COMMONWEALTH OF VIRGINIA
DEPARTMENT OF MEDICAL ASSISTANCE SERVICES

DUAL SPECIAL NEEDS PLAN (D-SNP) CONTRACT

January 1, 2024 to December 31, 2024

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1. Scope for Contract

This Contract, by and between the Virginia Department of Medical Assistance Services (hereinafter referred to as the Department or DMAS or the State), an administrative agency within the executive agency of the Commonwealth of Virginia responsible for operating a program of medical assistance under 42 USC. § 1396a et seq., and, the Code of Virginia § 32.1-325, et seq., and the Medicare Advantage Dual Eligible Special Needs Plan (herein referred to as the MA D-SNP or Contractor), a corporation organized under the laws of the State of Virginia and having a principal place of business in Virginia. This Contract is effective January 1, 2024 through December 31, 2024 and renews annually.

1.1 Applicable Laws and Regulations

The Contractor must provide the full scope of services and deliverables through an integrated and coordinated system of care as required, described, and detailed herein, consistent with all applicable laws and regulations, and in compliance with service and delivery timelines as specified. Applicable laws and regulations include, but are not limited to:

1. Federal statutes and regulations, as amended;
2. State statutes and regulations, as amended;
3. This Contract, including any Contractor specific terms and conditions negotiated and approved by the Department, and all amendments and attachments;
4. D-SNP Technical Manual; and
5. D-SNP memoranda, bulletins and other guidance documents.

The Contractor is also responsible for understanding and incorporating as necessary to fulfill the terms of this contract the federal and state laws and regulations applying to the Commonwealths Medicaid program. This includes, but is not limited to:

1. Virginia's State Plans for Medical Assistance Services and State Children's Health Insurance Program (CHIP);
2. The Department's 1915(b) Managed Care Waiver, 1915(c) HCBS Waivers, ARTS 1115 Waiver, and FAMIS MOMS 1115 Waiver; and
3. Medicaid memos, bulletins, and guidance as well as Department-issued memos, bulletins, manuals, and other guidance documents.

1.2 Operational Memoranda, Guidance Documents and Department Forms

The Department may issue guidance documents and program memoranda clarifying, elaborating upon, explaining, or otherwise relating to Contract administration and clarification of coverage. The Contractor must comply with all such program memoranda. In addition, for more information to assist in the coordination with Medicaid, refer to DMAS program policy manuals, Medicaid Memos and forms used in the administration of benefits for Medicaid individuals and are available on the DMAS web portal at this link.

1.3 Department and Dual Eligible Special Needs Plan Collaboration

The Contractor must work collaboratively with the Department on the Commonwealth's initiatives to enhance the DSNP program as well as all efforts to improve the existing operations of the DSNP

program. This includes, but is not limited to, attending meetings, participating in workgroups, and completing program, including IM systems, revisions within the Departments designated timeframes.

1.4 Required Reporting

Besides the specific reports required in Section 5.0, *Reporting and Other Deliverables,* of this contract, there are no other reporting requirements at this time. The Department may require additional reporting through separate guidance. As much as possible, the Department will provide at least 30 days before any new reporting requirements are added.

The Department may, at its discretion, change the content, format or frequency of reports. In addition, the Department may, at its discretion, require the Contractor to submit additional reports both ad hoc and recurring. If the Department requests any revisions to the reports already submitted, the Contractor must make the changes and re-submit the reports, according to the time period and format required by the Department.

1.4.1 Service Account

Unless otherwise noted in this contract or the Technical Manual, the Contractor is required to report using the Departments prescribed managed file transfer (MFT) process. To utilize the MFT process the Contractor must obtain and maintain a service account and regulate which staff can access the account in order to send and retrieve reports. The Contractor should contact the Department D-SNP contract monitor at mailto:dsnp@dmas.virginia.gov to create a service account. The Department will not create accounts for individual Contractor staff.

1.5 Contractor Requirements to Respond

The Contractor must acknowledge receipt of the Department's written, electronic, or telephonic requests for assistance, including, but not limited to, care management requests and requests to research and resolve member complaints, within the following time frames:

1. Within one (1) business day in instances where a potential/actual risk to the Member's health, safety or welfare exists; and
2. In all other instances within no later than two (2) business days of receipt of the request from the Department.

When the last day for submission to the Department of any requested information or reports, per this section, falls on a Saturday, Sunday, or legal holiday, the information may be delivered on the next day that is not a Saturday, Sunday, or legal holiday.

When the Department's requests for care management and/or requests for the Contractor to contact the Member/provider must occur within the time frame set forth by the Department through the written, electronic, or telephonic communication.

The Department's urgent requests for assistance, such as issues involving legislators, other governmental bodies, or as determined necessary by the Department, must be given priority by the Contractor and completed in accordance with Departmental instructions. The Department will provide guidance with respect to any necessary deadlines and requirements, including specifications to be submitted by the Contractor.

For requests involving litigation or legal representation of any type, the Contractor must ensure that all responses are timely, thoroughly detailed, professionally written, and legally sound.

The Contractor may request an extended timeframe for response and resolution of non-urgent requests, after initial acknowledgement of request and prior to the expiration of the original specified timeframe. Request for extension to include reason for extended timeframe for response and requested date for new response date.

1.6 Department Oversight

During the conduct of contract monitoring activities, the Department may assess the Contractor's compliance with any requirements set forth in this Contract and in the documents referenced herein. The Department reserves the right to audit, formally and/or informally, for compliance with any term(s) of this Contract, for compliance with the laws and regulations of the Federal Government and the Commonwealth of Virginia, and for compliance in the implementation of any term(s) of this Contract. The right to audit under this Section exists for ten (10) years from the final date of the contract period or from the date of completion of any audit, whichever is later. Records must be maintained in a searchable electronic format.

1.7 Contract Termination

This Contract may be terminated under the following conditions:

1. This Contract shall automatically terminate the day this Contract expires or is terminated.
2. This Contract may be terminated by mutual agreement of the parties. Such agreement must be in writing.
3. The State may terminate this Contract in whole or in part and at any time when, in its sole discretion, it determines that termination is in the best interests of the Commonwealth of Virginia. The termination will be effective on the date specified in the State's Notice of Termination. The State will provide the Contractor written notice of such termination at least 60 (sixty) calendar days prior to the effective date of termination, unless the State determines that circumstances warrant a shorter notice period.
4. In addition to the reasons set forth above, the State reserves the right to terminate this Contract, in whole or in part, upon the following conditions:
    a. The State may terminate this Contract at any time if a court of competent jurisdiction finds the Contractor failed to adhere to any laws, ordinances, rules, regulations or orders of any public authority having jurisdiction and such violation prevents or substantially impairs performance of the Contractor's duties under this Contract.
    b. The State may terminate the Contract at any time if the Contractor;
        i. Files for bankruptcy;
        ii. Becomes or is declared insolvent;
        iii. Does not meet the Virginia Bureau of Insurance financial requirements;
        iv. Is the subject of any proceedings related to its liquidation, insolvency, or the appointment of a receiver or similar officer for it;
        v. Makes an assignment for the benefit of all or substantially all of its creditors; or,
        vi. Enters into an agreement for the composition, extension, or readjustment of substantially all of its obligations.

c. The State will have the right to terminate this Contract at any time, and in whole or in part, if it determines, at its sole discretion, that the Contractor has breached the Contract.
d. The State has the right to terminate this Contract if the Contractor, or any of its contracted entities or subsidiaries, is determined to have a Star Rating of three stars or less; has been issued a Notice of Noncompliance; or, had sanctions imposed upon them by CMS.

5. The Contractor may terminate this Contract by providing the Department written notice at least ninety (90) calendar days prior to termination. The termination will be effective on the date specified in the Contractor's Notice of Termination.
6. If at any time the Managed Care contract is terminated by either the Contractor or the Department, the Contractor's D-SNP contract with the Department shall also be terminated.

2. DSNP Requirements for Operation

2.1 Contracting Requirements

Prior to operating within the Commonwealth, the Contractor, or an approved affiliate, must have entered into a Contract with the Department to provide, primary and acute care, behavioral health, nursing facility, HCBS Waiver, and Long Term Services and Supports ("LTSS") to qualified beneficiaries through a Cardinal Care Managed Care program contract.

Additionally, prior to operating within the Commonwealth, the Contractor must have entered, or has applied to enter, into a Medicare Advantage Dual-Eligible Special Needs Plan Contract ("MA Contract") with the Centers for Medicare and Medicaid Services ("CMS") whereby the Contractor provides or desires to provide Medicare Covered health care benefits to qualified Medicare beneficiaries under a Dual Eligible Special Needs Plan in the State of Virginia.

2.2 Contact Information

The Contractor must provide the Department with name and contact information responsible for the following duties: D-SNP National Lead, D-SNP State Lead, State Lead for D-SNP care coordination, State Lead for D-SNP coordination with Medicaid Plans, State Lead for D-SNP contracting and State Lead for D-SNP quality improvement and oversight. The same individual can fulfill one or more of the roles listed. See Technical Manual for specifications.

2.3 Standards, Licensure and Solvency

The Contractor must obtain and retain each of the following requirements.

2.3.1 Financial Stability

The Bureau of Insurance of the Virginia State Corporation Commission regulates the financial stability of all licensed plans in Virginia. The Contractor must comply with all Bureau of Insurance standards. Bureau of Insurance standards may be found on the State Corporation Commission's website at this link.

2.3.2 Statutory State Licensing and Certification Requirements

The Contractor must retain at all times during the period of this Contract a valid license issued by the Virginia State Corporation Commission and comply with all terms and conditions set forth in the Code of

Virginia §§ 38.2-4300 through 38.2-4323, 14 VAC 5-211-10 et. seq., and any and all other applicable laws of the Commonwealth of Virginia, as amended.

2.3.3 Quality Health Care and Consumer Protections

Pursuant to §32.1-137.1 through §32.137.6 Code of Virginia, and 12VAC5-408-10 et seq., all managed care health insurance plan licensees must obtain service area approval certification and remain certified by the Virginia State Health Commissioner Center for Quality Health Care Services and Consumer Protection to confirm the quality of health care services they deliver.

2.3.4 Authorization to Conduct Business in the Commonwealth

The Contractor, as a stock or non-stock corporation, limited liability company, business trust, limited partnership, or registered as a limited liability partnership, must be authorized to transact business in the Commonwealth as a domestic or foreign business entity if so required by Title 13.1 or Title 50 of the Code of Virginia or as otherwise required by law. Any business entity described above that enters into a contract with a public body pursuant to the Virginia Public Procurement Act must not allow its existence to lapse or its certificate of authority or registration to transact business in the Commonwealth, if so required under Title 13.1 or Title 50, to be revoked or cancelled at any time during the term of the contract. A public body may void any contract with a business entity if the business entity fails to remain in compliance with the provisions of this Section.

2.3.5 CMS Approved D-SNP

The Contractor must retain at all times during the period of this Contract signed approval by CMS to comply with all rules and regulations set forth in 42 CFR 422 and 42 CFR 123 and operate as a MA D-SNP to provide Medicare Covered health care benefits to qualified Medicare beneficiaries under this Contract in the State of Virginia.

2.4 Policy of Nondiscrimination

The Contractor and all subcontractors must comply with all applicable Federal and State laws and regulations relating to nondiscrimination and equal employment opportunity, and assure physical and program accessibility of all services to individuals with disabilities pursuant to § 504 of the Federal Rehabilitation Act of 1973, as amended (29 U.S.C. 794), and with all requirements imposed by applicable regulations in 45 CFR Part 84, Title VI of the Civil Rights Act, the Americans with Disabilities Act of 1990 as amended, title IX of the Education Amendments of 1972, the Age Discrimination and Employment Act of 1967, the Age Discrimination Act of 1975, and Section 1557 of the Patient Protection and Affordable Care Act. In connection with the performance of work under this Contract, the Contractor agrees not to discriminate against any employee or applicant for employment because of age, race, religion, color, handicap, sex, sexual orientation, gender identity, physical condition, developmental disability, or national origin. Any of the Contractor's contracts with subcontractors must comply with Virginia Code § 2.2-4311.

Furthermore, the Contractor must ensure that its network providers provide contract services to Members under this Contract in the same manner as they provide those services to all non-Medicare Members, including those with limited English proficiency or physical or mental disabilities.

2.5 Non-Debarment

The Contractor represents that neither it nor any of its employees, agents, officers or directors is presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in any State or Federal health care program.

3. Covered Populations and Enrollment

3.1 Eligible Populations

Enrollment shall be limited to individuals that meet the following criteria:

1) Individuals for whom DMAS only pays a limited amount each month toward their cost of care (e.g., deductibles), including non-full benefit Medicaid beneficiaries. Examples include:
   i. Qualified Medicare Beneficiaries (QMBs);
   ii. Special Low Income Medicare Beneficiaries (SLMBs);
   iii. Qualified Disabled Working Individuals (QDWIs); or,
   iv. Qualifying Individuals (QIs). Medicaid pays Part B premium.

The Contractor must indicate which types of partial duals they will serve through this PBP by selecting all options that apply:

☐	Qualified Medicare Beneficiaries (QMBs)
☐	Special Low Income Medicare Beneficiaries (SLMBs)
☐	Qualified Disabled Working Individuals (QDWIs);
☐	Qualifying Individuals (QIs)

3.2 Excluded Populations

The Contractor is prohibited from enrolling those who meet any of the following criteria:

1) Individuals who are entitled to benefits under Medicare Part A, B and D, and receiving full Medicaid benefits. Examples include:
   a. Qualified Medicare Beneficiary Plus (QMB+),
   b. Special Low Income Medicare Beneficiary Plus (SLMB+), and
   c. Other Full-Benefit Dual Eligible (FBDE).

2) Individuals enrolled in the Commonwealth's Title XXI CHIP programs (FAMIS, FAMIS MOMS).

3) Individuals enrolled in the Cardinal Care Managed Care program.

4) Individuals enrolled in a Program of All-Inclusive Care for the Elderly (PACE). However, PACE participants may enroll with the Contractor if they choose to disenroll from their PACE provider.

5) Individuals with temporary coverage or who are in limited coverage groups, including individuals enrolled in Plan First (DMAS' family planning program for coverage of limited benefits surrounding pregnancy prevention) who are not included in the Medicaid expansion population.

6) Individuals who are incarcerated. (Individuals on house arrest are not considered incarcerated.)

7) Individuals who have any insurance purchased through the Health Insurance Premium Payment (HIPP) program.

The Department shall, upon new State or Federal regulations or Department policy, modify the list of excluded individuals as appropriate. If the Department modifies the exclusion criteria, the Contractor must comply with the amended list of exclusion criteria.
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3.3 Determining Eligibility and Enrollment Responsibilities

3.3.1 Verifying Eligibility

The Contractor is responsible for accurately verifying both Medicare and Medicaid eligibility of potential and enrolled Members. The Contractor will be provided with the means to verify Medicaid eligibility by the Department as defined in Section 3.3 of this Contract.

The Department will provide the Contractor access to real-time, or near real-time, Medicaid eligibility information through a phone based system or through an online system operated by the Department or its contractor. The Department recommends the Contractor use the Virginia Medicaid Enterprise System Provider Portal or the 270/271 batch lookup process. More information on how to access the 270/271 process can be found here.

In the event the real-time online system is not operational, the Department will provide an alternative method. The Department will respond to all eligibility inquiries in no less than five (5) business days.

In the event the Contractor is not able to utilize the real-time online system through no fault of the Department, the Department may, but is not obligated to, provide an alternative method.

The Contractor and the Department each acknowledge that the Contractor is a "Covered Entity," as defined in the Standards for Privacy of Individually Identifiable Health Information (45 CFR Parts 160 and 164) pursuant to the Health Insurance Portability and Accountability Act of 1996 (the "Privacy Rule"). Access to the eligibility data is conditioned on the Contractor's Contract to abide by the requirements of the Health Insurance Portability and Accountability Act of 1996, the Health Information Technology for Economic and Clinical Health Act on 2009, and an executed Business Associate Agreement with the Department (see Attachment 7.2).

3.3.2 Non-Discrimination

Unless a dual eligible individual is otherwise excluded under federal Medicare Advantage plan rules or does not meet dual eligible Medicaid eligibility as described in Section 3.1, the Contractor will accept all dual eligibles who select the Contractor's D-SNP without regard to physical or mental condition, health status or need for or receipt of health care services, claims experience, medical history, genetic

information, disability, marital status, age, sex, sexual orientation (pursuant to Governor's Executive Order #1 and § 3.12 of the Department of General Services Agency Procurement and Surplus Property Manual), national origin, race, color, or religion. Furthermore, the Contractor will not implement any policy or practice that has the effect of such discrimination.

3.4 Disenrollment and Loss of Medicaid Eligibility

3.4.1 Loss of Medicaid Eligibility

When a Member losses Medicaid eligibility and the Contractor determines the individual is likely to regain Medicaid eligibility within six months of the termination date the Contractor must retain the Member for the full six months. The Contractor must apply the criteria used to determine if an individual is likely to regain Medicaid eligibility consistently to all Members and must fully inform all Members of its policy. See CMS' *Medicare Managed Care Manual, Chapter 2 – Medicare Advantage Enrollment and Disenrollment* for guidance on determining if an individual is likely to regain eligibility.

3.4.2 Sharing of Member Health Information

The Contractor must provide all pertinent health information, including assessments, plan(s) of care and Medicare encounter data, to another MA D-SNP contracted by the Department when a former Member enrolls with the other D-SNP and when the new D-SNP has requested such information.

4.0 Medicare-Medicaid Coordination Requirements

4.1 Behavioral Health

The Contractor must coordinate all carved out or excluded behavioral health benefits with the State's contract BHSA when appropriate and until those services are included in the Managed Care program.

4.2 Coordination with State

At the Department's request, the Contractor must meet with the Department in person or by phone regarding dual eligible Members and provide the Department with all requested data in a timely manner.

During the Contract year, the Contractor must be required to meet, discuss, collaborate with the Department and other DMAS contracted MA D-SNPs, and implement ways to simplify processes and/or notifications to Members that are enrolled in the health plan's Cardinal Care Managed Care plan and the Contractor's D-SNP.

4.3 Staff Training

The Contractor must train their Care Coordinators and other related staff on available Medicaid benefits and coordination of Medicare and Medicaid benefits.

The Contractor will also be required to train staff on topics as requested by the Department and within a timeframe designated by the Department. The Contractor will also be required to allow the Department to provide targeted training to their staff.

4.4 Provider Training

The Contractor must train network providers on available D-SNP and Cardinal Care Managed Care program benefits and services as requested by a provider or provider association.

4.5 Member Transition

The Contractor is required to participate in all activities as directed by the Department which relate to Member transition as a result of termination of this contract. This applies to terminations directed from the Department, CMS or the Contractor.

5.0 Reporting and Other Deliverables

Besides the specific reports required in other sections of this contract, there are no other reporting requirements at this time. The Department may require additional reporting through separate guidance. As much as possible, the Department will provide at least 30 days before any new reporting requirements are added.

The Department may, at its discretion, change the content, format or frequency of reports.

In addition, the Department may, at its discretion, require the Contractor to submit additional reports both ad hoc and recurring. If the Department requests any revisions to the reports already submitted, the Contractor must make the changes and re-submit the reports, according to the time period and format required by the Department.

5.1 Standards, License(s) and Certificates

5.1.1 Bureau of Insurance

The Contractor must submit to the Department a copy of all quarterly and annual filings submitted to the Bureau of Insurance. Any revisions to a quarterly and/or annual BOI financial statement shall be submitted to the Department on the same day on which it is submitted to the BOI.

5.1.2 MCHIP

The Contractor must submit to the Department biennial certifications by the Virginia State Health Commissioner Center for Quality Health Care Services to operate as a managed care health insurance plan (MCHIP).

5.1.3 Revocations

The Contractor must submit to the Department all revocations of the license(s) and certifications as described in Section 22 of this Contract.

5.1.4 Federal Authority

The Contractor must submit to the Department annual approval issued by CMS to operate a D-SNP in the Commonwealth of Virginia.

5.2 Member Communications

1) The Contractor must submit to the Department an electronic copy of the Evidence of Coverage annually and upon any significant change.

2) The Contractor must submit to the Department a completed copy of the “Summary of Benefit” document annually and upon significant change.

3) The Contractor must submit to the Department a copy of all marketing materials upon request of the Department. (Medicaid materials should be submitted through the proper individuals providing oversight to the Medicaid program.)

4) The Contractor must submit to the Department, for prior review thirty (30) days before use, the Contractor's enrollment notice that will be provided to default enrollment individuals, pursuant to 42 CFR 422.66(c)(2)(iv), as described in Section 4.7.2 of this Contract.

5.3 Actions, Sanctions and Audits

The Contractor must submit to the Department copy of any of the following that may be issued and/or required by CMS:

1) A copy of all CMS-issued compliance actions;

2) A copy of all CMS issued sanctions;

3) A copy of all corrective action(s) that are required to be provided to CMS in response to CMS-issued compliance actions and/or sanctions;

4) A copy of all CMS notices of audits (when the Contractor is provided the notice in advance); and

5) A copy of all CMS audit summary reports.

If the Department determines that the Contractor has violated any provision of this Contract, the Contractor must be required to submit a corrective action plan to the Department describing how the Contractor will implement improvements to ensure they resolve the error. If a resolution cannot be reached, the Contractor must submit a termination of this Contract.

5.4 Encounters

The Contractor must submit encounter data to the Department, in a format and frequency determined by the Department. Specifications are provided in the *Encounter Technical Manual* and *837 Companion Guide*. Encounters must be submitted within thirty (30) calendar days of the remittance.

6.0 Miscellaneous

6.1 Performance Evaluation

The Contractor may be subject to performance evaluation by the Department. Performance reviews may be conducted at the discretion of the Department upon reasonable prior written notice to the Contractor, and may relate to any responsibility and/or requirement of the Contractor under this Contract.

6.2 D-SNP Improvement Plan

If, at any time, the Department reasonably determines that the Contractor is deficient in the performance of its obligations under this Contract, DMAS may require the Contractor to develop and submit a D-SNP Improvement Plans (DIP) that is designed to correct such deficiencies. The DIP gives the Contractor the opportunity to analyze and identify the root causes of the identified findings and observations, and to develop a plan to address the findings and observations to ensure future compliance with this Contract and State/Federal regulations. The Department will approve, disapprove, or require modifications to the DIP based on their reasonable judgment as to whether the DIP will correct the deficiency.

Failure to implement the DIP may subject the Contractor to termination of the Contract by the Department as described in Section 1.7 of this contract.

6.3 Approved Service Areas

The Contractor must offer their D-SNP to eligible beneficiaries as described in Section 3.1. The Contractor must offer their D-SNP in the localities identified with the signature document (see Attachment 7.1).

6.4 Member Marketing and Education

The Contractor must communicate and market to Members in accordance with all applicable rules under 42 CFR Parts 422 and 423 as well as all CMS issued Medicare Communications and Marketing Guidelines.

All marketing or education materials and information that specifically discusses the Member's Medicaid health plan enrollment choice, or are generally designed to influence the Member's Medicaid health plan enrollment choice, must be considered Medicaid marketing or education and therefore must be reviewed and approved by the Department as required in the Section 4.3 of the Cardinal Care Managed Care contract. Marketing or education materials and information include, but are not limited to, letters, notices, call-scripts, scripts for in person communication, and electronic outlet platforms. The Contractor must ensure all staff interacting with Members, including contracted staff such as brokers, are aware of and follow the approved materials and information.

Upon request of the Department, the Contractor shall provide copies of any member marketing or educational materials to the Department.

6.5 Covered Services

6.5.1 Medicaid Covered Services

Partial dual eligible enrollees are not enrolled in Medicaid managed care nor are they eligible for the full suite of Medicaid benefits. The Department pays the cost-sharing, such as cop-pays and deductibles, for these members The Contractor is not responsible for working with the Department regarding cost-sharing issues for their enrollees if needed.

6.5.2 Cost Sharing Protections

The Contractor and its contracted providers are prohibited from imposing cost-sharing requirements on enrollees of this contract that would exceed the amounts permitted under 42 CFR §422.504(g) for

individuals for whom the State only pays a limited amount each month toward their cost of care (e.g., deductibles), including non-full benefit Medicaid beneficiaries.

6.6 DMAS Obligations

6.6.1 Benefit Information

The Department will provide the Contractor with information regarding the services offered under the Virginia State Plan and Medicaid Managed Care on an annual basis. The latest table of these services can be found in the Cardinal Care Managed Care contract, and is also included in this document as Section 11.0.

6.6.2 Financial Responsibility

The Department, or its contractors, shall retain financial responsibility for applicable Medicaid cost sharing obligations including premium payments, coinsurance and/or copayments to healthcare providers. The State's obligation shall be no greater than it would be if Members were not enrolled in the Contractor's D-SNP.

6.6.3 Medicaid Provider Information

Upon request of the Contractor, the Department will provide the Contractor with information on Medicaid provider participation on an annual basis.

7.0 Definitions and Acronyms

Listed below are the Definitions and Acronyms used in this Contract. The following terms, when used in this Contract, shall be construed and/or interpreted as follows, unless the context expressly requires a different construction and/or interpretation. In the event of a conflict in language between these Definitions, Attachments, and other sections of this Contract, the specific language in the Contract shall govern.

7.1 Definitions

Affiliate – A State approved entity formed under a corporate entity that differs from the corporate entity of the Cardinal Care Managed Care plan, but is owned by the same corporate parent.

Behavioral Health Services Administrator (BHSA) - An entity that manages or directs a behavioral health benefits program. The BHSA is currently responsible for administering the Department's behavioral health benefits for Medicaid recipients enrolled in fee-for-service and for Residential Treatment Services and Treatment Foster Care Case Management described in the Summary of Covered Services Chart for members enrolled in Managed Care including care coordination, provider management, and reimbursement of such behavioral health services.

Cardinal Care Managed Care – The program name for Virginia's mandatory integrated Medicaid Managed Care program. Cardinal Care Managed Care replaces Virginia's current Medicaid Managed Care programs, Medallion 4.0 and Commonwealth Coordinated Care (CCC) Plus. Also referred to in this contract 'Medicaid Managed Care Porgram" and "Managed Care program".

Coinsurance – A percentage of the costs normally paid for covered services by members of a MA D-SNP. Coinsurance amounts must comply with the terms of the MA Contract.

Commonwealth Coordinated Care Plus (CCC Plus) - The program name for the Department's former mandatory integrated care initiative for certain qualifying individuals, including dual eligible individuals and individuals receiving long term services or supports (LTSS). The CCC Plus program included individuals who receive services through Nursing Facility (NF) care, or from the Department's home and community-based services (HCBS) 1915(c) waivers.

Commonwealth Coordinated Care Waiver - The Department's Home- and Community-Based waiver that covers a range of community support services offered to older adults, individuals who have a disability, and individuals who are chronically ill or severely impaired, having experienced loss of a vital body function, and who require substantial and ongoing skilled nursing care. The individuals, in the absence of services approved under this waiver, would require admission to a Nursing Facility, or a prolonged stay in a hospital or specialized care Nursing Facility. The CCC Plus Waiver has two (2) benefit plans: the standard benefit plan and the technology assisted benefit plan. Individuals who are enrolled in the technology assisted benefit plan are technology dependent and have experienced loss of a vital body function, and require substantial and ongoing skilled nursing care. Individuals in this waiver are eligible to participate in the Cardinal Care Managed Care program.

Contract - This signed and executed D-SNP program document issued, including all Attachments or documents incorporated by reference.

Contract Amendment or Contract Modification – Any changes, modifications or amendments to the Contract that are mutually agreed to in writing by the Contractor and the Department or are mandated by changes in Federal or State laws or regulations.

Contractor – By execution of this Contract as a Dual Eligible Special Needs Plan (D-SNP), is contracted with CMS as a Medicare Advantage health plan to provide Medicare part A, B and D benefits to individuals who are dual eligible for both Medicare and Medicaid, and is also contracted with the Department of Medical Assistance Services to provide services under the Cardinal Care Managed Care program. The Contractor is not required to be the same "single entity" or "legal entity" that is contracted with the Department for the Cardinal Care Managed Care program but must be owned by the same parent organization.

Co-payments – Fixed dollar amounts that a MA Health Plan Member normally must pay for a medical service provided under a Medicare Advantage Product. Co-payments amounts must comply with the terms of the MA Contract.

Deductible – Fixed dollar amounts that a MA D-SNP Member normally must pay out-of-pocket before the costs of services are covered by the Contractor. Deductibles must comply with the terms of the MA Contract.

Department of Medical Assistance Services (DMAS/The State/The Department) – The single State agency that administers the Medicaid Program in the Commonwealth of Virginia.

Dual Eligible – Individuals who are eligible for coverage from Medicare (Medicare Part A, Part B, or both) and Virginia Medicaid. (See Full Benefit Dual Eligible and Partial Benefit Dual Eligible).

Dual Eligible Special Needs Plan (D-SNP) – A type of Medicare Advantage (MA) plan that only enrolls individuals who are entitled to both Medicare (title XVIII) and medical assistance from a state plan under Medicaid (title XIX).

Full Benefit Dual Eligible - A Medicare beneficiary who receives Medicare Part A, B, and/or D benefits and who also receives full Medicaid benefits (e.g., QMB Plus/Extended and SLMB Plus/Extended).

Fully Integrated Dual Eligible Special Needs Plan (FIDE) – As defined in 42 CFR 422.2, is a dual eligible special needs plan that: (1) That provides dual eligible individuals access to Medicare and Medicaid benefits under a single entity that holds both an MA contract with CMS and a Medicaid managed care organization contract under section 1903(m) of the Act with the applicable State; (2) Whose capitated contract with the State Medicaid agency provides coverage, consistent with State policy, of specified primary care, acute care, behavioral health, and long-term services and supports, and provides coverage of nursing facility services for a period of at least 180 days during the plan year; (3) That coordinates the delivery of covered Medicare and Medicaid services using aligned care management and specialty care network methods for high-risk beneficiaries; and (4) That employs policies and procedures approved by CMS and the State to coordinate or integrate beneficiary communication materials, enrollment, communications, grievance and appeals, and quality improvement.

Highly Integrated Dual Eligible Special Needs Plan (HIDE) – As defined in 42 CFR 422.2, is a dual eligible special needs plan offered by an MA organization that provides coverage, consistent with State policy, of long-term services and supports, behavioral health services, or both, under a capitated contract that meets one of the following arrangements: (1) The capitated contract is between the MA organization and the Medicaid agency; or (2) The capitated contract is between the MA organization's parent organization (or another entity that is owned and controlled by its parent organization) and the Medicaid agency.

Long-Term Services and Supports (LTSS) - Services and supports provided to beneficiaries of all ages who have functional limitations and/or chronic illnesses that have the primary purpose of supporting the ability of the beneficiary to live or work in the setting of their choice, which may include the individual's home, a worksite, a provider-owned or controlled residential setting, a nursing facility, or other institutional setting.

MA Contract – The Medicare Advantage Plan Contract between the MA Health Plan and CMS to provide MA Dual-Eligible Special Needs Plan.

MA Dual Eligible Special Needs Plan (MA D-SNP) – A Medicare Advantage Health Plan contracted with CMS to provide Medicare Part A, B and D benefits to beneficiaries who are dually eligible for Medicare and Medicaid as defined and pursuant to this Contract. (See definition for Contractor.)

Member – Enrollee or Beneficiary of the Medicaid and/or Medicare programs.

Other full benefit dual eligible (FBDE) - An individual who is entitled to Medicare, does not meet the income or resource criteria for QMB+ or SLMB+, but is eligible for full Medicaid coverage either categorically or through optional coverage groups based on Medically Needy status, special income levels for institutionalized individuals, or home and community-based waivers.

Partial Benefit Dual Eligible - Individuals who receive both Medicare and Medicaid coverage but who are NOT eligible for full Medicaid benefits (e.g., individuals who qualify as Specified Low-Income Medicare Member (SLMBs), Qualified Medicare Member (QMBs), Qualified Disabled and Working Individuals (QDWIs), or Qualifying Individuals (QIs)).

Qualified Disabled Working Individual (QDWI) - An individual who has income that does not exceed two hundred percent (200%) of the Federal Poverty Level (FPL) and whose resources do not exceed $2,000. The Medicaid agency pays Medicare Part A premiums. No other cost sharing is covered for these individuals. The Medicaid agency pays Medicare Part A premiums under a group premium payment arrangement for individuals in the QDWI group defined in subsection 26 of 12VAC30-30-10.

Qualified Individuals (QI) - An individual who has income that does not exceed one hundred thirty five percent (135%) of the Federal Poverty Level (FPL) and whose resources do not exceed the limit set for the Medicare Part D Low-Income Subsidy (LIS) program. The Medicaid agency pays their Part B premiums.

Qualified Medicare Beneficiary (QMB) - An individual who is entitled to Medicare Part A, has income that does not exceed 100% of the Federal Poverty Level (FPL), and whose resources do not exceed the limit set for the Medicare Part D Low-Income Subsidy (LIS) program. A QMB is eligible for Medicaid Payment of Medicare premiums, Deductibles, Coinsurance, and Co-payments (except for Medicare Part D). These individuals are not eligible for additional benefits available under the State Plan for fully eligible Medicaid recipients.

Qualified Medicare Beneficiary Plus (QMB+) - An individual who is entitled to Medicare and meets the Federal income standard of income equal to or less than 100 percent of the Federal Poverty Level (FPL) and is determined eligible for full Medicaid coverage. Some QMB Plus individuals may achieve eligibility through a spend-down. A QMB Plus is eligible for Medicaid Payment of Medicare Part A premiums, Medicare Part B premiums and Medicare coinsurance and Medicare deductibles for Medicare covered services (except for Medicare Part D). Also referred to as QMB Plus or QMB Extended.

Significant Change – A change (decline or improvement) in an individual's status that: (1) will not normally resolve itself without intervention or by implementing standard disease-related clinical or social interventions, is not "self-limiting;" or (2) impacts more than one area of the individual's health or psychosocial status; and (3) requires interdisciplinary review and/or revision of the ICP.

Special Low Income Medicare Beneficiary (SLMB) - An individual who has income that does not exceed 120% of the Federal Poverty Level (FPL) and whose resources do not exceed the limit set for the Medicare Part D Low-Income Subsidy (LIS) program. The Medicaid agency pays Medicare Part B premiums under the State buy-in process for individuals in the SLMB group defined in subsection 27 of 12VAC30-30-10.

Special Low Income Medicare Beneficiary Plus (SLMB+) - An individual who is entitled to Medicare and meets the Federal income standard of income greater than 100 percent but less than one hundred twenty percent (120%) of the FPL and who also meets the financial criteria for full Medicaid coverage. Some SLMB Plus individuals may achieve eligibility through a spend-down. The Medicaid agency pays

Medicare Part B premiums under the State buy-in process for individuals determined eligible as a SLMB+. Also referred to as SLMB Plus or SLMB Extended.

State Plan – The comprehensive written statement submitted to CMS by the Department describing the nature and scope of the Virginia Medicaid program and giving assurance that it will be administered in conformity with the requirements, standards, procedures, and conditions for obtaining Federal financial participation. The Department has the authority to administer the State Plan for Virginia under Code of Virginia § 32.1-325, as amended.

7.2 Acronyms

BHSA -- Behavioral Health Services Administrator

BOI -- Bureau of Insurance

CAHPS® -- Consumer Assessment of Healthcare Providers and Systems

CFR -- Code of Federal Regulations

CMS -- Centers for Medicare and Medicaid Services

DMAS -- Department of Medical Assistance Services

D-SNP -- Dual Eligible Special Needs Plan

ESRD -- End Stage Renal Disease

FBDE -- Full Benefit Dual Eligible

FIDE – Fully Integrated Dual Eligible Special Needs Plan

GAP -- Governor's Access Plan

HEDIS -- Healthcare Effectiveness Data and Information Set

HIDE – Highly Integrated Dual Eligible Special Needs Plan

HIPAA -- Health Insurance Portability and Accountability Act of 1996

HIPP -- Health Insurance Premium Payment

HOS -- Health Outcome Survey

HPMS – Health Plan Management System

IAH -- Independence at Home Demonstration

ICF/ID -- Intermediate Care Facility/Individuals with Intellectual Disabilities

ICP – Integrated Care Plan

LTSS -- Long Term Services & Supports

MA -- Medicare Advantage

MCHIP -- Managed Care Health Insurance Plan

MLTSS -- Managed Long Term Services and Supports

PACE -- Program of All-inclusive Care for the Elderly

QDWI -- Qualified Disabled Working Individual

QI -- Qualified Individual

QIP – Quality Improvement Plan

QMB -- Qualified Medicare Beneficiary

QMB+ -- Qualified Medicare Beneficiary Plus

RTC -- Residential Treatment Level C

SLMB -- Special Low Income Medicare Beneficiary

SLMB+ -- Special Low Income Medicare Beneficiary Plus

USC -- United States Code

VAC -- Virginia Administrative Code

8.0 Signature Page

Effective Dates: January 1, 2024 through December 31, 2024

Contract Name: Dual Special Needs Plan (D-SNP)

Issued By: Commonwealth of Virginia, Department of Medical Assistance Services

Contractor: <Health Plan>

This contract is governed by the laws of the Commonwealth of Virginia and interpreted in accordance with Virginia law, except to the extent preempted by Federal law. The parties of this Contract will carry out their obligations under this Contract in the manner prescribed by all applicable laws, regulations and policies, including Federal and State law governing the Medicare and Medicaid programs.

This Contract is effective January 1, 2024 and shall continue through December 31, 2024.

1. By signature of this Contract, the Contractor agrees to adhere to all D-SNP Contract provisions. As part of this signature document, the Contractor shall operate in all localities noted on the following Locality Listing.

2. This contract is contingent upon receipt of final approval from the Centers for Medicare and Medicaid Services (CMS). Any revisions needed shall be completed through a subsequent contract Amendment.

3. By signature of this Contract, the Contractor agrees to adhere to all D-SNP program 2024 Contract provisions, including compliance with Federal conflict of interest provisions and compliance with requirements in 42 CFR § 438.610 prohibiting Contractor affiliations with individuals debarred by Federal agencies.

IN WITNESS HEREOF, the parties have caused this Contract Amendment to be duly executed intending to be bound thereby.

CONTRACTOR:	COMMONWEALTH OF VIRGINIA:
<Health Plan Name>	Department of Medical Assistance Services
BY: _____	BY: _____
NAME and DATE: _____	NAME and DATE: _____
TITLE: _____	TITLE: Director _____

8.1 Verifying Service Area

The Contractor is required to identify which localities it has been approved to operating within.

D-SNP CONTRACT LOCALITY LISTING **(Place X Beside Participating Locality)**							
Accomack County			Franklin County			Norton City	
Albemarle County			Frederick County			Nottoway County	
Alexandria City			Fredericksburg City			Orange County	
Alleghany County			Galax City			Page County	
Amelia County			Giles County			Patrick County	
Amherst County			Gloucester County			Petersburg City	
Appomattox County			Goochland County			Pittsylvania County	
Arlington County			Grayson County			Poquoson City	
Augusta County			Greene County			Portsmouth City	
Bath County			Greensville County			Powhatan County	
Bedford County			Halifax County			Prince Edward County	
Bland County			Hampton City			Prince George County	
Botetourt County			Hanover County			Prince William County	
Bristol City			Harrisonburg City			Pulaski County	
Brunswick County			Henrico County			Radford City	
Buchanan County			Henry County			Rappahannock County	
Buckingham County			Highland County			Richmond City	
Buena Vista City			Hopewell City			Richmond County	
Campbell County			Isle of Wight County			Roanoke City	
Caroline County			James City County			Roanoke County	
Carroll County			King and Queen County			Rockbridge County	
Charles City County			King George County			Rockingham County	
Charlotte County			King William County			Russell County	
Charlottesville City			Lancaster County			Salem City	
Chesapeake City			Lee County			Scott County	
Chesterfield County			Lexington City			Shenandoah County	
Clarke County			Loudoun County			Smyth County	
Colonial Heights City			Louisa County			Southampton County	
Covington City			Lunenburg County			Spotsylvania County	
Craig County			Lynchburg City			Stafford County	
Culpeper County			Madison County			Staunton City	
Cumberland County			Manassas City			Suffolk City	

Danville City			Manassas Park City			Surry County	
Dickenson County			Martinsville City			Sussex	
Dinwiddie County			Mathews County			Tazewell County	
Emporia City			Mecklenburg County			Virginia Beach City	
Essex County			Middlesex County			Warren County	
Fairfax City			Montgomery County			Washington County	
Fairfax County			Nelson County			Waynesboro City	
Falls Church City			New Kent County			Westmoreland County	
Fauquier County			Newport News City			Williamsburg City	
Floyd County			Norfolk City			Winchester City	
Fluvanna County			Northampton County			Wise County	
Franklin City			Northumberland County			Wythe County	
						York County	
TOTAL LOCALITIES = _____ OF 133							

9.0 Business Associate Agreement

THIS ATTACHMENT supplements and is made a part of the Business Associate Agreement (herein referred to as "Agreement") by and between the Department of Medical Assistance Services (herein referred to as "Covered Entity") and [name Business Associate] (herein referred to as "Business Associate").

General Conditions

This BAA ("Agreement" or "BAA") is made as of January 1, 2024 by the Department of Medical Assistance Services ("Covered Entity"), with offices at 600 East Broad Street, Richmond, Virginia, 23219, and _____ ("Business Associate"), with an office at _____. This is a non-exclusive agreement between the Covered Entity, which administers Medical Assistance, and the Business Associate named above.

The Covered Entity and Business Associate, as defined in 45 CFR § 160.103, have entered into this Business Associate Agreement to comply with all applicable provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), P.L. 104-191, as amended, the current and future Privacy and Security requirements for such an Agreement, the Health Information Technology for Economic and Clinical Health (HITECH) Act, (P.L. 111-5) Section 13402, requirements for business associates regarding breach notification, as well as our duty to protect the confidentiality and integrity of Protected Health Information (PHI) required by law, Department policy, professional ethics, and accreditation requirements.

DMAS and Business Associate ("parties") shall fully comply with all current and future provisions of the Privacy and Security Rules and regulations implementing HIPAA and HITECH, as well as Medicaid requirements regarding Safeguarding Information on Applicants and Recipients of 42 CFR 431, Subpart F, and Virginia Code § 32.1-325.3. The parties desire to facilitate the provision of or transfer of electronic PHI in agreed formats and to assure that such transactions comply with relevant laws and regulations. The parties intending to be legally bound agree as follows:

Definitions. As used in this agreement, the terms below will have the following meanings:

a. Business Associate has the meaning given such term as defined in 45 CFR § 160.103.
b. Covered Entity has the meaning given such term as defined in 45 CFR § 160.103.
c. Provider: Any entity eligible to be enrolled and receive reimbursement through Covered Entity for any Medicaid-covered services.
d. MMIS: The Medicaid Management Information System, the computer system that is used to maintain Member, provider, and claims data for administration of the Medicaid program.
e. Protected Health Information (PHI) has the meaning of individually identifiable health information as those terms are defined in 45 CFR § 160.103.
f. Breach has the meaning as that term is defined at 45 CFR § 164.402.
g. Required by law shall have the meaning as that term is defined at 45 CFR § 160.103.
h. Unsecured Protected Health Information **has** the meaning as that term is defined at 45 CFR § 164.402.

i. Transport Layer Security (TLS): A protocol (standard) that ensures privacy between communicating applications and their users on the Internet. When a server and client communicate, TLS ensures that no third party may eavesdrop or tamper with any message. TLS is the successor to the Secure Sockets Layer (SSL).

Terms used, but not otherwise defined, in this Agreement shall have the same meaning given those terms under HIPAA, the HITECH Act, and other applicable federal law.

I. Notices

1. Written notices regarding impermissible use or disclosure of unsecured protected health information by the Business Associate shall be sent via email or general mail to the DMAS Chief Financial Officer (with a copy to the DMAS contract administrator in II.2) at:

DMAS Chief Financial Officer
Department of Medical Assistance Services
600 East Broad Street
Richmond, Virginia 23219
DSNP@dmas.virginia.gov

2. Other written notices to the Covered Entity should be sent via email or general mail to DMAS contract administrator at:

Contact: DMAS Division of Integrated Care
Department of Medical Assistance Services
600 East Broad Street
Richmond, Virginia 23219
DSNP@dmas.virginia.gov

II. Special Provisions to General Conditions

1) Uses and Disclosure of PHI by Business Associate. The Business Associate
   a. May use or disclose PHI received from the Covered Entity, if necessary, to carry out its legal responsibilities and for the proper management and administration of its business.
   b. Shall not use PHI otherwise than as expressly permitted by this Agreement, or as required by law.
   c. Shall have a signed confidentiality agreement with all individuals of its workforce who have access to PHI.
   d. Shall not disclose PHI to any member of its workforce except to those persons who have authorized access to the information, and who have signed a confidentiality agreement.
   e. Shall ensure that any agents and subcontractors to whom it provides PHI received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity, agree in writing to all the same restrictions, terms, special provisions and general conditions in this BAA that apply to Business Associate. In addition, Business Associate shall ensure that any such subcontractor or agent agrees to implement reasonable and appropriate

safeguards to protect Covered Entity's PHI. In instances where one DMAS Business Associate is required to access DMAS PHI from another DMAS Business Associate, the first DMAS Business Associate shall enter into a business associate agreement with the second DMAS Business Associate.

f. Shall provide Covered Entity access to its facilities used for the maintenance and processing of PHI, for inspection of its internal practices, books, records, and policies and procedures relating to the use and disclosure of PHI, for purpose of determining Business Associate's compliance with this BAA.

g. Shall make its internal practices, books, records, and policies and procedures relating to the use and disclosure of PHI received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity, available to the Secretary of Department of Health and Human Services (DHHS) or its designee and provide Covered Entity with copies of any information it has made available to DHHS under this section of this BAA.

h. Shall not directly or indirectly receive remuneration in exchange for the provision of any of Covered Entity's PHI, except with the Covered Entity's consent and in accordance with 45 CFR§ 164.502. Shall make reasonable efforts in the performance of its duties on behalf of Covered Entity to use, disclose, and request only the minimum necessary PHI reasonably necessary to accomplish the intended purpose with the terms of this Agreement.

i. Shall comply with 45 CFR § 164.520 regarding Notice of privacy practices for protected health information.

2. Safeguards - Business Associate shall

a. Implement administrative, physical and technical safeguards that reasonably and appropriately protect the confidentiality, integrity and availability of electronic PHI that it creates, receives, maintains or transmits on behalf of Covered Entity as required by the HIPAA Security Rule, 45 CFR Parts 160, 162, and 164 and the HITECH Act.

b. Include a description of such safeguards in the form of a Business Associate Data Security Plan.

c. In accordance with the HIPAA Privacy Rule, the Security Rule, and the guidelines issued by the National Institute for Standards and Technology (NIST), Business Associate shall use commercially reasonable efforts to secure Covered Entity's PHI through technology safeguards that render PHI unusable, unreadable and indecipherable to individuals unauthorized to access such PHI.

d. Business Associate shall not transmit PHI over the Internet or any other insecure or open communication channel, unless such information is encrypted or otherwise safeguarded using procedures no less stringent than described in 45 CFR § 164.312(e).

e. Business Associate shall cooperate and work with Covered Entity's contract administrator to establish TLS-connectivity to ensure an automated method of the secure exchange of email.

3. Accounting of Disclosures - Business Associate shall

a. Maintain an ongoing log of the details relating to any disclosures of PHI outside the scope of this Agreement that it makes. The information logged shall include, but is not limited to;

i. the date made,

ii. the name of the person or organization receiving the PHI,

iii. the recipient's (Member) address, if known,

iv. a description of the PHI disclosed, and the reason for the disclosure.

b. Provide this information to the Covered Entity to respond to a request by an individual for an accounting of disclosures of PHI in accordance with 45 CFR § 164.528.

4. Sanctions - Business Associate shall

   a. Implement and maintain sanctions for any employee, subcontractor, or agent who violates the requirements in this Agreement or the HIPAA privacy regulations.
   b. As requested by Covered Entity, take steps to mitigate any harmful effect of any such violation of this agreement.

5. Business Associate also agrees to all of the following:

   a. In the event of any impermissible use or disclosure of PHI or breach of unsecured PHI made in violation of this Agreement or any other applicable law, the Business Associate shall notify the DMAS Privacy Officer.
      i. Initial notification regarding any impermissible use or disclosure by the Business Associate must be immediate or as soon as possible after discovery. Formal notification shall be delivered within 5 business days from the first day on which such breach is known or reasonably should be known by Business Associate or an employee, officer or agent of Business Associate other than the person committing the breach, and

      ii. Written notification to DMAS Privacy Officer shall include the identification of each individual whose unsecured PHI has been, or is reasonably believed by the Contractor to have been, accessed, acquired, used or disclosed during the breach. Business Associate shall confer with DMAS prior to providing any notifications to the public or to the Secretary of HHS.

   b. Breach Notification requirements.
      i. In addition to requirements in 5.a above, in the event of a breach or other impermissible use or disclosure by Business Associate of PHI or unsecured PHI, the Business Associate shall be required to notify in writing all affected individuals to include,
         a) a brief description of what happened, including the date of the breach and the date the Business Associate discovered the breach;
         b) a description of the types of unsecured PHI that were involved in the breach;
         c) any steps the individuals should take to protect themselves from potential harm resulting from the breach;
         d) a brief description of what Business Associate is doing to investigate the breach, mitigate harm to individuals, and protect against any future breaches, and, if necessary,
         e) Establishing and staffing a toll-free telephone line to respond to questions.
      ii. Business Associate shall be responsible for all costs associated with breach notifications requirements in 5b, above.

iii. Written notices to all individuals and entities shall comply with 45 CFR § 164.404(c)(2), 164.404(d)(1), 164.406, 164.408 and 164.412.

6. Amendment and Access to PHI - Business Associate shall

a. Make an individual's PHI available to Covered Entity within ten (10) days of an individual's request for such information as notified by Covered Entity.
b. Make PHI available for amendment and correction and shall incorporate any amendments or corrections to PHI within ten (10) days of notification by Covered Entity per 45 CFR § 164.526.
c. Provide access to PHI contained in a designated record set to the Covered Entity, in the time and manner designated by the Covered Entity, or at the request of the Covered Entity, to an individual in order to meet the requirements of 45 CFR § 164.524.

7. Termination

a. Covered Entity may immediately terminate this agreement if Covered Entity determines that Business Associate has violated a material term of the Agreement.
b. This Agreement shall remain in effect unless terminated for cause by Covered Entity with immediate effect, or until terminated by either party with not less than thirty (30) days prior written notice to the other party, which notice shall specify the effective date of the termination; provided, however, that any termination shall not affect the respective obligations or rights of the parties arising under any Documents or otherwise under this Agreement before the effective date of termination.
c. Within thirty (30) days of expiration or earlier termination of this agreement, Business Associate shall return or destroy all PHI received from Covered Entity (or created or received by Business Associate on behalf of Covered Entity) that Business Associate still maintains in any form and retain no copies of such PHI.
d. Business Associate shall provide a written certification that all such PHI has been returned or destroyed, whichever is deemed appropriate by the Covered Entity. If such return or destruction is infeasible, Business Associate shall use such PHI only for purposes that make such return or destruction infeasible and the provisions of this agreement shall survive with respect to such PHI.

8. Amendment

a. Upon the enactment of any law or regulation affecting the use or disclosure of PHI, or the publication of any decision of a court of the United States or of this state relating to any such law, or the publication of any interpretive policy or opinion of any governmental agency charged with the enforcement of any such law or regulation, Covered Entity may, by written notice to the Business Associate, amend this Agreement in such manner as Covered Entity determines necessary to comply with such law or regulation.
b. If Business Associate disagrees with any such amendment, it shall so notify Covered Entity in writing within thirty (30) days of Covered Entity's notice. If the parties are unable to agree on an amendment within thirty (30) days thereafter, either of them may terminate this Agreement by written notice to the other.

9. Indemnification. Business Associate shall indemnify and hold Covered Entity harmless from and against all claims, liabilities, judgments, fines, assessments, penalties, awards, or other expenses, of any kind or nature whatsoever, including, without limitation, attorney's fees, expert witness fees, and costs of investigation, litigation or dispute resolution, relating to or arising out of any breach or alleged breach of this Agreement by Business Associate.

10. This Agreement shall have a document, attached hereto and made a part hereof, containing the following:

a. The names and contact information for at least one primary contact individual from each party to this Agreement.
b. A complete list of all individuals, whether employees or direct contractors of Business Associate, who shall be authorized to access Covered Entity's PHI
c. A list of the specific data elements required by Business Associate in order to carry out the purposes of this Agreement.
d. The purposes for which such data is required.
e. A description of how Business Associate intends to use, access or disclose such data in order to carry out the purposes of this Agreement.

Business Associate agrees to update the above noted information as needed in order to keep the information current. Covered Entity may request to review the above-referenced information at any time, including for audit purposes, during the term of this Agreement.

11. Disclaimer. COVERED ENTITY MAKES NO WARRANTY OR REPRESENTATION THAT COMPLIANCE BY BUSINESS ASSOCIATE WITH THIS AGREEMENT OR THE HIPAA REGULATIONS WILL BE ADEQUATE OR SATISFACTORY FOR BUSINESS ASSOCIATE'S OWN PURPOSES OR THAT ANY INFORMATION IN BUSINESS ASSOCIATE'S POSSESSION OR CONTROL, OR TRANSMITTED OR RECEIVED BY BUSINESS ASSOCIATE, IS OR WILL BE SECURE FROM UNAUTHORIZED USE OR DISCLOSURE, NOR SHALL COVERED ENTITY BE LIABLE TO BUSINESS ASSOCIATE FOR ANY CLAIM, LOSS OR DAMAGE RELATED TO THE UNAUTHORIZED USE OR DISCLOSURE OF ANY INFORMATION RECEIVED BY BUSINESS ASSOCIATE FROM COVERED ENTITY OR FROM ANY OTHER SOURCE. BUSINESS ASSOCIATE IS SOLELY RESPONSIBLE FOR ALL DECISIONS MADE BY BUSINESS ASSOCIATE REGARDING THE SAFEGUARDING OF PHI.