

MARYLAND PRIMARY CARE PROGRAM

CARE TRANSFORMATION ARRANGEMENT

This Care Transformation Arrangement (“Arrangement”) is between Netrin Accountable Care, a care transformation organization (the “CTO”), and [Name of Practice] **SAMPLE Only – Do NOT Complete Now** __, (the “Practice”) (each a “Party,” and collectively the “Parties”).

The CTO has been selected by the Centers for Medicare and Medicaid Services (“CMS”), Center for Medicare and Medicaid Innovation (“CMMI”), to serve as a care transformation organization in the Maryland Primary Care Program (“MDPCP”). The Practice is a primary care practice that provides health care services to Medicare beneficiaries, among others, in the State of Maryland.

This Arrangement sets forth the terms and conditions under which the CTO will provide to the Practice certain care transformation services and resources consistent with MDPCP requirements.

1. **Participation Agreements.** Prior to the Effective Date of this Arrangement, the CTO must sign an MDPCP Participation Agreement with CMMI (the “CTO Participation Agreement”). Prior to the Effective Date of this Arrangement, the Practice must sign an MDPCP Participation Agreement with CMMI (the “Practice Participation Agreement”). If either Party does not sign a Participation Agreement with CMMI prior to the Effective Date of this Arrangement, then this Arrangement shall be deemed null ab initio.
2. **Effective Date.** The Effective Date of this Arrangement is the later of January 1, 2022, or January 1 of the year following the date this Arrangement is signed by the last Party to sign it (as indicated by the date associated with that Party’s signature). A Party’s performance obligations under this Arrangement shall not begin prior to the Effective Date.
3. **Term of Arrangement.** This Arrangement is effective for a minimum of one full Performance Year, which consists of a 12-month period beginning on January 1 of each year, and will renew automatically on January 1 of each year, until terminated by either party in accordance with Section 12 of this Arrangement, or upon the execution of a new CTO Arrangement. This Arrangement is subject to early termination by either Party only if: (1) CMS terminates either the CTO Participation Agreement or the Practice Participation Agreement, or (2) if CMS authorizes, in writing, such early termination of this Arrangement.
4. **Offer and Selection of CTO Services.** The Practice is responsible for meeting the Care Transformation Requirements as listed in Appendix A. The CTO will support the Practice in meeting those requirements including any support specified in the either the CTO or Practice Participation Agreements. The CTO has offered to provide any and all of the CTO Services to the Practice, as listed in the package selected in Appendix B. The CTO offers these same CTO Services to all participating practices within the same service option level and Track.
5. **Care Management Fees.** CMS will calculate the Practice’s Care Management Fees (“CMF”) according to the CTO Participation Agreement, the Practice Participation Agreement, and the methodologies described therein. In accordance with the Practice’s selection that was submitted to CMS, the CMF payment split will be as follows:
 - CTO will receive **30%** of the practice’s CMF payment amount calculated by CMS, and the remaining **70%** of such CMF payment amount will be paid to the Practice
 - CTO will receive **50%** of the practice’s CMF payment amount calculated by CMS and the remaining **50%** of such CMF payment amount will be paid to the Practice.
6. **Lead Care Manager.** For practices choosing the 50% option, the CTO will provide the Practice with one or more individuals who are fully dedicated to care management functions of the Practice (the “Lead Care Manager”), and additional services selected in accordance with Section 4. For practices choosing the 30% option, the practice will have its own care manager(s) to work in conjunction with the CTO and the CTO’s offerings in accordance with Section 4.
7. **Data Sharing and Privacy.** The Practice authorizes the CTO to have access to all clinical data available in the electronic medical records or shared through the State-Designated Health Information Exchange (“HIE”), including personal health information, of MDPCP Beneficiaries attributed to the Practice. The Practice authorizes the CTO to have access via CRISP to quality and utilization reports available to the Practice. The CTO will include a Business Associate Agreement (“BAA”) for the Practice to approve. The BAA will govern their data sharing, use, and confidentiality, a copy of which is in Appendix C. Each Party will comply with HIE policies and regulations, including patient education requirements, and will execute any separate agreement that may be required by CRISP.

MARYLAND PRIMARY CARE PROGRAM

CARE TRANSFORMATION ARRANGEMENT

8. Notification of Changes in Medicare Enrollment. The Practice will notify the CTO of any changes to the Practice's Medicare beneficiary enrollment information within thirty (30) days after such changes occur.
9. No Remuneration Provided. Neither the CTO nor the Practice has offered, given, or received remuneration in return for, or to induce business other than the business covered under this CTO Arrangement.
10. Practice of Medicine or Professional Services Not Limited by this Arrangement. The Arrangement does not limit or restrict in any way the ability of the Practice and its clinician(s) to make medical decisions that they consider in their professional judgment to be in the best interest of a MDPCP Beneficiary.
11. Compliance with All Applicable Laws. This Arrangement does not alter or amend the Parties' being bound to comply with all relevant federal and State laws, including, but not limited to, health care fraud and abuse laws, HIPAA, and the Maryland Medical Practice Act. The CTO will continue to be bound by the terms of the CTO Participation Agreement, and the Practice will continue to be bound by the terms of the Practice Participation Agreement.
12. Termination. Either Party may terminate this Arrangement annually or earlier by providing written notice of termination to the other Party, CMS and the Program Management Office. If the Practice or CTO decides to terminate this Arrangement for any reason, it must provide written notice in accordance with the notification and termination requirements stated in the applicable MDPCP Participation Agreements. This Arrangement automatically terminates on the Effective Date of the termination of either the CTO Participation Agreement or the Practice Participation Agreement.
13. Copies and Retention of Arrangement. The Practice will provide a copy of this Arrangement to the CTO and the Maryland Department of Health, Program Management Office, within thirty (30) days of execution. The CTO will retain copies of this Arrangement for a period of ten (10) years following expiration or termination of the CTO Participation Agreement. The CTO will, upon request, provide copies of this Arrangement to the federal government, including, but not limited to, CMS, the HHS Office of the Inspector General, or the Comptroller General.
14. Amendments. The Parties may amend this Arrangement including, but not limited to, the CTO Services offered and provided, at any time upon mutual written consent. The CTO must continue to offer the same CTO Services to all participating practices within the same service option level and Track, as specified in Section 4 of this Arrangement.

IN WITNESS THEREOF, and in acknowledgement of the aforementioned, the authorized representatives of the CTO and the Practice do hereby indicate their approval and consent:

**FOR THE CARE TRANSFORMATION ORGANIZATION:
(NETRIN ACCOUNTABLE CARE LLC.)**

SAMPLE Only – Do NOT Complete Now

Signature

SAMPLE Only – Do NOT Complete Now

Printed Name

SAMPLE Only – Do NOT Complete Now

MDPCP CTO ID

SAMPLE Only – Do NOT Complete Now

Title

SAMPLE Only – Do NOT Complete Now

Date Signed

FOR THE PRACTICE:

SAMPLE Only – Do NOT Complete Now

Signature

SAMPLE Only – Do NOT Complete Now

Printed Name

SAMPLE Only – Do NOT Complete Now

MDPCP Practice ID

SAMPLE Only – Do NOT Complete Now

Title

SAMPLE Only – Do NOT Complete Now

Date Signed

Appendix A:
Care Transformation Requirements

Comprehensive Primary Care Functions of Advanced Primary Care	Care Transformation Requirement	Practice Track Requirement
Access and Continuity	1.1 Empanel attributed beneficiaries to practitioner or care team.	Track 1 + 2
	1.2 Ensure attributed beneficiaries have 24/7 access to a care team or practitioner with real-time access to the EHR.	Track 1 + 2
	1.3 Ensure attributed beneficiaries have regular access to the care team or practitioner through at least one alternative care strategy.	Track 2 only
Care Management	2.1 Ensure all empaneled, attributed beneficiaries are risk stratified.	Track 1 + 2
	2.2 Ensure all attributed beneficiaries identified as increased risk and likely to benefit receive targeted, proactive, relationship-based (longitudinal) care management.	Track 1 + 2
	2.3 Ensure attributed beneficiaries receive a follow-up interaction from your practice within one week for ED discharges and two business days for hospital discharges.	Track 1 + 2
	2.4 Ensure targeted, attributed beneficiaries who have received follow-up after ED, hospital discharge, or other triggering events receive short-term (episodic) care management.	Track 1 + 2
	2.5 Ensure attributed beneficiaries in longitudinal care management are engaged in a personalized care planning process, which includes at least their goals, needs, and self-management activities.	Track 2 only
	2.6 Ensure attributed beneficiaries in longitudinal care management have access to comprehensive medication management.	Track 2 only
Comprehensiveness and Coordination across the Continuum of Care	3.1 Ensure coordinated referral management for attributed beneficiaries seeking care from high-volume and/or high-cost specialists as well as EDs and hospitals.	Track 1 + 2
	3.2 Ensure attributed beneficiaries with behavioral health needs have access to care consistent with at least one option from a menu of options for integrated behavioral health supplied to attributed beneficiaries by the Practice	Track 1 + 2
	3.3 Facilitate access to resources that are available in your community for beneficiaries with identified health-related social needs	Track 2 only
Beneficiary & Caregiver Experience	4.1 Convene a Patient-Family/ Caregiver Advisory Council (PFAC) at least annually and integrate PFAC recommendations into care and quality improvement activities.	Track 1 + 2
	4.2 Engage attributed beneficiaries and caregivers in a collaborative process for advance care planning	Track 2 only
Planned Care for Health Outcomes	5.1 Continuously improve your performance on key outcomes, including cost of care, electronic clinical quality measures, beneficiary experience, and utilization measures.	Track 1 + 2

Appendix B:
CTO Services/Personnel Offered and Practice Selection

Package A (50%)

Service Category	Care Requirement & Quality Measure	Description	Staff Type	Ratio of staff (FTE) to practice
Behavioral Health Integration (BHI)	Comprehensiveness & Coordination 3.2, NQF 0004	Access to integrated psychiatrist for CoCM assistance and maintenance with establishment of the primary care behaviorist model. Netrin uses predictive analytics using two models to identify patients that need BHI. This is in addition to any referrals from the PCPs. Conduct regular multidisciplinary team huddles to review cases on a periodic basis to optimize CoCM; All protocols and methodologies for all categories are reviewed and categorized with Physician input. Providers will have access to behavioral health therapists that are aligned with Netrin.	Psychiatrist Lead Care Manager	All practices 1: 2K patients
Medication Management	Care Management 2.6	Netrin's Pharmacists available to review high risk patient medications list and identify interventions during transitions of care and patients with chronic conditions. With PCP's request, identify opportunities to provide care and achieve quality measures; Pharmacist perform drug utilization reviews, education protocols and methodologies for all categories with Physician input. Netrin pharmacist also reviews areas of optimization of using Generics where applicable with Physician oversight and without impacting efficacy. Providers will have the option of prescribing medications to Netrin's aligned pharmacy that provides pre-packaged medications for patients in order to increase patient adherence. Lead care manager will facilitate referrals between PCPs and the pharmacist.	Pharmacist Lead Care Manager	All practices 1:2K Patients
Social Determinants Screening & Referral	Comprehensiveness & Coordination 3.3	Netrin has integrated with the Social Determinants of health (SDOH) using Netrin's Care Management framework. We utilize best of breed solutions in SDOH screening. Netrin currently captures this data real-time from the Care Management system. Identification and establishment of social service resources and ongoing updating of these resources. Maintaining a social service resource contact for point of care referrals. Adding all the Social Determinants of Health screening questions at the point of care system. These are also asked by the Care Team during the Care Team visits (virtual) with the patients. We integrate with Aunt Bertha and Netrin's Social Connect to connect the complex needs of our patients to the right community resources.	Lead Care Manager Care Coordination Assistant	1:2K Patients 1 per 10 practices
Alternative Care (e.g., Telehealth, home visits)	Access & Continuity 1.3	Netrin has integrated virtual visits into its existing Care Management Process and tools. Providers will have access to Netrin's telemedicine solution that is rated number one in ease of use by multiple sources. The solution is available via mobile phone or desktop. Netrin has the ability to integrate other remote patient monitoring devices. Providers will have the option of implementing remote patient monitoring through the help of the Netrin team with discounted pricing.	Lead Care Manager Care Coordination Assistant	1:2K Patients 1 per 10 practices
Transitional Care Management (TCM)	Care Management 2.2, 2.3, 2.4, 2.5, 2.6	Netrin team will train practices to establish optimized workflow for care transitions, improving health outcomes and revenue for the practice. Care managers monitor the ENS notifications from CRISP to enable Transition Care Management for all patients in care management and reaches out to schedule for transitional care visit. We will also conduct medicine reconciliation for the TCM visits as needed. We will review any gaps in care and update this information in the practice EMR where applicable. This will minimize any gaps in care. We will activate the TCM based on CRISP Encounter Notification Services. ENS notifications create alerts to the Care Team. Netrin care team will assist with Care Alerts for care management patients. We also have automated texting abilities to increase practice revenue for TCM visit responses.	Lead Care Manager Care Coordination Assistant	1:2K Patients 1 per 10 practices
Care Planning & Self-Management	Care Management 2.5, Beneficiary & Caregiver Experience 4.2	Netrin provides Care Management to patients based on three mechanisms. First level is based on any referrals from the practices. Second level is based on predictive analytics and tools created by Netrin. Netrin uses the HCC Risk scoring,	Lead Care Manager	1 per 5 practices, 1:2K patients 1 per 10 practices

Support		ACG Risk, and Netrin’s proprietary color-coded models to refer patients to our Care Management teams. Third is based on the patients that we touch as part of the CRISP reporting tools in Pre-AH, Preventable Hospital Indicators, and encounter notification system. Netrin utilizes multiple ways of engaging patients into Care Planning on our proprietary platform that will integrate care plans into your EMR. Netrin uses the various predictive analytics to identify patients that need care management services. Netrin also has mechanisms for practices to direct patients into Care Management services. Netrin constantly monitors the patient experience and Care giver’s experience at all stages of the process on a periodic basis. Care Team huddle prioritizes the patients on a regular basis to discuss patient centered care goals.	Care Coordination Assistant Pharmacist	All practices
Population Health Management & Analytics	Planned Care for Health Outcomes 5.1, eQMs, Utilization	Netrin leverages 2 different Population Health Analytics tools. Netrin is able to consume the claims data, clinical data and the social determinants of health data within its data infrastructure. Netrin loads the Cost and Utilization data within our data system.	Population Health Data Analyst Team Practice Transformation Specialist	All practices
Clinical & Claims Data Analysis	Care Management 2.1-2.4, Utilization	Practice will provide access to their practice EMR systems for Netrin specialist. Netrin is able to load the CCLF files if made available. If the practice is also on the Netrin ACO, Netrin is able to have access to all the CCLF data for all the Medicare lives attributed to the practices.; Netrin team has access to the CRISP CRS as well as the Netrin Care Management Module. Netrin gathers the data from the CRISP CRS and creates data uploads the Netrin home grown Care Management. Netrin creates 3 flavors of Care Management. Netrin also integrates the social determinants of health data.	Population Health Data Analyst Team Practice Transformation Specialist	All practices
Patient Family Advisory Councils (PFACs)	Beneficiary & Caregiver Experience 4.1	Netrin will assess the Practice’s readiness for partnering with patients and their families. Netrin prepares clinician and staff for PFAC collaboration. Netrin will define the PFAC’s Purpose, Structure and Membership selecting the PFAC. Netrin will assist and train practices to set up PFAC at their practices in the mood that is best for the practice. Netrin will help practices prioritize follow-up and quality improvement based on PFAC feedback.	Medical Director Lead Care Manager Care Coordination Assistant	All practices 1 per 5 practices 1 per 10 practices
Quality & Utilization Performance	Planned Care for Health Outcomes 5.1, eQMs	CTO will consistently track and measure the cost, utilization and Quality performance for all patients that are attributed to the CTO. Based on this tracking / measuring, the CTO will make suggestions to improve each practice’s performance on key outcomes, including cost of care, electronic clinical quality measures, beneficiary experience, and utilization measures. Suggestions could involve changes to the workflow of the practice, data entry by the practice into its relevant EHR and based on data that is made available to the CTO, via the CRISP Portal. This process may help in the success of annual clinical quality data submission, which is a requirement for both the CTO and the participating practice.	Population Health Data Analyst Team Medical Director	All practices
24/7 Access	Access & Continuity 1.2	Patients will have 24x7 Access the Care team. Netrin staff will have 24x7 Access to the patient medical record. Netrin Care Team also have 24x7 Telemedicine / Secure Video conferencing module.	Lead Care Manager Care Coordination Assistant	1:5 practices 1:10 practices
Referral Management	Comprehensiveness & Coordination 3.1	Netrin’s care team will facilitate timely, appropriate referrals for patients to quality specialists. Education of the participating practices on distribution of high cost specialists and high cost hospitals based on CMS claims reports will be conducted.	Lead Care Manager Care Coordination Assistant	1:5 practices 1:10 practices
Other	HCC Training	Netrin would train the practice staff on HCCs coding	Population Health Data Analyst Team	All practices

Package B - (30%)*

Service Category	Care Requirement & Quality Measure	Description	Staff Type	Ratio of staff (FTE) to practice
Behavioral Health Integration (BHI)	Comprehensiveness & Coordination 3.2, NQF 0004	Access to psychiatrist for CoCM assistance and maintenance with establishment of the primary care behaviorist model. Netrin uses predictive analytics using two models to identify patients that need BHI. This is in addition to any referrals from the PCPs. Conduct regular multidisciplinary team huddles to review cases on a periodic basis to optimize CoCM.; All protocols and methodologies for all categories are reviewed and categorized with Physician input. Providers will have access to behavioral health therapists that are aligned with Netrin.	Psychiatrist Care Coordination Assistant	All practices 1 per 10 practices
Medication Management	Care Management 2.6	Netrin’s Pharmacists available to review top 5% high risk patient’s medications list and identify interventions during transitions of care and patients with chronic conditions. Based on PCP’s request, we will have periodic virtual huddles with the practices on demand.; Pharmacist reviews the medications for certain frequent fliers. All protocols and methodologies for all categories are reviewed and categorized with Physician input. Netrin also reviews areas of optimization of using Generics where applicable with Physician oversight and without impacting efficacy. Providers will have the option of prescribing medications to Netrin’s aligned pharmacy that provides pre-packaged medications for patients in order to increase patient adherence.	Pharmacist	All practices
Social Determinants Screening & Referral	Comprehensiveness & Coordination 3.3	Identification and establishment of social service resources and ongoing updating of these resources. Maintaining a social service resource contact for point of care referrals. We utilize best of breed solutions in SDOH screening. Advising providers in integration of Social Determinants of Health screening questions at the point of care system. Consult available for difficult patient cases.	Care Coordination Assistant	1 per 10 practices
Alternative Care (e.g., Telehealth, home visits)	Access & Continuity 1.3	Netrin has created the Telehealth module technology. This works on Mobile devices and Care Management Consoles. Netrin has the ability to integrate other remote patient monitoring devices. Providers will have the option of implementing remote patient monitoring through the help of the Netrin team.	Care Coordination Assistant	1 per 10 practices
Transitional Care Management (TCM)	Care Management 2.2, 2.3, 2.4, 2.5, 2.6	Netrin team will train practices to establish optimized workflow for care transitions, improving health outcomes and revenue for the practice. Practices will be trained to review any gaps in care and update this information in the practice EMR where applicable. This will minimize any gaps in care. We will assist the practice to activate the workflow for TCM based on CRISP Encounter Notification Services.	Care Coordination Assistant	1 per 10 practices
Care Planning & Self-Management Support	Care Management 2.5, Beneficiary & Caregiver Experience 4.2	Netrin will offer training to practice’s care manager on how to provide episodic and longitudinal care management. Netrin will offer customized care plan and training materials to the practice. Practices will receive Netrin’s priority risk algorithms to assist in identifying patients for care management in conjunction with CRISP reports. Consults available for difficult patients.	Care Coordination Assistant Pharmacist	1 per 10 practices 1 per 20 practices
Population Health Management & Analytics	Planned Care for Health Outcomes 5.1, eCQMs, Utilization	Netrin leverages 2 different Population Health Analytics tools. Netrin is able to consume the claims data, clinical data and the social determinants of health data within its data	Population Health Data Analyst Team	All practices

		infrastructure.		
Clinical & Claims Data Analysis	Care Management 2.1-2.4, Utilization	Netrin is able to load the CCLF files if made available. If the practice is also on the Netrin ACO, Netrin is able to have access to all the CCLF data for all the Medicare lives attributed to the practices.; Netrin team has access to the CRISP CRS as well as the Netrin Care Management Module. Netrin gathers the data from the CRISP CRS and creates data uploads the Netrin home grown Care Management. Netrin creates 3 flavors of Care Management. Netrin also integrates the social determinants of health data.	Population Health Data Analyst Team	All practices
Patient Family Advisory Councils (PFACs)	Beneficiary & Caregiver Experience 4.1	Netrin will assess the Practice's readiness for partnering with patients and their families. Netrin prepares clinician and staff for PFAC collaboration. Netrin will define the PFAC's Purpose, Structure and Membership selecting the PFAC. Netrin will assist and train practices to set up PFAC at their practices in the mood that is best for the practice.	Care Coordination Assistant	1 per 10 practices
Quality & Utilization Performance	Planned Care for Health Outcomes 5.1, eCQMs	CTO will consistently track and measure the cost, utilization and Quality performance for all patients that are attributed to the CTO. Based on this tracking / measuring, the CTO will make suggestions to improve each practice's performance on key outcomes, including cost of care, electronic clinical quality measures, beneficiary experience, and utilization measures. Suggestions could involve changes to the workflow of the practice, data entry by the practice into its relevant EHR and based on data that is made available to the CTO, via the CRISP Portal. This process may help in the success of annual clinical quality data submission, which is a requirement for both the CTO and the participating practice.	Population Health Data Analyst Team Medical Director	All practices All practices
24/7 Access	Access & Continuity 1.2	Practices will have the option to use Netrin's 24x7 Telemedicine / Secure Video conferencing module.	Care Coordination Assistant	1 to 10 practices
Referral Management	Comprehensiveness & Coordination 3.1	Education of the participating practices on distribution of high cost specialists and high cost hospitals based on CMS claims reports will be conducted.	Care Coordination Assistant	1 to 10 practices

* Practice will have its own care manager to work in conjunction with the CTO and the CTO's offerings.

Final Practice Selection

_____ **Package A (50%)**

_____ **Package B (30%)**

CTO Signature **SAMPLE Only – Do NOT Complete Now**

Practice Signature **SAMPLE Only – Do NOT Complete Now**

Appendix C:

**Business Associate Agreement
between the CTO and the Practice**

BUSINESS ASSOCIATE AGREEMENT

This Business Associate Agreement (the "Agreement") is made effective the _____ day of _____, 20____, by and between _____, hereinafter referred to as "Covered Entity," and **Netrin Accountable Care LLC**, hereinafter referred to as "Business Associate" (individually, a "Party" and collectively, the "Parties").

WHEREAS, the Parties wish to enter into a Business Associate Agreement to ensure compliance with the Privacy and Security Rules of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA Privacy and Security Rules") (45 C.F.R. Parts 160 and 164); and

WHEREAS, the Health Information Technology for Economic and Clinical Health ("HITECH") Act of the American Recovery and Reinvestment Act of 2009, Pub. L. 111-5, modified the HIPAA Privacy and Security Rules (hereinafter, all references to the "HIPAA Privacy and Security Rules" include all amendments thereto set forth in the HITECH Act and any accompanying regulations); and

WHEREAS, the Parties have entered into a written or oral arrangement or arrangements (the "Underlying Agreements") whereby Business Associate will provide certain services to Covered Entity that require Business Associate to create, receive, maintain, or transmit Protected Health Information on Covered Entity's behalf, and accordingly Business Associate may be considered a "business associate" of Covered Entity as defined in the HIPAA Privacy and Security Rules; and

WHEREAS, Business Associate and Covered Entity wish to comply with the HIPAA Privacy and Security Rules, and Business Associate wishes to honor its obligations as a Business Associate to Covered Entity. THEREFORE, in consideration of the Parties' new or continuing obligations under the Underlying Agreements, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree to the provisions of this Agreement.

Except as otherwise defined herein, any and all capitalized terms in this Agreement shall have the definitions set forth in the HIPAA Privacy and Security Rules. In the event of an inconsistency between the provisions of this Agreement and mandatory provisions of the HIPAA Privacy and Security Rules, the HIPAA Privacy and Security Rules in effect at the time shall control. Where provisions of this Agreement are different than those mandated by the HIPAA Privacy and Security Rules but are nonetheless permitted by the HIPAA Privacy and Security Rules, the provisions of this Agreement shall control.

The Parties acknowledge and agree that from time to time, Business Associate may be providing services to Covered Entity both when Covered Entity is acting as a "business associate" to another Covered Entity and at other times, when Covered Entity is itself a Covered Entity. This Agreement shall relate only to those times when Covered Entity is a Covered Entity and not when it is acting as a prime business associate. The Parties agree that those times when Covered Entity is acting as a business associate shall be covered by a separate business associate agreement, provided, however, that if the Parties have not entered into such separate business associate agreement, this Agreement shall remain applicable.

I. PERMITTED USES AND DISCLOSURES BY BUSINESS ASSOCIATE

a. Business Associate may use or disclose Protected Health Information to perform functions, activities, or services for, or on behalf of, Covered Entity as specified in the Underlying Agreements, provided that such use or disclosure would not violate the HIPAA Privacy and Security Rules if done by Covered Entity.

b. Business Associate may use Protected Health Information in its possession for its proper management and administration and to fulfill any present or future legal responsibilities of Business Associate, provided that such uses are permitted under state and federal confidentiality laws. Notwithstanding the

foregoing, Business Associate may not de-identify or aggregate such data, regardless of what state or federal laws allow, except as required of the Business Associate under the Underlying Agreements.

c. Business Associate may disclose Protected Health Information in its possession to employees or contractors for the purposes of its proper management and administration or to fulfill any present or future legal responsibilities of Business Associate, provided that:

1. the disclosures are required by law; or

2. Business Associate obtains reasonable assurances from the third parties to whom the Protected Health Information is disclosed that the information will remain confidential and be used or further disclosed only as required by law or for the purpose for which it was disclosed to the third party, and that such third parties will notify Business Associate of any instances of which they are aware in which the confidentiality of the information has been breached.

II. OBLIGATIONS AND ACTIVITIES OF BUSINESS ASSOCIATE

a. Business Associate agrees not to use or further disclose Protected Health Information other than as permitted or required by this Agreement or the Underlying Agreements or as required by law.

b. Business Associate agrees to use appropriate safeguards, and to comply, where applicable, with 45 C.F.R. Part 164, Subpart C with respect to Electronic Protected Health Information, to prevent use or disclosure of Protected Health Information other than as provided for by this Agreement. Specifically, Business Associate will:

1. implement the administrative, physical, and technical safeguards set forth in 45 C.F.R. §§ 164.308, 164.310, and 164.312 that reasonably and appropriately protect the confidentiality, integrity, and availability of any Protected Health Information that it creates, receives, maintains, or transmits on behalf of Covered Entity, and, in accordance with 45 C.F.R. § 164.316, implement and maintain reasonable and appropriate policies and procedures to enable it to comply with the requirements outlined in 45 C.F.R. §§ 164.308, 164.310, and 164.312; and

2. report to Covered Entity any Security Incident that does not rise to the level of a Breach of Unsecured Protected Health Information ("Breach"), and any use or disclosure of Protected Health Information that is not provided for by this Agreement but that does not rise to the level of a Breach, of which Business Associate, or any third party becomes aware or should have been aware. The report shall be made as soon as practical, and in any event within ten (10) days of Business Associate's or such third party's discovery (or, if earlier, when it should have been aware) of the Security Incident or the impermissible use or disclosure.

c. Business Associate shall require each subcontractor that creates, receives, maintains, or transmits Protected Health Information on its behalf to enter into a business associate agreement containing the same restrictions on access, use, and disclosure of Protected Health Information as those applicable to Business Associate under this Agreement. Furthermore, to the extent that Business Associate provides Electronic Protected Health Information to a subcontractor, Business Associate shall require such subcontractor to comply with all applicable provisions of 45 C.F.R. Part 164, Subpart C.

d. Business Associate agrees to comply with any requests for restrictions on certain disclosures of Protected Health Information to which Covered Entity has agreed in accordance with 45 C.F.R. § 164.522 of which Business Associate has been notified by Covered Entity.

e. If Business Associate maintains a designated record set on behalf of Covered Entity, at the request of Covered Entity and in a reasonable time and manner, Business Associate agrees to make available Protected Health Information required for Covered Entity to respond to an individual's request for access to his or her Protected Health Information in accordance with 45 C.F.R. § 164.524. If Business Associate maintains Protected Health Information in an electronic designated record set, it agrees to make such Protected Health Information available electronically to Covered Entity or, upon Covered Entity's specific request, to the individual requesting it. If Business Associate receives a request from an individual for access to his or her Protected Health Information, Business Associate shall promptly (within 1 business day) notify Covered Entity.

f. If Business Associate maintains a designated record set on behalf of Covered Entity, at the request of Covered Entity and in a reasonable time and manner, Business Associate agrees to make available Protected Health Information required for amendment by Covered Entity in accordance with the requirements of 45 C.F.R. § 164.526.

g. Business Associate agrees to document any disclosures of Protected Health Information, and to make Protected Health Information available for purposes of accounting of disclosures, as required by 45 C.F.R. § 164.528.

h. If Business Associate is to carry out one or more of Covered Entity's obligations under 45 C.F.R. Part 164, Subpart E, Business Associate shall comply with the requirements of Subpart E that apply to Covered Entity in the performance of such obligation(s).

i. Business Associate agrees that it will make its internal practices, books, and records relating to the use and disclosure of Protected Health Information received from, or created or received by Business Associate on behalf of, Covered Entity, available to the Secretary, in a time and manner designated by the Secretary, to enable the Secretary to determine Business Associate's or Covered Entity's compliance with the HIPAA Privacy and Security Rules. Business Associate also shall cooperate with the Secretary and, upon the Secretary's request, pursuant to 45 C.F.R. § 160.310, shall disclose Protected Health Information to the Secretary to enable the Secretary to investigate and review Business Associate's or Covered Entity's compliance with the HIPAA Privacy and Security Rules.

- j. Unless expressly authorized in the Underlying Agreements, Business Associate shall not:
1. use Protected Health Information for marketing or fundraising;
 2. use Protected Health Information to create a limited data set or to de-identify the information;
 3. use Protected Health Information to provide data aggregation services; or
 4. use or disclose Protected Health Information in exchange for remuneration of any kind, whether directly or indirectly, financial or non-financial, other than such remuneration as Business Associate receives from Covered Entity in exchange for Business Associate's provision of the services specified in the Underlying Agreements.

III. BUSINESS ASSOCIATE'S MITIGATION AND BREACH NOTIFICATION OBLIGATIONS

a. Business Associate agrees to mitigate, to the extent requested by Covered Entity or as otherwise required by law, any harmful effect of a use or disclosure of Protected Health Information by

Business Associate in violation of the requirements of this Agreement or applicable law.

b. Following the discovery of a Breach, Business Associate shall notify Covered Entity of such Breach without unreasonable delay and in no case later than three (3) calendar days after discovery of the Breach, and shall assist in Covered Entity's breach analysis process, including risk assessment, if requested. A Breach shall be treated as discovered by Business Associate as of the first day on which such Breach is known to Business Associate or, through the exercise of reasonable diligence, would have been known to Business Associate. The Breach notification shall be provided to Covered Entity in the manner specified in 45 C.F.R. § 164.410(c) and shall include the information set forth therein to the extent known. If, following the Breach notification, Business Associate learns additional details about the Breach, Business Associate shall notify Covered Entity promptly as such information becomes available. Covered Entity shall determine whether Business Associate or Covered Entity will be responsible for providing notification of any Breach to affected individuals, the media, the Secretary, and/or any other parties required to be notified under the HIPAA Privacy and Security Rules or other applicable law. If Covered Entity determines that Business Associate will be responsible for providing such notification, Business Associate may not carry out notification until Covered Entity approves the proposed notices in writing.

c. Business Associate shall bear all of Covered Entity's costs of any Breach and resultant notifications, if applicable, when the Breach arises from Business Associate's negligence, willful misconduct, violation of law, violation of the Underlying Agreements, or violation of this Agreement.

IV. OBLIGATIONS OF COVERED ENTITY

a. Covered Entity shall provide Business Associate with any changes in, or revocation of, permission by an individual to use or disclose Protected Health Information, if such changes or revocation could reasonably be expected to affect Business Associate's permitted or required uses and disclosures.

b. Covered Entity shall notify Business Associate of any restriction on the use or disclosure of Protected Health Information to which Covered Entity has agreed in accordance with 45 C.F.R. § 164.522, and Covered Entity shall inform Business Associate of the termination of any such restriction, and the effect that such termination shall have, if any, upon Business Associate's use and disclosure of such Protected Health Information.

V. TERM AND TERMINATION

a. This Agreement shall be effective as of the date first written above, and shall terminate upon the later of the following events: (i) in accordance with Section V.c., when all of the Protected Health Information provided by Covered Entity to Business Associate or created or received by Business Associate on behalf of Covered Entity is returned to Covered Entity or destroyed (and a certificate of destruction is provided) or, if the parties agree that such return or destruction is infeasible, when protections are extended to such information; or (ii) upon the expiration or termination of the last of the Underlying Agreements.

b. Upon either Party's knowledge of a material breach by the other Party of its obligations under this Agreement, the non-breaching Party shall, notify the breaching Party, and the breaching Party shall have thirty (30) days from receipt of that notice to cure the breach or end the violation. If the breaching Party fails to take reasonable steps to effect such a cure within such time period, the non-breaching Party may terminate this Agreement and the Underlying Agreements without penalty.

Where either Party has knowledge of a material breach by the other Party and determines that cure is infeasible, prior notice is not required and the non-breaching Party shall terminate the portion of the Underlying Agreements affected by the breach without penalty. Furthermore, Covered Entity may terminate this Agreement and the Underlying Agreements immediately upon a breach, if Covered Entity determines that it is in the best interest of Covered Entity to immediately terminate this Agreement, or as may be required by law.

c. Effect of Termination.

1. Except as provided in paragraph 2 of this subsection c., upon termination of this Agreement, the Underlying Agreements or upon request of Covered Entity, whichever occurs first, Business Associate shall within ten (10) days return or destroy all Protected Health Information received from Covered Entity or created or received by Business Associate on behalf of Covered Entity. This provision shall apply to Protected Health Information that is in the possession of subcontractors of Business Associate. Neither Business Associate nor its subcontractors shall retain copies of the Protected Health Information except as required by law.

2. In the event that the parties agree that returning or destroying the Protected Health Information is infeasible, Business Associate shall provide within ten (10) days to Covered Entity notification of the conditions that make return or destruction infeasible. Upon such event, Business Associate, and its applicable subcontractors, shall extend the protections of this Agreement to such Protected Health Information and limit further uses and disclosures of such Protected Health Information to those purposes that make the return or destruction infeasible, for so long as Business Associate and its applicable subcontractors maintain such Protected Health Information.

VI. MISCELLANEOUS

a. Indemnification. Each Party shall indemnify and hold the other harmless from and against all claims, liabilities, judgments, fines, assessments, penalties, awards, or other expenses, of any kind or nature whatsoever, including, without limitations, attorneys' fees, expert witness fees, and costs of investigation, litigation or dispute resolution, relating to or arising out of any breach of this Agreement, or any Breach, by that Party or its subcontractors or agents.

b. No Rights in Third Parties. Except as expressly stated herein or in the HIPAA Privacy and Security Rules, the Parties to this Agreement do not intend to create any rights in any third parties.

c. Survival. The obligations of Business Associate under Section V.c. of this Agreement shall survive the expiration, termination, or cancellation of this Agreement, the Underlying Agreements, and/or the business relationship of the Parties, and shall continue to bind Business Associate, its agents, employees, contractors, successors, and assigns as set forth herein. Furthermore, the Parties' indemnification obligations pursuant to Section VI.a. of this Agreement shall survive the expiration, termination, or cancellation of this Agreement, the Underlying Agreements, and/or the business relationship of the Parties, and shall continue to bind the Parties, their agents, employees, contractors, successors, and assigns as set forth herein.

d. Amendment. The Parties agree that this Agreement will be amended automatically to conform to any changes in the HIPAA Privacy and Security Rules as are necessary for each of them to comply with the current requirements of the HIPAA Privacy and Security Rules and the Health Insurance Portability and Accountability Act, unless a particular statutory or regulatory provision requires that the terms of this Agreement be amended to reflect any such change. In those instances where an amendment to this Agreement is required by law, the Parties shall negotiate in good faith to amend the

terms of this Agreement within sixty (60) days of the effective date of the law or final rule requiring the amendment. If, following such period of good faith negotiations, the Parties cannot agree upon an amendment to implement the requirements of said law or final rule, then either Party may terminate this Agreement and the Underlying Agreements upon ten (10) days written notice to the other Party. Except as provided above, this Agreement may be amended or modified only in a writing signed by the Parties.

e. Assignment. Neither Party may assign its respective rights and obligations under this Agreement without the prior written consent of the other Party.

f. Independent Contractor. None of the provisions of this Agreement are intended to create, nor will they be deemed to create, any relationship between the Parties other than that of independent parties contracting with each other solely for the purposes of effecting the provisions of this Agreement and any other agreements between the Parties evidencing their business relationship. Nothing in this Agreement creates or is intended to create an agency relationship.

g. Governing Law. To the extent this Agreement is not governed exclusively by the HIPAA Privacy and Security Rules or other provisions of federal statutory or regulatory law, it will be governed by and construed in accordance with the laws of the Commonwealth of Virginia and shall be brought exclusively in the state courts located in Loudoun or Fairfax County, VA or in the federal courts located in Alexandria, VA. Each party consents to the sole jurisdiction of the courts located in such venues and no party shall make any claim of an inconvenient or improper forum.

h. No Waiver. No change, waiver, or discharge of any liability or obligation hereunder on any one or more occasions shall be deemed a waiver of performance of any continuing or other obligation, or shall prohibit enforcement of any obligation, on any other occasion.

i. Interpretation. Any ambiguity of this Agreement shall be resolved in favor of a meaning that permits Covered Entity and Business Associate to comply with the HIPAA Privacy and Security Rules.

j. Severability. In the event that any provision of this Agreement is held by a court of competent jurisdiction to be invalid or unenforceable, the remainder of the provisions of this Agreement will remain in full force and effect.

k. Notice. Any notification required in this Agreement shall be made in writing to the representative of the other Party who signed this Agreement or the person currently serving in that representative's position with the other Party.

l. Certain Provisions Not Effective in Certain Circumstances. The provisions of this Agreement relating to the HIPAA Security Rule shall not apply to Business Associate if Business Associate does not receive, create, maintain, or transmit any Electronic Protected Health Information from or on behalf of Covered Entity.

m. Entire Agreement. This Agreement constitutes the entire understanding of the Parties with respect to the subject matter hereof and supersedes all prior agreements, oral or written. In the event of any inconsistency between this Agreement and any other agreement between the Parties concerning the use and disclosure of Protected Health Information and the Parties' obligations with respect thereto, the terms of this Agreement shall control. Notwithstanding the foregoing, if the Parties have entered into a subcontract business associate agreement for those times that the Covered Entity is acting as a Prime Business Associate, rather than as a Covered Entity, this Agreement shall not supersede

such other agreement.

n. Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same Agreement.

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the day and year written above.

Covered Entity:

_ SAMPLE Only – Do NOT Complete Now _

By: *_ SAMPLE Only – Do NOT Complete Now _*

Name: *_ SAMPLE Only – Do NOT Complete Now _*

Title: *_ SAMPLE Only – Do NOT Complete Now _*

Business Associate:

_ SAMPLE Only – Do NOT Complete Now _

By: *_ SAMPLE Only – Do NOT Complete Now _*

Name: *_ SAMPLE Only – Do NOT Complete Now _*

Title: *_ SAMPLE Only – Do NOT Complete Now _*

