CMS BUNDED PAYMENTS FOR CARE IMPROVEMENT MODEL 4

JERSEY SHORE UNIVERSITY MEDICAL CENTER, A DIVISION OF MERIDIAN HOSPITALS CORPORATION

PARTICIPATING GAINSHARING AGREEMENT

THIS PARTICIPATING GAINSHARING AGREEMENT (the “Agreement”) is made as of the 25th day of November, 2013 (the “Effective Date”) by and among Jersey Shore University Medical Center, a Division of Meridian Hospitals Corporation (“JSUMC”) and the practice identified on the signature page hereof (the “Practice”) and physician(s) (“Physician” or “Participating Physician”) identified on Exhibit A. JSUMC, the Practice and the Participating Physician are the “Parties,” and each is a “Party.”

Introduction

JSUMC has entered into an agreement (“Model 4 Agreement”), with the Centers for Medicare & Medicaid Services (“CMS”) to participate in the Medicare Bundled Payments for Care Improvement Model 4 initiative (“Model 4”) to provide services to Medicare fee-for-service beneficiaries (each, a “Model 4 Beneficiary”) eligible for Part A and enrolled in Part B, and who receive inpatient hospital care at JSUMC for a Clinical Episode (as defined below). Under the Model 4 Agreement, JSUMC is the Awardee, the Episode Initiator, the BCPI Entity, and the Episode-Integrated Provider (or EIP) and no other entity fills these roles. For purposes of this Agreement, JSUMC is referred to as “Awardee” or “EIP”. The goal of Model 4 is to incentivize Care Redesign; protect beneficiaries; and learn and diffuse best practices, in order to inform potential changes to the Medicare fee-for-service (FFS) program. This Agreement sets forth the terms and conditions that will apply to Participating Physicians and other licensed health care providers employed by, or contracted with, the Practice and who bill for items and services furnished to Model 4 Beneficiaries under the Medicare billing number assigned to the tax identification number (“TIN”) of the Practice (each, a “Provider”). The Practice wishes for its Participating Physicians and other Providers to provide and arrange for care to Model 4 Beneficiaries in accordance with the terms and conditions set forth in this Agreement and the terms of the Model 4 Agreement, including the Implementation Protocol submitted to CMS in accordance with the Model 4 Agreement, and the provisions of Exhibit B, attached hereto and incorporated herein (“Model 4 Requirements”).

Article 1 - Definitions

1.1 “Care Redesign” means the specific planned interventions and changes to the Awardee’s current health care model(s) that are described herein and set forth with particularity in the Implementation Protocol that will be submitted to CMS by Awardee. Care Redesign elements may include, but are not limited to, the following:

a. Interventions and changes to improve quality of care, beneficiary outcomes, and beneficiary experience of care that are intended to result in Internal Cost Savings; and

b. Quality performance measures and targets.
1.2 **Clinical Episode** means the following family of related MS-DRGs for a clinical condition to be tested through an Episode of Care under Model 4:

- **DRG 231** Coronary Bypass w/ PTCA w/ MCC*
- **DRG 232** Coronary Bypass w/ PTCA w/o MCC*
- **DRG 233** Coronary Bypass w/ Cardiac Cath w/ MCC*
- **DRG 234** Coronary Bypass w/ Cardiac Cath w/o MCC*
- **DRG 235** Coronary Bypass w/o Cardiac Cath w/ MCC*
- **DRG 236** Coronary Bypass w/o Cardiac Cath w/o MCC*

*MCC = major co-morbidities or complications

1.3 **Covered Services** means all medical, surgical and related health care services provided by Practice or its Participating Physicians or other Providers to a Model 4 Beneficiary during a Clinical Episode, which are eligible for Medicare Part B payment.

1.4 **Episode of Care** means a Model 4 Beneficiary’s first inpatient stay at EIP for a Clinical Episode and the 30-day period immediately following the Model 4 Beneficiary’s discharge from EIP for the Clinical Episode.

1.5 **Evaluation and Monitoring Plan** means the written plan, developed by CMS, which outlines the steps to be taken to evaluate and monitor the performance of all participants in Model 4 at EIP.

1.6 **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.


1.8 **Implementation Protocol** means the written implementation protocol, developed by Awardee subject to CMS approval, which outlines processes to implement Care Redesign under Model 4.

1.9 **Medically Necessary** means reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member.

1.10 **NPI** means National Provider Identifier.
“Policies and Procedures” means any and all of Awardee’s standards, policies, protocols, regulations, and procedures set forth in writing and made available to Practice and Participating Physicians and Providers during the term of this Agreement, including, but not limited to, any Care Redesign.

“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 Model 4 as contemplated in, and subject to the terms and conditions of, this Agreement and the Model 4 Agreement, Implementation Protocol and Evaluation and Monitoring Plan. Practice and the Participating Physicians acknowledge that Awardee has provided access to the Model 4 Agreement. Once the Implementation Protocol has been approved by CMS, Awardee will similarly provide access to the Implementation Protocol and Evaluation and Monitoring Plan. Practice and the Participating Physicians agree to abide by the Awardee’s Policies and Procedures, and to comply with the Model 4 Agreement and the Implementation Protocol and Evaluation and Monitoring Plan to the extent applicable to Practice, its Providers and the Participating Physicians. Awardee 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. Awardee may also amend the Implementation Protocol at any time, subject to review by CMS, 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 amendments necessary to comply with laws and regulations do not require thirty (30) days prior notice and shall be effective as stated in such notice. The Parties acknowledge that CMS may unilaterally amend the Model 4 Agreement and/or the Evaluation and Monitoring Plan upon notice to Awardee. Awardee will inform Practice of such changes in a timely manner. Participating Physicians shall and Practice shall, and shall ensure that its Providers, abide by the determinations of Awardee’s Board in all matters related to Participating Physicians’, Practice’s and its Providers’ compliance with the Policies and Procedures, the Implementation Protocol, and Evaluation and Monitoring Plan, the Model 4 Agreement, and this Agreement.

2.2 **Model 4 Requirements.** Practice, on behalf of it and its Providers, and Participating Physicians hereby agree to comply with all Model 4 Requirements, as set forth in this Agreement and attached as Exhibit B. In the event of a conflict or inconsistency between this Agreement and/or the Awardee’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, in compliance with all Medicare provider enrollment requirements at 42 C.F.R. 424.500 et seq., including having a valid and active TIN/NPI, and 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 EIP, a New Jersey hospital that is accredited by an accrediting body recognized by CMS.

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 EIP in writing and EIP 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 EIP 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 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 that 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 EIP within thirty (30) days of any change:
a. of Practice’s address(es), phone number(s), or TIN;

b. in Practice’s roster of Participating Physicians or Providers participating in Model 4, including the termination or retirement of any Participating Physician or Provider; or

c. of Practice’s, any Participating Physician’s, or any Provider’s NPI.

2.6 **Care Redesign.** Practice and each Participating Physician agrees to use commercially reasonable efforts to assist the EIP in implementing its Care Redesign program, which includes, but is not limited to, the promotion of evidence-based medicine, the promotion of patient engagement, and the development of an infrastructure for the EIP and the Participating Physicians to internally report on quality and cost metrics that will enable the EIP to monitor, provide feedback, and evaluate performance and to use these results to provide quality care, improved outcomes, and improved health for Model 4 Beneficiaries, and lower cost for Medicare. Practice and the Participating Physicians understand that Care Redesign and the success of Model 4 require Practice’s and the Participating Physicians’ active and ongoing participation. Practice, therefore, agrees that it and its Participating Physicians shall cooperate in the implementation of EIP’s Care Redesign program.

2.7 **Medical Necessity.** 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.

2.8 **Joinder Agreement.** The Practice acknowledges and agrees that EIP shall require from each Participating Physician a signature and the requested information on the form attached hereto as Exhibit A.

2.9 **Billing and Collecting Fees for Professional Services.** Practice, or each Participating Physician, shall submit claims to Medicare for services rendered to Model 4 Beneficiaries in the usual manner. **Such claims shall be submitted on a weekly basis, but in any event within thirty (30) days of the provision of care.** Practice and the Participating Physicians understand that the success of Model 4 depends in part on EIP having timely access to information regarding services provided to Model 4 Beneficiaries, and delays in submitting Part B claims to CMS may jeopardize the ongoing success of the program. Claims for services provided while the Model 4 Beneficiary is an inpatient at EIP during an Episode of Care will, however, be considered “no-pay” claims by Medicare (subject to the “opt out” provision set forth below). If a Part B no-pay claim is paid by Medicare for a Model 4 Beneficiary, the claim will be reprocessed by Medicare and payment will be recouped from the Practice or Participating Physician. EIP will receive a report each week from CMS of all of the no-pay claims associated with Model 4 at EIP. EIP will then process payment (through EIP’s contractor, EA Health) to Practice or its Participating Physicians at a rate equivalent to the amount that would have been paid for those services under the Medicare Physician Fee Schedule. Receipt of such payment shall be considered payment in full for services furnished by Practice or its Providers or Participating Physicians to Model 4 Beneficiaries during an Episode of Care. Payment will not be made under applicable Medicare FFS payment rules unless the Provider or Participating Physician has opted out of the Model 4 payment methodology in accordance
with the process described below. Practice and its Participating Physicians and other Providers shall cooperate in the billing and claims payment process so that payment may be made in accordance with the Model 4 Agreement. Unassigned Part B claims are excluded from Model 4.

2.10 **Opt Out.** Participation in Model 4 is voluntary. The Participating Physicians or Practice’s other Providers may opt out of Model 4. In order to opt out, the individual opting out must include a specific HCPCS modifier on each and every claim for services provided to Model 4 Beneficiaries. In those instances, payment will be made by CMS in accordance with regular Medicare FFS payment rules. If a claim is submitted or resubmitted to CMS with the modifier after payment has been made by EIP, the Practice or Participating Physician, as appropriate, will promptly return to EIP the payment made by EIP so that only one payment is made (by CMS or EIP). Practice or the Participating Physician shall give prompt notice to EIP in the event of an opt out.

2.11 **Gainsharing.** Subject to compliance with the requirements set forth on Exhibit C attached hereto, Practice and/or Participating Physicians may be eligible to receive Incentive Payments (as defined on Exhibit C hereto). A Practice and/or Participating Physician who opts out is not eligible for Incentive Payments.

**Article 3 – Awardee/EIP Obligations**

3.1 **Quality Performance Activities.** As part of its Model 4 obligations, Awardee 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 Model 4 obligations, Awardee will define processes to promote Model 4 Beneficiary 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 Participating Physician or other Provider’s relationship with his or her patients. The final decision to provide, or withhold, Covered Services is to be made by each Participation Physician or other 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 EIP has sufficient data and information related to patient care to achieve success in Model 4, Practice agrees that EIP, acting in its capacity as Practice’s and Participating Physicians’ business associate under the Business Associate Agreement attached hereto as Exhibit D, 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 Model 4 Beneficiary. Such data may be compiled into reports and used by EIP to monitor Covered Services provided to Model 4 Beneficiaries and each Participating Physician’s performance in relation to EIP’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 Audits and Fraud, Waste, and Abuse. Consistent with federal regulations, Practice and its Providers and the Participating Physicians shall fully cooperate with Awardee’s initiatives, policies, procedures, processes, and programs relating to: (a) Awardee’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 Awardee’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 Effective Date first noted above and will remain in effect until 180 calendar days after the final settlement following the end of the final performance year under the Model 4 Agreement, unless otherwise terminated in accordance with Section 4.2 below.

4.2 Termination.

a. Insolvency. Either Awardee 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.

b. Termination for Breach. Either Awardee 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.

c. Termination of Model 4 Agreement. This Agreement shall automatically terminate if Awardee’s Model 4 Agreement with CMS terminates for any reason. Awardee shall give Practice notice of such termination in accordance with the Model 4 Agreement.

d. Termination of Practice, Participating Physician or Provider by CMS. Under the Model 4 Agreement, CMS has the authority to direct Awardee to terminate the Practice, a Participating Physician, or another Provider for any of the reasons set forth in the Model 4 Agreement. This Agreement shall terminate upon receipt of notice of such action by CMS, provided, however, that if such notice is limited to one or more but not all Participating Physicians or other Providers, and does not apply to the Practice or other Participating Physicians or other Providers, then this Agreement shall continue in full force and effect without participation by the terminated individuals unless otherwise terminated as provided herein.
Corrective Action Plan. If CMS requires Awardee to submit a corrective action plan to avoid termination of the Model 4 Agreement, then Practice, the Participating Physicians and other Providers shall comply with all applicable provisions of the corrective action plan to ensure compliance with the Model 4 Agreement.

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 agree 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, Awardee 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 Model 4 requirements, do not require the consent of Practice or Participating Physicians and shall be effective as stated in Awardee’s notice of amendment. In the event CMS unilaterally amends the Model 4 Agreement in a manner that affects the terms of this Agreement, this Agreement shall be amended accordingly and Awardee shall provide notice of such amendment to Practice, which notice shall specify the effective date of such amendment.

5.5 Confidentiality. This Agreement is confidential between the Parties, and the Parties hereto shall not release information concerning this Agreement, the Model 4 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, Awardee 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 Awardee 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 Awardee’s participation in Model 4, 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 Awardee 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.** Awardee 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 Model 4 Beneficiary or other third party in connection with the delivery of
Covered Services. Awardee 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 Awardee 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:**

_____________________________

**AWARDEE/EIP:**

JERSEY SHORE UNIVERSITY MEDICAL CENTER, A DIVISION OF MERIDIAN HOSPITALS CORPORATION

By: __________________________

Name: _________________________

Title: __________________________

Tax Identification No.:___________

**Address for Notices:**

_____________________________

_____________________________

_____________________________

_____________________________

Jersey Shore University Medical Center

1945 State Route 33

Neptune, New Jersey 07753

Attention: President

**With a Copy To:**

1350 Campus Parkway

Neptune, New Jersey 07753

Fax: (732) 751-7544

Attn: Legal Department
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 Model 4 through Awardee, and agrees that all notices shall be delivered to him/her at the address set forth for the Practice.

PARTICIPATING PHYSICIAN

__________________________________________________________________________
Print Name: ____________________________
TIN: _______________ NPI: _______________
Make payments to me__ or Practice ___ (check one)
I do___/do not___ (check one) participate in CMS’
Physician Quality Reporting System (PQRS)

PARTICIPATING PHYSICIAN

__________________________________________________________________________
Print Name: ____________________________
TIN: _______________ NPI: _______________
Make payments to me__ or Practice ___ (check one)
I do___/do not___ (check one) participate in CMS’
Physician Quality Reporting System (PQRS)

PARTICIPATING PHYSICIAN

__________________________________________________________________________
Print Name: ____________________________
TIN: _______________ NPI: _______________
Make payments to me__ or Practice ___ (check one)
I do___/do not___ (check one) participate in CMS’
Physician Quality Reporting System (PQRS)

PARTICIPATING PHYSICIAN

__________________________________________________________________________
Print Name: ____________________________
TIN: _______________ NPI: _______________
Make payments to me__ or Practice ___ (check one)
I do___/do not___ (check one) participate in CMS’
Physician Quality Reporting System (PQRS)

MAKE ADDITIONAL COPIES OF THIS PAGE IF NEEDED.
EXHIBIT B

CMS REQUIREMENTS FOR MODEL 4 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 Model 4 Beneficiaries under this Agreement and pursuant to the terms of the Model 4 Agreement and Implementation Protocol.

1. **Model 4 Mission.** Participating Physicians and Practice agree, and Practice shall require its Providers, to use commercially reasonable efforts to assist EIP in fulfilling its purpose (the “Model 4 Mission”) under Model 4. The Model 4 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 providers to internally report on quality and cost metrics that enables the EIP to monitor, provide feedback, and evaluate its providers’ performance and to use these results to provide better care and improved health for Model 4 Beneficiaries and lower cost for Medicare.

2. **Compliance with Model 4 Agreement.** Participating Physicians and Practice agree, and shall require its Providers, to comply with the applicable terms and conditions of the Model 4 Agreement and to be subject to all submissions made by Awardee to CMS related to Model 4, including without limitation, the Implementation Protocol, as they may be amended from time to time. Awardee will provide access to such documentation through a web-based portal.

3. **Compliance with Law.** Participating Physicians and Practice shall comply, and Practice shall contractually require its employees and its Providers providing services hereunder to make medically necessary services available to Model 4 Beneficiaries in accordance with law, and to comply, with any and all applicable federal and state laws, regulations and guidance, 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); and (f) those requirements specified in the Model 4 Agreement (collectively the “Applicable Requirements”).

4. **Model 4 Beneficiary Inducements.** Practice, its Providers and Participating Physicians are prohibited from:

   a. providing gifts or other remuneration to Model 4 Beneficiaries as inducements for receiving items or services from, or remaining in, the EIP or with Practice, a Participating Physician, or its other Providers, or receiving items or services from Practice, a Participating Physician, or its other Providers; provided, Practice or a Participating Physician may provide in-kind items or services to Model 4 Beneficiaries if there is a reasonable connection between the items and services and the medical care of the Model 4 Beneficiary and the items or services are preventive care items or services or advance a clinical goal for the Model 4 Beneficiary, including adherence to a treatment regimen, adherence to a drug regimen, 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 other Provider on referrals of Federal health care program business or the volume or value of business between the parties.
c. participating in adverse patient selection (such as avoidance of difficult to treat patients), care stinting, inappropriate cost shifting, inappropriate increases in utilization, or inappropriate steering of patients with respect to potential or actual Model 4 Beneficiaries.

d. committing any act or omission, or adopting any policy, that inhibits Model 4 Beneficiaries from exercising their freedom of choice to obtain health care services from other health care providers.

5. **Model 4 Information.** Participating Physicians and Practice agree to participate in the Model 4 Beneficiary notification process if requested by EIP. Neither the Participating Physicians, the Practice, nor the other Providers, shall publish or release any information, report, or statistical/analytical material that references his/her/its participation in Model 4 or the terms of the Model 4 Agreement.

6. **Confidentiality of Records and Enrollment Information.** Participating Physicians and Practice shall comply, and Practice shall require each Provider 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, and Providers, maintain with respect to Model 4 Beneficiaries. Nothing herein shall be construed to limit or restrict appropriate sharing of Protected Health Information and medical record data with the EIP or other Medicare fee-for-service providers and suppliers if such sharing is done in accordance with HIPAA and other federal and state health care privacy and security laws and regulations.

7. **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 periodically thereafter, to ensure compliance with this Section 6;

   b. provide documentation, upon written request by EIP, of such screening;

   c. immediately notify EIP 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 EIP based on the above notification.

8. **Model 4 Beneficiaries Hold Harmless.** Neither Practice, nor Participating Physicians, nor Providers shall, in any event, including, without limitation, insolvency of EIP 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 Model 4 Beneficiary or any other person acting on behalf of any Model 4 Beneficiary for Covered Services. Practice agrees that neither Practice, nor any Participating Physician or Provider shall
maintain any action at law or equity against a Model 4 Beneficiary to collect sums owed to Practice or any Participating Physician or Provider pursuant to this Agreement. 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 Model 4 Beneficiaries; 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 Model 4 Beneficiary or a person acting on an Model 4 Beneficiary’s behalf.

9. **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 Model 4 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, EIP’s policies, and the Model 4 Agreement, and shall be sufficient to allow EIP 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, EIP 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) Awardee’s compliance with the Model 4 Agreement or Practice’s, any Participating Physician’s or any Provider’s compliance with the Model 4 Requirements; (2) the quality of services performed and determination of amounts due to or from CMS under the Model 4 Agreement; (3) patient safety, (4) Medicare Part A and Part B billing during an Episode of Care, and (5) any other lawful purpose related to Model 4.

   c. Practice shall furnish copies of Records at no additional cost to EIP, and EIP will provide such Records directly to the applicable regulatory agency unless EIP, in its discretion, directs Practice to furnish copies directly to the applicable regulatory agency.

   d. Practice shall permit CMS, HHS, the Comptroller General and EIP 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 8, 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 Model 4 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 EIP 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 EIP, Practice, a Participating Physician, a Provider, EIP’s providers or other individuals or entities performing functions or services related to EIP’s activities.
under the Model 4 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.

10. Monitoring. Practice acknowledges and understands that EIP has a contractual obligation to CMS to comply with the Applicable Requirements and that EIP is ultimately responsible and accountable to CMS for compliance with all terms and conditions of the Model 4 Agreement. Practice shall permit EIP, directly or through its representatives, to monitor the services furnished under this Agreement on an on-going basis, in any reasonable manner that EIP or CMS deems appropriate for compliance with EIP’s obligations to CMS.

11. Non-compliance. When necessary, EIP 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 EIP 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 quality performance standards, EIP may use progressive remedial processes and sanctions to improve compliance and performance. Such measures may include adoption and implementation of corrective action plans, and the potential for expulsion. The EIP will adopt specific Policies and Procedures regarding non-compliance issues.

12. 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 EIP, or to CMS as directed by EIP, 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 EIP’s reporting obligations under the Model 4 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 Participating Physicians and other Providers. Such data and information shall be submitted by Practice and the Participating Physicians in compliance with the Applicable Requirements.

   b. Prior to any data submission to CMS and at any time thereafter, EIP shall have the right to review and audit the data that will be submitted by Practice so that EIP 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 11 shall survive termination of this Agreement, regardless of the cause giving rise to termination.

13. Compliance Program and Anti-Fraud Initiatives. EIP 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 Model 4 and the federal healthcare program generally. Practice and Participating Physicians shall, and Practice shall contractually require its Providers to, comply with all requirements of EIP’s compliance program. EIP’s compliance program shall be appropriate to EIP’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 EIP and reports directly to the EIP’s governing body;

b. mechanisms for identifying and addressing compliance problems related to the EIP’s operations and performance;

c. a method for Participating Physicians, employees or contractors of the Practice including Providers, and other providers to anonymously report suspected problems related to the EIP to the compliance officer;

d. make available compliance training for Practice, Participating Physicians, Providers and other providers; and

e. a requirement that EIP, Practice Participating Physicians, and Providers report probable violations of law to an appropriate law enforcement agency.

14. Certifications/Attestation. Practice and the Participating Physicians hereby certify and attest, and Practice certifies and attests with respect to the Providers, that:

a. The Practice, each of its Participating Physicians, and each of its Providers are currently, and for the duration of this Agreement shall remain, in compliance with all Medicare provider enrollment requirements at 42 C.F.R. 424.500 et seq., including having a valid and active TIN/NPI, and shall remain participants in the Medicare fee-for-service program;

b. 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 Model 4 Beneficiaries treated at EIP under Model 4; (b) will comply with and implement EIP’s processes to promote evidence-based medicine and patient engagements; and (c) shall be held accountable for meeting EIP’s performance standards for each required process as required under this Agreement;

c. Practice, Participating Physicians, and Providers are, to the best of Practice’s knowledge, information and belief, in compliance with the Model 4 Requirements and act consistent with the Model 4 Mission; and

d. 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 EIP’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.

15. Reservation of Rights. Nothing contained in this Agreement is intended or shall be construed as a waiver by the United States Department of Justice, the Internal Revenue Service, the Federal Trade Commission, HHS Office of the Inspector General, CMS or any other governmental authority of any right to audit, evaluate, inspect or institute any proceeding or action against EIP, Practice, the Participating Physicians, the Providers, or any other person or entity for violations of any statutes, rules or regulations administered by the government, or to prevent or limit the rights of the government to obtain relief under any other federal statutes or regulations, or on account of
any violation of this Agreement or any other provision of law. This Agreement shall not be construed to bind any government agency.
EXHIBIT C
CMS REQUIREMENTS FOR GAINSHARING PROVISIONS FOR MODEL 4

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 C with respect to participating in the Gainsharing program related to Model 4 and pursuant to the terms of the Model 4 Agreement and Implementation Protocol. For purposes of this Exhibit C, Practice and Participating Physicians shall be referred to as “Gainsharers”.

A. Additional Definitions:

1. “BPCI Savings Pool” means a collection of funds that consists solely of contributions from EIP of Internal Cost Savings (collectively, “BPCI Savings”) that are made available to distribute as Incentive Payments pursuant to this Agreement.

2. “Gainsharing” means the arrangement, memorialized in this Agreement, for (i) the generation of Internal Cost Savings attributable to Care Redesign; (ii) the collection of Internal Cost Savings amounts to be contributed to the BPCI Savings Pool from EIP; and (iii) the distribution of Incentive Payments from the BPCI Savings Pool to the EIP and/or the Practice and/or Participating Physicians and other participating practices and/or participating physicians.

3. “Incentive Payment” means (i) a payment made directly or indirectly from the BPCI Savings Pool to EIP, pursuant to this Agreement, or (ii) a payment of a portion of BPCI Savings from EIP to a gainsharing Practice or Physician, pursuant to this Agreement.

4. “Internal Cost Savings” means the measurable, actual, and verifiable cost savings realized by EIP resulting from Care Redesign undertaken by EIP in connection with providing items and services to Model 4 Beneficiaries within specific Episodes of Care. Internal Cost Savings does not include savings realized by any individual or entity that is not EIP.

B. Additional Requirements:

1. Gainsharers shall be limited to cardiothoracic surgeons, cardiothoracic anesthesiologists, and cardiologists who provide services to a Model 4 Beneficiary during an Episode of Care and who qualify to receive an Incentive Payment under the methodology for computation and distribution of payments set forth in Section C below. Practices and Participating Physicians who opt out of Model 4 are not eligible to receive Incentive Payments.

2. Neither the Awardee nor any Gainsharer shall condition the opportunity to receive Incentive Payments on the volume or value of past or anticipated referrals or other business generated to, from, or among the Awardee and any Gainsharer.

3. Gainsharers that fail to meet the gainsharing quality performance targets described with particularity in the Implementation Protocol and the quality specifications in the Evaluation and Monitoring Plan will not be eligible to receive Incentive Payments either directly or indirectly.

4. Incentive Payments must not induce EIP and/or Gainsharers to reduce or limit Medically Necessary services to any Medicare beneficiary.
5. Individual physicians and nonphysician practitioners shall retain their ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments.

6. Gainsharing methodologies for calculating Incentive Payments shall not directly account for volume or value of referrals, or business otherwise generated, between or among EIP and/or Gainsharers.

7. Incentive Payments shall be derived solely from the BPCI Savings contained in the BPCI Savings Pool.

8. The total amount of Incentive Payments for a contract year paid to a Gainsharer shall not exceed a cap which is determined by taking 50 percent of the total Medicare expenditures paid under the Physician Fee Schedule to all physicians or nonphysician practitioners and Gainsharers for furnishing services to Model 4 Beneficiaries by Clinical Episode during that contract year divided by the total number of physicians or nonphysician practitioners and Gainsharers furnishing services to Model 4 Beneficiaries by Clinical Episode during that contract year. Incentive Payments are also subject to the limitations set forth in the methodology for computation and distribution of payments set forth in Section C below.

9. Gainsharers shall comply with all applicable Medicare laws, rules and regulations, and shall comply with any Corrective Action Plan instituted by CMS pursuant to the Model 4 Agreement.

10. If CMS determines that any TIN/NPI/other identifier associated with a Gainsharer is no longer valid or active, and CMS notifies the Awardee that the Gainsharer is no longer eligible, upon receipt of such notification, Awardee shall immediately suspend the distribution of all Incentive Payments to the affected Gainsharer(s). Further, upon CMS’ termination of the Model 4 Agreement, Awardee shall immediately cease the distribution of funds from the BPCI Savings Pool.

11. Gainsharers shall provide sufficient access to all necessary records, data, and information to Awardee to enable it to carry out its responsibilities with respect to monitoring and enforcing the payment provisions, quality provisions, and gainsharing provisions of this Agreement and the Model 4 Agreement.

12. Gainsharers shall participate in all applicable CMS quality reporting initiatives, including the Physician Quality Reporting System (PQRS), and shall provide all required quality reporting data as required pursuant to the Evaluation and Monitoring Plan.

13. Gainsharers shall participate in regular compliance training made available for individuals participating in Model 4 at the Awardee.

14. Practice will receive regular reports (at least bi-annually) of group and individual Participating Physician performance relative to EIP’s performance initiatives and on the CMS performance standards, which Practice shall distribute to Participating Physicians.
15. In order for a particular Model 4 case to be eligible for inclusion in the Savings Pool, all quality indicators must be met by all Gainsharers providing services to the Model 4 Beneficiary.

C. **Incentive Payments.** Incentive Payments will be calculated according to the following process and computation:

1. **Methodology:** Every 6 months the EIP will perform a reconciliation to determine the fiscal impact from the Model 4 Program and the potential Gainsharing Incentive Payments. This will involve three calculations:
   
   1. The Benchmark Cost of the Model 4 Program (Cost B).
   2. The Actual Cost of the Model 4 Program (Cost A).
   3. The BPCI Savings Pool.

   1. The Benchmark Cost (Cost B) will be the sum of four components over a six month timeframe which are then averaged as a cost per case and volume adjusted. These 4 components include:
      a. Direct costs of the DRG from the hospital cost accounting system.
      b. Part B costs taken from the CMS data.
      c. Readmission Part A payments taken from CMS data.
      d. Readmission Part B costs taken from CMS data.

      **Note:** Retrospective CMS data utilized will be the most recent six months available and will be updated to mirror any updates CMS performs to the baseline assessment period.

   2. The Actual Cost (Cost A) of the Model 4 Program will be the sum of four components which are averaged as a cost per case and volume adjusted. These 4 components include:
      a. The actual direct costs of the DRG from the hospital cost accounting system over the 6 month timeframe for admissions and any readmission to the EIP.
      b. Part B payments for the initial Episode of Care and readmissions to EIP.
      c. The Medicare withholds that occur for readmissions at other hospitals (outside readmissions Part A).
      d. The Medicare withholds that occur for the readmission Part B fees at other hospitals (outside readmissions Part B).


   *Each DRG (231, 232, 233, 234, 235, & 236) will have a separate Savings Pool, but follow an identical methodology.*
2. **Distribution of Incentive Payments:** The BPCI Savings Pool will undergo several adjustments to establish the Gainsharing Incentive Payment:

a. Subtracted from the BPCI Savings Pool will be the EIP expenses for the Model 4 Program
   i. Bundled Payment Discount
   ii. Physician payment management service (outside vendor).

b. “Quality adjustment” will be calculated.
   i. Multiplied by the percentage of index cases meeting 100% compliance with Gainsharing Quality Performance Targets. These cases are called “eligible cases”.

c. Balance will be allocated as follows for eligible cases:
   i. 50% Cardiothoracic (CT) Surgeon
   ii. 25% Cardiothoracic (CT) Anesthesiologist
   iii. 25% Cardiologist.*

d. A maximum incentive payment threshold for the Gainsharers determined by multiplying 25% of the Part B payments for their specialty in this index admission for each eligible case.

e. Incentive Payment for Gainsharer specialty will be the lower of the two calculations
   i. The quality adjusted allocation OR
   ii. The maximum incentive payment threshold

f. Incentive payments to the CT Surgical group and CT Anesthesiology group will be in aggregate, while payment for the Cardiologists will be by group or be individualized.

g. Incentive payments are expected to be made bi-annually.

h. Any excess funds will be retained by the hospital, for example:
   i. Ineligible cases from quality adjustment
   ii. Incentive payment beyond threshold

*The Cardiologist incentive payment will be determined as follows:

<table>
<thead>
<tr>
<th>Description</th>
<th>Gainsharing Physician</th>
</tr>
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<tbody>
<tr>
<td>Without Cath Intervention</td>
<td>Post-op cardiologist</td>
</tr>
<tr>
<td>With Cath Intervention – pre and post-op cardiologists from the same physician practice</td>
<td>Interventional cardiologist</td>
</tr>
<tr>
<td>With Cath Intervention – pre and post-op cardiologists from different physician practices</td>
<td>Interventional cardiologist</td>
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</tbody>
</table>
EXHIBIT D
BUSINESS ASSOCIATE ADDENDUM

THIS BUSINESS ASSOCIATE ADDENDUM (the “Agreement”) supplements and is made a part of the Participating Third Party Provider Agreement (“Underlying Agreement”) by and between Practice (“Covered Entity”) and Jersey Shore University Medical Center, a division of Meridian Hospitals Corporation (“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 the CMS Bundled Payment for Care Improvement Model 4 initiative (“Model 4”) as implemented pursuant to an agreement between Business Associate and the Centers for Medicare and Medicaid Services (“CMS”); and

WHEREAS, if and only to the extent that Business Associate uses and/or discloses Covered Entity’s PHI in connection with the Underlying Agreement, 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
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.