Medicaid, or any other state or federal health care reimbursement program, (ii) a party to a settlement agreement, corporate integrity agreement, certification of compliance agreement or similar agreement with any state or federal government agency or body or other payor, (iii) convicted of or indicted for any criminal offense related to healthcare, or (iv) to Participant's knowledge, otherwise engaged in conduct for which a person or entity can be so convicted, indicted, or listed. Participant shall conduct checks of all of Participant's Personnel on the United States Department of Health and Human Services Office of Inspector General List of Excluded Individuals/Entities, the General Service Administration Excluded Parties List System and the Food and Drug Administration Debarment List prior to any such person providing services for or on behalf of Participant, and Participant shall conduct such checks on all new hires and shall make monthly checks on all of Participant's Personnel during the Term of this Agreement.

## **SECTION 5 – BILLING AND DISTRIBUTION OF SHARED SAVINGS**

5.1 Continued Fee-For-Service Billing. Participant shall continue to bill the Medicare program for services rendered to all Medicare fee-for-service beneficiaries. Participant, in its billing and collection activities for such services, shall act in full compliance with applicable law and other Medicare payment requirements.

5.2 Share of Savings. Notwithstanding anything in this Agreement or any of the Policies to the contrary, Participant acknowledges and agrees that it shall not be entitled to, nor shall it, receive any portion or amount of any distributions of any shared savings paid to the Company and ACO under the MSSP, if any.

5.3 Access to Records. Participant and its Personnel shall permit the Company, the ACO, CMS, the U.S. Department of Health and Human Services, the Comptroller General, the Federal Government, or their designees, to audit, inspect, investigate and evaluate any books, contracts, documents or other evidence of Participant and of other individuals and entities performing functions related to ACO activities that pertain to:

- a. ACO's or Participant's compliance with the MSSP;
- b. the quality of services performed and any determination of the amount due to or from CMS under the ACO participation agreement; and
- c. the ability of ACO to bear the risk of potential losses and to repay any amounts due CMS.

5.4 Maintenance of Records. Participant shall maintain such books, contracts, records and other evidence described in Section 5.3 for a period of ten (10) years from the final

date of the ACO participation agreement period or from the date of completion of any audit, evaluation or inspection, whichever is later, as such date may be extended by CMS.

## **SECTION 6 – CONFIDENTIALITY**

6.1 Maintenance of Medical Records. Participant shall, and shall cause its Contract Providers to, maintain adequate medical records relating to the provision of health care services by its Participating Providers to Medicare beneficiaries and their participation in the ACO, in such form and containing such information as is required by applicable law, applicable National Committee for Quality Assurance (“NCQA”) standards, and in accordance with any applicable policies and requirements under the MSSP.

6.2 Confidentiality/HIPAA Compliance. Participant and its Personnel shall treat medical records and personal health information of Medicare fee-for-service beneficiaries as confidential in compliance with all applicable federal and state laws, including the Health Insurance Portability and Accountability Act of 1996, and the privacy and security rules promulgated thereunder, the Health Information Technology for Economic and Clinical Health (“HITECH”) Act (collectively, “HIPAA”), and the state law requirements and the regulations promulgated thereunder. For purposes of this Agreement, “Protected Health Information” (“PHI”) and “Electronic Protected Health Information” (“ePHI”) shall have the meaning ascribed to those terms in HIPAA.

6.2.1. The Company is a “business associate” (as defined in HIPAA) of Participant under this Agreement and shall use reasonable efforts to preserve the confidentiality of PHI it receives from Participant hereunder. Company is only permitted to use and disclose such PHI to the extent that Participant is permitted to use and disclose such information pursuant to HIPAA and applicable state law. Company may use PHI for Health Care Operations (as defined in HIPAA) of the Company and the ACO.

6.2.2. The Company agrees, as a business associate, to comply with the provisions of Exhibit B (Business Associate Exhibit).

6.3 Proprietary Information. The parties shall comply with all applicable state and federal laws respecting the confidentiality of financial, operating, proprietary or business information relating to this Agreement which is not otherwise public information; as well as hold in strict confidence any information specified in writing by any party hereto as confidential information. The parties shall each exercise best efforts to prevent any of their respective agents, employees or independent contractors or any other person involved in doing business with or controlled by the recipient party from disclosing or transmitting to any third party any such confidential or proprietary information obtained from the disclosing party; provided, however, that nothing herein shall prohibit a recipient party from disclosing or transmitting information to the extent necessary or appropriate under this Agreement or as required by law.

6.4 Participant Confidential Information. Except to the extent required by applicable law, information obtained by the Company that is proprietary to the Participant and directly relates to the Participant, its Contract Providers shall be kept confidential by the

Company, and shall be used by the Company as required or reasonably necessary to perform under the MSSP and for its internal operations. The Company shall treat such information as confidential, and provide reasonable protections for such information consistently with how it treats its own confidential information.

## **SECTION 7 – TERM AND TERMINATION**

7.1 Term. This Agreement shall be effective as of the date of execution and shall continue throughout the term of the Company's MSSP participation agreement with CMS, unless earlier terminated as provided for herein (the "Term"). This Agreement shall be utilized for any renewal participation agreement the Company seeks with CMS, provided either party may elect not to continue this Agreement for any renewal agreement with CMS by providing not less than one hundred and twenty (120) days' prior written notice of the desire not to participate in the renewal.

### **7.2 Termination for Cause.**

a. The Company may immediately terminate this Agreement, with written notice to Participant, in the event of any action or breach on part of Participant or any of its Personnel which violates the terms of the MSSP Regulations.

b. Participant may terminate this Agreement on written notice to the Company in the event of a material breach by the Company that is not cured within thirty (30) days of notice of such breach.

c. The Company may terminate this Agreement on written notice to the Participant in the event of a breach by the Participant (that is not a violation of a MSSP Regulation) that is not cured within thirty (30) days of notice of such breach.

d. Participant may terminate this Agreement on thirty (30) days prior written notice to Company: (i) in the event of a finding by a governmental authority of violations by the Company of applicable law related to the ACO or MSSP program requirements, or (ii) if Participant reasonably determines as reflected in an opinion of legal counsel that its continued participation in the ACO would have a material negative effect on [its continued status as a tax-exempt entity] or its continued participation in the ACO would violate any applicable law that would materially and adversely affect Participant.

7.3 Automatic Termination. This Agreement shall automatically terminate upon the termination or expiration of the Company's MSSP participation agreement with CMS. This Agreement shall terminate automatically in the event that either party dissolves, liquidates, becomes insolvent, makes an assignment for benefit of creditors, files a voluntary bankruptcy petition, or is the subject of an involuntary bankruptcy petition that is not dismissed within ninety (90) days after response thereto. In the event Participant and Company enter into Company's Participation Agreement, this Agreement shall automatically terminate and the Participation Agreement shall govern the parties relationship and Participant's participation in the ACO.

7.4 Effect of Termination. In the event this Agreement is terminated Participant acknowledges and agrees that it shall not be entitled to any potential distribution of shared savings as set forth in Section 5.2 herein.

7.5 Termination of Services of a Contract Provider. This Agreement shall terminate automatically with respect to a Contract Provider and such Contract Provider shall no longer have a right to participate hereunder, if:

- a. the Contract Provider's license to practice medicine (or other applicable license or certification required for the performance of his or her duties) is terminated;
- b. the Contract Provider's license to practice medicine (or other applicable license or certification required for the performance of his or her duties) is suspended; provided, however, this Agreement shall be reinstated as to such Contract Provider as of the time such suspension is no longer in effect;
- c. the Contract Provider is convicted of a felony, or any crime of moral turpitude, dishonesty, false statement, or other acts which may be grounds for suspension or termination of the Contract Provider's right to practice, notwithstanding any right of appeal of said conviction;
- d. a Contract Provider ceases, for any reason to be employed or engaged by Participant;
- e. a Contract Provider dies or becomes permanently disabled. Permanent disability shall be defined as having occurred when the Contract Provider, by reason of a physical or mental impairment as reasonably determined by the Company, ceases to provide clinical services;
- f. a Contract Provider loses staff privileges at any hospital (or applicable clinical or other privileges) for reasons relating to the Contract Provider's practice; provided, however, this Agreement shall be reinstated in the event such staff privileges are reinstated;
- g. a Contract Provider is convicted of a felony, or any crime of moral turpitude, dishonesty, false statement, or other acts that may be grounds for suspension or termination of the Contract Provider's right to practice, notwithstanding any right of appeal of said conviction; or
- h. a Contract Provider is excluded, suspended or debarred from Contract in any federal or state health care payment program, or from the program of any third party payor.

## **SECTION 8 –NOTICES**

Whenever notice is required to be given under the terms of this Agreement, it shall be given in writing, either delivered by email, fax, hand delivery, overnight delivery or by certified mail, at the addresses indicated on the signature page of this Agreement. If notice is given by email, fax, overnight delivery or hand delivery, notice shall be deemed given upon confirmation of receipt or delivery receipt (in the case of overnight delivery). If notice is given by certified mail, notice shall be deemed given three days after the date of mailing. Each party shall notify the other promptly of any change in address in accordance with the notice provisions of this Section 8.

## **SECTION 9 – MISCELLANEOUS**

9.1 Relationship to CMS Agreement and MSSP Regulations. The provisions of this Agreement are subject to the terms of the ACO participation agreement between the Company and CMS and the MSSP Regulations. In the event of a conflict between this Agreement or the provisions of the ACO participation agreement between the Company and CMS and/or the MSSP Regulations, the MSSP Regulations, followed by the terms of the ACO participation agreement between the Company and CMS shall supersede with respect to the conflict. In the event Participant identifies a perceived conflict it shall notify the Company of the potential conflict and the parties shall collaborate to determine if a conflict actually exists, and, if required, address and/or rectify any actual conflict.

9.2 Independent Contractors. The Company and Participant (together with its Contract Providers) are and shall be independent contractors and neither party shall be construed to be the agent of or a joint venturer with the other. These undertakings shall survive any termination of or the expiration of the Term of this Agreement.

9.3 Suspension of Contract Provider Participation. CMS may immediately suspend a Contract Provider's participation in the ACO in the event that any act or omission attributable to the Contract Provider materially impairs the life, health or safety of a Medicare fee-for-service beneficiary.

9.4 Entire Agreement. This Agreement constitutes and expresses the entire agreement and understanding between the parties hereto in reference to all matters herein referred to, and supersedes all previous discussions, promises, representations, and understandings, whether either oral or written, among the parties.

9.5 Assignment. This Agreement shall be binding upon and inure to the benefit of the parties' heirs, successors, assigns and representatives. This Agreement may not be assigned, nor the duties hereunder delegated, by either party without the other party's written consent, provided that the Company may assign this Agreement, without the consent of Participant, to any entity this is owned or controlled by the Company or under common ownership or control with the Company or ACO, or that is a successor to the business of the Company by virtue of merger, consolidation or sale of all or substantially all of the Company's assets.

9.6 Amendment. This Agreement may be amended by the Company giving Participant at least thirty (30) days' prior written notice of such amendment. Such amendment shall automatically become effective at the end of such thirty (30) day notice period, unless Participant objects in writing to the Company within that period; provided Participant has no right to contest an amendment required by CMS or the MSSP Regulations. If Participant objects in writing to the Company in a timely manner, then the amendment shall not go into effect with respect to Participant, and the Company may, at its option, terminate this Agreement upon thirty (30) days' notice. Participant

9.7 Severability. Should any provision of this Agreement or application thereof be held invalid or unenforceable, the remainder of this Agreement shall not be affected and shall continue to be valid and enforceable to the fullest extent permitted by law unless its continued validity and enforcement would defeat the purpose of this Agreement. Notwithstanding the foregoing, the parties agree to modify this Agreement if either party reasonably determines that such modification is required in order to comply with any change in applicable laws or regulations or the official interpretation thereof. If the parties are unable to agree upon a modification, either party may terminate the Agreement by thirty (30) days' advance written notice to the other.

9.8 Waiver. The failure by a party at any time to require performance of any provision of this Agreement shall not constitute a waiver of such provision and shall not affect the right of such party to require performance at a later time. Any waiver of the breach of any term or condition of this Agreement by either party shall not be a continuing waiver and shall not operate to bar the waiving party from claiming a breach of this Agreement for any subsequent breach hereunder.

9.9 No Third Party Beneficiaries. This Agreement shall not create in any manner whatsoever any rights in any third party including, but not limited to, any Medicare fee-for-service beneficiary, but shall be construed to create obligations for the Participating Providers as contemplated herein, provided that CMS shall be considered a third party beneficiary of this Agreement with the right to enforce its terms if required by the MSSP Regulations.

9.10 Governing Law. This Agreement shall be governed and construed in accordance with the laws of the Commonwealth of Pennsylvania.

9.11 Dispute Resolution. In the event of any dispute under this Agreement, the parties agree that they shall 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.

9.12 Counterparts. This Agreement shall be executed in duplicate original, and all notices and amendments made as provided herein shall be made in duplicate and attached to



the respective duplicate originals. Both duplicate originals shall together constitute one and the same instrument.

9.13 Use of Names. The Company may use Participant's name and the name of its Participating Providers and their specialty, address, telephone number ("Identifying Information") in any provider or similar directory. Use of the Participant's name other than in a submission to or as required by CMS or by the MSSP regulations or in directories or in a list of members, such as in advertising that is not a list or directory, shall require Participant's advance written consent, not to be unreasonably withheld.

*[Signature Page Follows]*

**IN WITNESS WHEREOF**, the undersigned have set their hands and seals this \_\_\_\_\_ day of \_\_\_\_\_, 2014.

**[COMPANY NAME]**

By: \_\_\_\_\_  
\_\_\_\_\_, [President]

Address:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Fax #: \_\_\_\_\_

Email: \_\_\_\_\_

**[PARTICIPANT NAME]**

By: \_\_\_\_\_  
Its: \_\_\_\_\_

Address:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Fax #: \_\_\_\_\_

Email: \_\_\_\_\_

**EXHIBIT A**

**List of TINs and NPIs; List of Eligible Professionals  
and those Contract Providers Who Provide Primary Care Services**

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## **EXHIBIT B**

### **Business Associate Exhibit**

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#### **1. DEFINITIONS**

The following are key terms in this Exhibit. The definitions of other terms not defined herein shall have the meaning set forth in the Health Insurance Portability and Accountability Act of 1996 and regulations promulgated thereunder (“HIPAA”), the Health Information Technology for Economic and Clinical Health Act as incorporated in the American Recovery and Reinvestment Act of 2009 and its implementing regulations and guidance as amended from time to time (the “HITECH Act”), as applicable, and as all may be amended, extended or replaced from time to time.

A. “Breach” has the meaning given to such term under the HITECH Act, and regulations and guidance promulgated or issued thereto, as amended, and shall include any incident constituting a suspected, unconfirmed Breach.

B. “Business Associate” means Quality Health Alliance-ACO, LLC.

C. “Covered Entity” means Group.

D. “Designated Record Set” has the meaning set forth in HIPAA.

E. “Disclose” and “Disclosure” mean, with respect to Protected Health Information, the release, transfer, provision of access to, or divulging in any other manner of Protected Health Information outside Business Associate’s internal operations or to other than its workforce.

F. “Electronic Protected Health Information” and “Electronic PHI” mean Protected Health Information or PHI that is transmitted by or maintained in electronic media.

G. “Privacy Officer” means the person who is responsible for the development, implementation and oversight of Covered Entity’s protection of the privacy and confidentiality of Protected Health Information. The Privacy Officer may be contacted via telephone at \_\_\_\_\_ or via U.S. Mail at \_\_\_\_\_.

H. “Protected Health Information” and “PHI” mean 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 received by Business Associate from or on behalf of Covered Entity, or is created by Business Associate, or is made accessible to Business Associate by Covered Entity.

- I. “Required by Law” has the meaning set forth in HIPAA.
- J. “Secretary” means the Secretary of the U.S. Department of Health and Human Services.
- K. “Security Incident” has the meaning set forth in HIPAA.
- L. “Use” and “Uses” mean with respect to Protected Health Information, the sharing, employment, application, utilization, examination or analysis of such Protected Health Information within Business Associate’s internal operations.

## **2. OBLIGATIONS OF BUSINESS ASSOCIATE**

A. Permitted Uses and Disclosures of PHI. Business Associate recognizes and agrees that it is obligated by law to comply with the applicable provisions of the HITECH Act and HIPAA. Business Associate shall Use and Disclose PHI solely as necessary to perform functions, activities or services for, or on behalf of, Covered Entity, provided that such Use or Disclosure would not violate the Privacy Regulations if done by Covered Entity. Business Associate shall not Use or Disclose PHI for any other purpose, except that if necessary, Business Associate may Use and Disclose PHI for the proper management and administration of Business Associate 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) Business Associate obtains a written agreement from the person to whom the PHI is to be Disclosed that such person shall hold the PHI in confidence and shall not use and further disclose such PHI except as Required by Law and for the purpose(s) for which it was Disclosed by Business Associate to such person, and that such person shall notify Business Associate of any instances of which it is aware in which the confidentiality of the PHI has been breached.

B. Adequate Safeguards for PHI. Business Associate warrants that it shall implement and maintain appropriate safeguards to prevent the Use or Disclosure of PHI in any manner other than as permitted by this Exhibit.

C. Mitigation. Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a Use or Disclosure of PHI by Business Associate in violation of the requirements of this Exhibit or of a Breach.

D. Reporting Non-Permitted Use or Disclosure, Security Incident or Breach. Business Associate shall report to Covered Entity’s Privacy Officer each Use or Disclosure that is made by Business Associate, its employees, representatives, agents or subcontractors that is not specifically permitted by this Exhibit. In addition, Business Associate shall report to Covered Entity’s Privacy Officer each Security Incident or Breach of which it becomes aware or discovers has occurred to Business Associate or its agents or subcontractors.

E. Reports of Non-Permitted Uses or Disclosures; Security Incidents. The initial report of any non-permitted Use or Disclosure or Security Incident shall be made by telephone call to Covered Entity’s Privacy Officer within forty-eight (48) hours from the time that Business Associate becomes aware of the non-permitted Use or Disclosure or Security

Incident, followed by a written report to the Covered Entity's Privacy Officer no later than five (5) days from the date that Business Associate becomes aware of the non-permitted Use or Disclosure or Security Incident.

F. Reports of Breach. The initial report of a Breach shall be made by telephone call to Covered Entity's Privacy Officer no later than twenty-four (24) hours from the time that Business Associate discovers a Breach, followed by a written report to Covered Entity's Privacy Officer no later than two (2) business days from the date that Business Associate discovers such Breach. To the extent the information is available to Business Associate, Business Associate's written report to Covered Entity shall include the information required by 45 CFR §164.410, as may be amended from time to time. Business Associate shall promptly supplement the written report with additional information regarding the Breach as it obtains such information.

i. Business Associate shall document and retain records of its investigation of any Breach, including its reports to Covered Entity under this Section 2.4.2 (Reports of a Breach).

ii. Business Associate shall cooperate with Covered Entity in meeting Covered Entity's obligations under the HITECH Act with respect to such Breach. Covered Entity shall have sole control over the timing and method of providing notification of such Breach to the affected individual(s) or others as required by the HITECH Act ("Notification").

iii. Business Associate shall reimburse Covered Entity for Covered Entity's reasonable costs and expenses in providing Notification, including, but not limited to, any administrative costs associated with providing notice, printing and mailing costs, and costs of mitigating the harm (which may include the costs of obtaining credit monitoring services and identity theft insurance, among other costs) for affected individuals whose PHI has or may have been compromised as a result of the Breach. This Section 2.4.2(C) shall be in addition to, and shall in no way limit Business Associate's indemnification obligations set forth in Section 4.3, below.

G. Availability of Internal Practices, Books and Records to Government Agencies. Business Associate agrees to make its internal practices, books and records relating to the Use and Disclosure of PHI available to the Secretary, in a time and manner designated by the Covered Entity or the Secretary, for purposes of determining Covered Entity's compliance with the Privacy Regulations. Business Associate shall immediately notify Covered Entity of any such requests made by the Secretary and, upon Covered Entity's request, provide Covered Entity any copies of such documents Business Associate provided to the Secretary.

H. Access to and Amendment of PHI. Business Associate shall, to the extent Covered Entity determines that any PHI constitutes a Designated Record Set: (a) make the PHI specified by Covered Entity available to the individual(s) identified by Covered Entity as being entitled to access and copy that PHI; and (b) make any amendments to PHI that are requested by Covered Entity. Business Associate shall provide such access and make such amendments

within the time and in the manner specified by Covered Entity, including making PHI available in an electronic format to the individual(s) identified by Covered Entity as being entitled to obtain access to that PHI in an electronic format, as necessary for Covered Entity to comply with 45 CFR § 164.524, as amended by the HITECH Act.

I. Accounting of Disclosures. Upon Covered Entity's request, Business Associate shall provide to Covered Entity an accounting of each Disclosure of PHI made by Business Associate or its employees, agents, representatives or subcontractors as required by the Privacy Regulations. Any accounting provided by Business Associate under this Section (Accounting of Disclosures) shall include: (a) the date of the Disclosure; (b) the name, and address if known, of the entity or person who received the PHI; (c) a brief description of the PHI disclosed; and (d) a brief statement of the purpose of the Disclosure. For each Disclosure that requires an accounting under this Section (Accounting of Disclosures), Business Associate shall track the information specified in (a) through (d), above, and shall securely maintain the information for six (6) years from the date of the Disclosure.

Upon the effective date specified in the HITECH Act, if Business Associate is deemed to use or maintain an electronic health record on behalf of Covered Entity, then in addition to maintaining an accounting of Disclosures as set forth above, Business Associate shall maintain an accounting of any Disclosures made through the electronic health record for treatment, payment and health care operations, as applicable. Such accounting shall comply with the requirements of the HITECH Act. Upon request by Covered Entity, Business Associate shall provide such accounting to Covered Entity in the time and manner specified by the HITECH Act. Alternatively, if Covered Entity responds to an individual's request for an accounting of disclosures made through an electronic health record by providing the requesting individual with a list of all business associates acting on behalf of Covered Entity, then Business Associate shall provide such accounting directly to the requesting individual in the time and manner specified by the HITECH Act.

J. Use of Subcontractors and Agents. Business Associate shall require each of its agents and subcontractors that receive PHI from Business Associate to execute a written agreement obligating the agent or subcontractor to comply with all the terms of this Exhibit. Business Associate shall impose appropriate sanctions against any such agents or subcontractors that violate any requirements, restrictions or conditions that apply to Business Associate through this Exhibit.

K. Security. Business Associate shall maintain a comprehensive, written privacy and security program protecting the confidentiality, integrity and availability of PHI that Business Associate creates, receives, maintains or transmits on behalf of Covered Entity, which includes administrative, technical and physical safeguards appropriate to the size and complexity of Business Associate's operations and the nature and scope of its activities, and as otherwise required by HIPAA. Business Associate shall:

Implement and maintain administrative safeguards as required by 45 CFR § 164.308, physical safeguards as required by 45 CFR § 164.310 and technical safeguards as required by 45 CFR § 164.312;

Implement and document reasonable and appropriate policies and procedures as required by 45 CFR § 164.316;

Comply with all requirements of the HITECH Act related to security and applicable as if Business Associate were a covered entity; and

Use its best efforts to implement and maintain technologies and methodologies that render PHI unusable, unreadable or indecipherable to unauthorized individuals as specified in the HITECH Act.

L. Compliance with Privacy Rule Provisions. Business Associate shall only Use and Disclose PHI in compliance with each applicable requirement of 45 CFR § 164.504(e). Business Associate shall comply with all requirements of the HITECH Act related to privacy and applicable as if Business Associate were a covered entity. Business Associate shall develop and implement policies, procedures and processes to put into practice all applicable requirements of the HITECH Act no later than the applicable effective dates set forth in the HITECH Act.

M. Agreement to Restriction on Disclosure. If Covered Entity is required to comply with a restriction on the disclosure of PHI pursuant to Section 13405 of the HITECH Act, then Covered Entity shall, to the extent needed to comply with such restriction, provide written notice to Business Associate of the name of the individual requesting the restriction and the PHI affected thereby. Business Associate shall, upon receipt of such notification, not Disclose the identified PHI to any health plan for the purposes of carrying out payment or health care operations, except as otherwise Required by Law.

N. Limited Use of PHI. To the extent required by the HITECH Act, Business Associate shall limit its Use, Disclosure or request of PHI to a limited data set or, if needed, to the minimum necessary to accomplish the intended Use, Disclosure or request, respectively. Effective on the date the Secretary issues guidance on what constitutes “minimum necessary” for purposes of HIPAA, Business Associate shall limit its Use, Disclosure or request of PHI to only the minimum necessary as set forth in such guidance.

O. Remuneration for PHI. Upon the effective date specified in the HITECH Act, Business Associate agrees that it shall not, directly or indirectly, receive remuneration in exchange for any PHI of Covered Entity except as otherwise permitted by the HITECH Act.

P. Limitations on Use of PHI for Marketing Purposes. Business Associate shall not Use or Disclose PHI for the purpose of making a communication about a product or service that encourages recipients of the communication to purchase or use the product or service, unless such communication: (a) complies with the requirements of subparagraph (i), (ii) or (iii) of paragraph (1) of the definition of marketing contained in 45 CFR § 164.501, and (b) complies with the requirements of subparagraphs (A), (B) or (C) of Section 13406(a)(2) of the HITECH Act and implementing regulations or guidance that may be issued or amended from time to time.



Q. Privacy/Security Audits. Business Associate shall provide Covered Entity or its third party designee, upon request and reasonable notice, with access to its premises and environment to perform an audit of Business Associate's practices, procedures and mechanisms for protecting the privacy and security of PHI. Notwithstanding the foregoing, Covered Entity is not obligated to conduct any audits of Business Associate. Neither the lack of audit by Covered Entity, nor the failure by Covered Entity to detect or notify Business Associate of unsatisfactory practices, relieves Business Associate of its obligations to comply with this Exhibit, HIPAA and the HITECH Act, or constitutes Covered Entity's acceptance of such practices or a waiver of Covered Entity's rights under this Exhibit.

R. Insurance. In addition to any insurance Business Associate is required to maintain under the terms of the underlying agreement in which Covered Entity shares PHI with Business Associate, Business Associate agrees to procure and maintain errors and omissions insurance and other liability insurance in amounts as shall be necessary to insure Business Associate against any and all claims arising out of its performance of its duties and obligations under this Exhibit. Business Associate shall provide Covered Entity with evidence of such coverage upon Covered Entity's request.

S. No Offshore Work. In performing the functions, activities or services for, or on behalf of, Covered Entity, Business Associate shall not, and shall not permit any of its subcontractors, to transmit or make available any PHI to any entity or individual outside the United States without the prior written consent of Covered Entity.

### **3. TERM AND TERMINATION**

A. Term and Termination. The term of this Exhibit shall be the term of the underlying agreement to which it is an exhibit in which Covered Entity shares PHI with Business Associate. In addition to and notwithstanding any termination provisions set forth in the underlying agreement in which Covered Entity shares PHI with Business Associate, this Exhibit and such underlying agreement(s) may be terminated, in whole or in part, as determined by Covered Entity:

i. if Business Associate has breached a provision of this Exhibit and Business Associate fails to cure such breach (to the extent a cure for such breach is possible) in thirty (30) days of receiving notice from Covered Entity of such breach; or

ii. immediately upon written notice by Covered Entity to Business Associate, if Covered Entity determines, in its sole discretion, that Business Associate has breached a provision of this Exhibit and cure is not possible (it is understood that the cure of a Use and/or Disclosure of PHI made in violation of this Exhibit is not possible for purposes of this Exhibit).

B. Termination by Business Associate. If Business Associate knows of a pattern of activity or practice of Covered Entity that constitutes a material breach or violation of Covered Entity's obligations under this Exhibit, then Business Associate shall immediately notify Covered Entity. With respect to such breach or violation, Business Associate shall (a)

take reasonable steps to cure such breach or end such violation, if possible; or (b) if such steps are either not possible or are unsuccessful, upon written notice to Covered Entity, terminate its relationship with Covered Entity; or (c) if such termination is not feasible, report the Covered Entity's breach or violation to the Secretary. Business Associate shall notify Covered Entity prior to reporting the Covered Entity's breach or violation to the Secretary.

C. Disposition of PHI Upon Termination or Expiration. Upon termination or expiration of the underlying agreement in which Covered Entity shares PHI with Business Associate, Business Associate shall either return or destroy, in Covered Entity's sole discretion and in accordance with any instructions by Covered Entity, all PHI in the possession or control of Business Associate and its agents and subcontractors related to such agreement. However, if Covered Entity determines that neither return nor destruction of PHI is feasible, Business Associate may retain PHI provided that Business Associate: (a) continues to comply with the provisions of this Exhibit for as long as it retains PHI; and (b) further limits Uses and Disclosures of PHI to those purposes that make the return or destruction of PHI infeasible.

#### **4. MISCELLANEOUS**

A. Survival. Business Associate's obligations under Section 2 shall survive the termination or expiration of this Exhibit.

B. No Third Party Beneficiaries. There are no third party beneficiaries to this Exhibit.

C. Ownership. Covered Entity shall retain all ownership rights to the PHI that Business Associate receives, has access to, or creates, in order to perform functions, activities or services on behalf of Covered Entity and any information derived from such PHI.

D. Amendment to Comply with Law. The parties acknowledge that state and federal laws relating to electronic data security and privacy are rapidly evolving and that amendment of this Exhibit may be required to provide for procedures to ensure compliance with such developments. The parties specifically agree to take such action as is necessary to implement the standards and requirements of HIPAA, the HITECH Act and other applicable laws relating to the security or privacy of PHI. Upon Covered Entity's request, Business Associate agrees to promptly enter into negotiations with Covered Entity concerning the terms of any amendment to this Exhibit embodying written assurances consistent with the standards and requirements of HIPAA, the HITECH Act or other applicable laws. Covered Entity may terminate the Exhibit upon thirty (30) days written notice in the event Business Associate does not enter into an amendment to this Exhibit providing assurances regarding the safeguarding of PHI that Covered Entity, in its sole discretion, deems sufficient to satisfy the standards and requirements of HIPAA, the HITECH Act or other applicable laws.

E. Relationship to Other Exhibit Provisions. In the event that a provision of this Exhibit is contrary to a provision of an underlying agreement(s) in which Covered Entity shares PHI with Business Associate, the provision of this Exhibit shall control. Otherwise, this Exhibit shall be construed under, and in accordance with, the terms of such underlying agreement(s) between Business Associate and Covered Entity.

F. Modification Of Exhibit. No alteration, amendment, or modification of the terms of this Exhibit shall be valid or effective unless in writing and signed by Business Associate and Covered Entity.

G. Non-Waiver. A failure of any party to enforce at any time any term, provision or condition of this Exhibit, or to exercise any right or option herein, shall in no way operate as a waiver thereof, nor shall any single or partial exercise preclude any other right or option herein; in no way whatsoever shall a waiver of any term, provision or condition of this Exhibit be valid unless in writing, signed by the waiving party, and only to the extent set forth in such writing.

H. Exhibit Drafted By All Parties. This Exhibit is the result of arm's length negotiations between the parties and shall be construed to have been drafted by all parties such that any ambiguities in this Exhibit shall not be construed against either party.

I. Severability. If any provision of this Exhibit is found to be invalid or unenforceable by any court, such provision shall be ineffective only to the extent that it is in contravention of applicable laws without invalidating the remaining provisions hereof.

J. Section Headings. The section headings contained herein are for convenience in reference and are not intended to define or limit the scope of any provision of this Exhibit.

K. Notices. Any notices required or permitted to be given under this Exhibit by either party to the other shall be given in writing: (a) by personal delivery; (b) by electronic facsimile with confirmation sent by United States first class registered or certified mail, postage prepaid, return receipt requested; (c) by bonded courier or by a nationally recognized overnight delivery service; or (d) by United States first class registered or certified mail, postage prepaid, return receipt requested, in each case, addressed to the parties at the addresses set forth on the first page of this Exhibit (or to such other addresses as the parties may request in writing by notice given pursuant to this Section (Notices)). Notices shall be deemed received on the earliest of personal delivery, upon delivery by electronic facsimile with confirmation from the transmitting machine that the transmission was completed, twenty-four (24) hours following deposit with a bonded courier or overnight delivery service; or seventy-two (72) hours following deposit in the U.S. Mail as required herein.

L. Applicable Law. This Exhibit shall be governed by and construed in accordance with the internal laws of the Commonwealth of Pennsylvania (without regard to principles of conflicts of laws).

M. Interpretation. Any ambiguity in this Exhibit shall be resolved to permit Covered Entity to comply with HIPAA and the HITECH Act, as applicable.