MARYLAND MEDICAID

REGULATORY REQUIREMENTS APPENDIX

DOWNSTREAM PROVIDER

THIS MARYLAND MEDICAID REGULATORY REQUIREMENTS APPENDIX (this "Appendix") supplements and is made part of the provider agreement (the "Agreement") between UnitedHealthcare Insurance Company or one of its Affiliates and the party named in the Agreement ("Provider").

SECTION 1 APPLICABILITY

The requirements of this Appendix apply to Medicaid benefit plans sponsored, issued or administered by UnitedHealthcare of the Mid-Atlantic, Inc. (referred to in this Appendix as "United") under the State of Maryland Medicaid Managed Care Program (the "State Program") as governed by the State's designated regulatory agencies. In the event of a conflict between this Appendix and other appendices or any provision of the Agreement, the provisions of this Appendix shall control except with regard to benefit plans outside the scope of this Appendix or unless otherwise required by law. In the event United is required to amend or supplement this Appendix as required or requested by the State to comply with federal or State regulations, United will unilaterally initiate such additions, deletions or modifications.

SECTION 2 DEFINITIONS

Unless otherwise defined in this Appendix, all capitalized terms shall be as defined in the Agreement. For purposes of this Appendix, the following terms shall have the meanings set forth below; provided, however, in the event any definition set forth in this Appendix or the Agreement is inconsistent with any definitions under the applicable State Program, the definitions shall have the meaning set forth under the applicable State Program.

- **2.1 Affiliate:** Those entities controlling, controlled by, or under common control with UnitedHealthcare Insurance Company.
- **2.2 Covered Person:** An individual who is currently enrolled with United for the provision of services under a State Program. A Covered Person may also be referred to as an Enrollee, Member or Customer under the Agreement.
- **2.3 Covered Services:** Health care services or products for which a Covered Person is enrolled with United to receive coverage under the State Contract.
- **2.4 Department:** The Maryland Department of Health or its authorized agents acting on behalf of the Department.
- **2.5 State:** The State of Maryland or its designated regulatory agencies.
- **State Contract:** United's contract with the Department for the purpose of providing and paying for Covered Services to Covered Persons enrolled in the State Program.

2.7 State Program or HealthChoice Program: The State of Maryland's Medicaid Managed Care Program. For purposes of this Agreement, State Program or HealthChoice Program may refer to the State agency(ies) that administer the State Program (e.g., the Maryland Department of Health).

SECTION 3 PROVIDER REQUIREMENTS

The State Program, through contractual requirements and federal and State statutes and regulations, requires the Agreement to contain certain conditions that United and Provider agree to undertake, which include the following:

- 3.1 Definitions Related to the Provision of Covered Services. Provider shall follow the applicable State Contract's requirements for the provision of Covered Services. Provider's decisions affecting the delivery of acute or chronic care services to Covered Persons shall be made on an individualized basis and in accordance with the following definitions:
 - i) <u>Emergency Medical Condition</u>: A medical condition characterized by sudden onset and symptoms of sufficient severity, including severe pain, such that the absence of immediate medical attention could reasonably be expected by a prudent layperson, who possesses an average knowledge of health and medicine, to result in any of the following: (i) placing the patient's health, or with respect to a pregnant woman, the health of the woman or unborn child, in serious jeopardy; (ii) serious impairment to bodily functions; or (iii) serious dysfunction of any bodily organ or part.
 - ii) Emergency Services: Those health care services that are provided in a hospital emergency facility after the sudden onset of a medical condition that manifests itself by symptoms of sufficient severity, including severe pain, such that the absence of immediate medical attention could reasonably be expected by a prudent layperson, who possesses an average knowledge of health and medicine, to result in: (i) placing the patient's health, or with respect to a pregnant woman, the health of the woman or unborn child, in serious jeopardy; (ii) serious impairment to bodily functions; or (iii) serious dysfunction of any bodily organ or part.
 - iii) Medically Necessary or Medical Necessity: A service or benefit that is:
 - a) Directly related to diagnostic, preventive, curative, palliative, rehabilitative, or ameliorative treatment of an illness, injury, disability, or health condition;
 - b) Consistent with current accepted standards of good medical practice;
 - c) The most cost efficient service that can be provided without sacrificing effectiveness or access to care; and
 - d) Not primarily for the convenience of the consumer, the consumer's family, or the Provider.
 - iv) <u>Urgent Care</u>: Health care services for a medical condition that manifests itself by symptoms of sufficient severity such that the absence of medical attention within forty-eight (48) hours could reasonably be expected, by a prudent layperson who possesses an average knowledge of health and medicine, to result in an emergency medical condition.

- **3.2 Medicaid or CHIP Participation.** Provider must be enrolled with the State as a Medicaid or CHIP provider, as applicable to participate in United's Medicaid or CHIP network. Upon notification from the State that Provider's enrollment has been denied or terminated, United must terminate Provider immediately and will notify affected Covered Persons that Provider is no longer participating in the network. United will exclude from its network any provider who has been terminated or suspended from the Medicare, Medicaid or CHIP program in any state.
- **3.3** Accessibility Standards. Provider shall provide for timely access for Covered Person appointments in accordance with the appointment availability requirements established under the State Contract, as further described in the applicable provider manual.
- **3.4 Hours of Operation; Appointments.** Provider shall offer hours of operation that are no less than the hours of operation offered to commercial beneficiaries or comparable to Medicaid feefor-service if Provider serves only Medicaid beneficiaries. As applicable, Provider will make Covered Services available 24 hours a day, 7 days a week when medically necessary.
- 3.5 Hold Harmless. Except for any applicable cost-sharing requirements under the State Contract, Provider shall look solely to United for payment of Covered Services provided to Covered Persons pursuant to the Agreement and the State Contract and hold the State, the U.S. Department of Health and Human Services and Covered Persons harmless in the event that United cannot or will not pay for such Covered Services. In accordance with 42 CFR Part 447.15, as may be amended from time to time, the Covered Person is not liable to Provider for any services for which United is liable and as specified under the State's relevant health insurance or managed care statutes, rules or administrative agency guidance. Provider shall not require any copayment or cost sharing for Covered Services provided under the Agreement unless expressly permitted under the State Contract. Provider shall also be prohibited from charging Covered Persons for missed appointments if such practice is prohibited under the State Contract or applicable law. Neither the State, the Department nor Covered Persons shall be in any manner liable for the debts and obligations of United and under no circumstances shall United, or any providers used to deliver services covered under the terms of the State Contract, charge Covered Persons for Covered Services.

If the medical assistance services are not Covered Services, prior to providing the service, Provider shall inform the Covered Person of the non-covered service and have the Covered Person acknowledge the information. If the Covered Person still requests the service, Provider shall obtain such acknowledgement in writing prior to rendering the service. If United determines a Covered Person was charged for Covered Services inappropriately, such payment may be recovered, as applicable.

This provision shall survive any termination of the Agreement, including breach of the Agreement due to insolvency.

3.6 Indemnification. To the extent applicable to Provider in performance of the Agreement, Provider shall indemnify, defend and hold the Department and its employees harmless from and against all injuries, deaths, losses, damages, claims, suits, liabilities, judgments, costs and expenses, including court costs and attorney fees, to the extent proximately caused by any negligent act or other intentional misconduct or omission of Provider, its agents, officers, employees or contractors arising from the Agreement. The Department may waive this requirement for public entities if Provider is a state agency or sub-unit as defined by the State or a public health entity

with statutory immunity. This clause shall survive the termination of the Agreement for any reason, including breach due to insolvency.

- **3.7 Provider Selection.** To the extent applicable to Provider in performance of the Agreement, Provider shall comply with 42 CFR 438.214, as may be amended from time to time, which includes, but is not limited to the selection and retention of providers, credentialing and recredentialing requirements and nondiscrimination. If United delegates credentialing to Provider, United will provide monitoring and oversight and Provider shall ensure that all licensed medical professionals are credentialed in accordance with United's and the State Contract's credentialing requirements.
- **3.8 Restrictions on Referrals.** Provider shall not make inappropriate referrals for designated health services to health care entities with which Provider or a member of Provider's family has a financial relationship, pursuant to federal anti-kickback and physician self-referral laws that prohibit such referrals
- **Subcontracts.** If Provider subcontracts or delegates any functions of the Agreement, in accordance with the terms of the Agreement, the subcontract or delegation must be in writing and include all of the requirements of this Appendix, applicable requirements of the State Contract, and applicable laws and regulations. Provider further agrees to promptly amend its agreements with such subcontractors, in the manner requested by United, to meet any additional State Program requirements that may apply to the services.
- 3.10 Records Retention. As required under State or federal law or the State Contract, Provider shall maintain an adequate record keeping system for recording services, charges, dates and all other commonly accepted information elements for services rendered to Covered Persons. All financial records shall follow generally accepted accounting principles. Medical records and supporting management systems shall include all pertinent information related to the medical management of each Covered Person. Other records shall be maintained as necessary to clearly reflect all actions taken by Provider related to services provided under the State Contract. Provider shall retain all records including, as applicable, grievance and appeal records and any other records related to data, information, and documentation for a period of not less than 10 years from the close of the Agreement, or such other period as required by law. If records are under review or audit, they must be retained for a minimum of 10 years following resolution of such action. Prior approval for the disposal of records must be requested and approved by United if the Agreement is continuous.
- **3.11 Records Access.** Provider acknowledges and agrees that the State, the U.S. Department of Health and Human Services and other authorized federal and state personnel shall have complete access to all records pertaining to services provided to Covered Persons. Provider shall provide immediate access to facilities, records and supportive materials pertinent to the State Contract for State or Federal fraud investigators.
- 3.12 Government Audit; Investigations. Provider acknowledges and agrees that the State, CMS, the Office of Inspector General, the Comptroller General, and the U.S. Department of Health and Human Services and their designees or their authorized representatives shall at any time have the right to inspect, audit or otherwise evaluate the quality, appropriateness, and timeliness of services provided under the terms of the State Contract and any other applicable rules, including the right to inspect and audit any records or documents of Provider and its subcontractors, and the right to inspect the premises, physical facilities, and equipment where Medicaid-related activities or work is conducted. The right to audit under this section exists for 10 years from the end date of

the State Contract or from the date of completion of any audit, whichever is later. There shall be no restrictions on the right of the State or federal government to conduct whatever inspections and audits are necessary to assure quality, appropriateness or timeliness of services provided pursuant to the State Contract and the reasonableness of their costs.

3.13 Privacy; Confidentiality. Provider understands that the use and disclosure of information concerning Covered Persons is restricted to purposes directly connected with the administration of the State Program and shall maintain the confidentiality of Covered Person's information and records as required by the State Contract and in federal and State law including, but not limited to, all applicable privacy, security and Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), Public Law 104-191, and associated implementing regulations, including but not limited to 45 CFR Parts 160, 162, 164, as applicable and as may be amended from time to time, and shall safeguard information about Covered Persons in accordance with applicable federal and State privacy laws and rules including but not limited to 42 CFR §438.224, 42 CFR Part 2, and 42 CFR Part 431, Subpart F; 42 CFR Part 434 and 42 CFR 438.6 (if applicable), as may be amended from time to time.

Access to member identifying information shall be limited by Provider to persons or agencies that require the information in order to perform their duties in accordance with this Agreement, including the U.S. Department of Health and Human Services (HHS), the Department and other individuals or entities as may be required. (See 42 CFR §431.300, et seq. and 45 CFR Parts 160 and 164.) Any other party shall be granted access to confidential information only after complying with the requirements of state and federal laws, including but not limited to HIPAA, and regulations pertaining to such access. Provider is responsible for knowing and understanding the confidentiality laws listed above as well as any other applicable laws. Nothing herein shall prohibit the disclosure of information in summary, statistical or other form that does not identify particular individuals, provided that deidentification of protected health information is performed in compliance with the HIPAA Privacy Rule.

Federal and State Medicaid regulations, and some other federal and State laws and regulations, including but not limited to those listed above, are often more stringent than the HIPAA regulations. Provider shall notify United and the Department of any breach of confidential information related to Covered Persons within the time period required by applicable federal and State laws and regulations following actual knowledge of a breach, including any use or disclosure of confidential information, any breach of unsecured PHI, and any Security Incident (as defined in HIPAA regulations) and provide United and the Department with an investigation report within the time period required by applicable federal and State laws and regulations following the discovery. Provider shall work with United and the Department to ensure that the breach has been mitigated and reporting requirements, if any, complied with.

3.14 Disclosures without Covered Person Authorization. As required by §4-306 of the Health-General Article, Annotated Code of Maryland, Provider shall disclose a medical record without the authorization of a person in interest to a unit of State or local government, or to a member of a multidisciplinary team assisting the unit, for purposes of investigation or treatment in case of suspected abuse or neglect of a child, adult, subject to the conditions listed in §4-306 of the Health-General Article, Annotated Code of Maryland.

- **3.15 Compliance with Law.** Provider shall comply with all applicable federal and State laws and regulations, including but not limited to the following to the extent applicable to Provider in performance of the Agreement:
 - i) Title VI of the Civil Rights Act of 1964; title IX of the Education Amendments of 1972 (regarding education programs and activities); the Age Discrimination Act of 1975; the Rehabilitation Act of 1973; Americans with Disabilities Act; and section 1557 of the Patient Protection and Affordable Care Act; and their implementing regulations, as may be amended from time to time.
 - ii) All relevant federal and State statutes, regulations and orders related to equal opportunity in employment, including but not limited to compliance with E.O. 11246, "Equal Employment Opportunity," as amended by E.O. 11375, "Amending Executive Order 11246 Relating to Equal Employment Opportunity," and as supplemented by regulations at 41 CFR part 60, "Office of Federal Contract Compliance Programs, Equal Employment Opportunity, Department of Labor."
 - iii) If the Agreement is for an amount in excess of \$100,000, Provider shall comply with all applicable standards, orders or regulations issued pursuant to the Clean Air Act, 42 U.S.C. 7401 et seq., and the Federal Water Pollution Control Act, as amended, 33 U.S.C. 1251 et seq. Any violations shall be reported to DHHS and the appropriate Regional Office of the Environmental Protection Agency.
 - iv) 42 CFR 438.214 and 42 CFR 455.105, as may be amended from time to time.
- 3.16 Physician Incentive Plans. In the event Provider participates in a physician incentive plan ("PIP") under the Agreement, Provider agrees that such PIPs must comply with 42 CFR 417.479, 42 CFR 438.3, 42 CFR 422.208, and 42 CFR 422.210, as may be amended from time to time. Neither United nor Provider may make a specific payment directly or indirectly under a PIP to a physician or physician group as an inducement to reduce or limit Medically Necessary services furnished to an individual Covered Person. PIPs must not contain provisions that provide incentives, monetary or otherwise, for the withholding of services that meet the definition of Medical Necessity.
- **3.17 Lobbying.** Provider agrees to comply with the following requirements related to lobbying:
 - Prohibition on Use of Federal Funds for Lobbying: By signing the Agreement, Provider certifies to the best of Provider's knowledge and belief, pursuant to 31 U.S.C. Section 1352 and 45 CFR Part 93, as may be amended from time to time, that no federally appropriated funds have been paid or will be paid to any person by or on Provider's behalf for the purpose of influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the award of any federal contract, the making of any federal grant, the making of any federal loan, the entering into of any cooperative agreement, or the extension, continuation, renewal, amendment, or modification of any federal contract, grant, loan, or cooperative agreement.
 - ii) <u>Disclosure Form to Report Lobbying</u>: If any funds other than federally appropriated funds have been paid or will be paid to any person for the purpose of influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection

with the award of any federal contract, the making of any federal grant, the making of any federal loan, the entering into of any cooperative agreement, or the extension, continuation, renewal, amendment or modification of any federal contract, grant, loan, or cooperative agreement and the value of the Agreement exceeds \$100,000, Provider shall complete and submit Standard Form-LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions.

- **3.18 Excluded Individuals and Entities.** By signing the Agreement, Provider certifies to the best of Provider's knowledge and belief that neither it nor any of its employees, principals, nor any providers, subcontractors or consultants or persons with an ownership or controlling interest in the Provider (an owner including the Provider himself or herself), or an agent or managing employee of the Provider, with whom Provider contracts and who are providing items or services that are significant and material to Provider's obligations under the Agreement is:
 - i) excluded from participation in federal health care programs under either Section 1128 or section 1128A of the Social Security Act; or
 - debarred, suspended or otherwise excluded from participating in procurement activities under the Federal Acquisition Regulation or from participating in nonprocurement activities under regulations issued under Executive Order no. 12549 or under guidelines implementing Executive Order No. 12549; or an affiliate, as defined in the Federal Acquisition Regulation, of such a person.
 - Provider acknowledges and agrees that payment will not be made for any items or iii) Covered Services provided by an excluded individual pursuant to 42 CFR §1001.1901(b) and is obligated to screen all employees, contractors, and subcontractors for exclusion as required under applicable State and Federal laws. Additionally, Provider acknowledges that pursuant to 42 CFR §1003.102(a)(2) civil monetary penalties may be imposed against Provider if he or she employs or enters into contracts with excluded individuals or entities to provide items or Covered Services to Covered Persons under this Agreement. Provider agrees not to employ or subcontract with individuals or entities whose owner, those with a controlling interest, or managing employees are on a State or Federal exclusion list to provide items or Covered Services under this Agreement. Provider shall immediately report to United any exclusion information discovered. Provider can search the HHS-OIG website, at no cost, by the names of any individuals or entities. The database is called LEIE and can be accessed http://www.oig.hhs.gov/fraud/exclusions.asp. The GSA EPLS/SAM database can be accessed at https://www.sam.gov. Federal and State exclusion databases must be reviewed monthly to ensure that no employee or contractor has been excluded. Applicable state exclusion databases can be accessed through the State's Medicaid website. United will terminate the Agreement immediately and exclude from its network any provider who has been terminated from the Medicare, Medicaid or CHIP program in any state. United may also terminate the Agreement if Provider or Provider's owners, agents, or managing employees are found to be excluded on a State or Federal exclusion list.
- **3.19 Disclosure.** Provider must be screened and enrolled into the State's Medicaid or CHIP program, as applicable, and submit disclosures to Department on ownership and control, significant business transactions, and persons convicted of crimes, including any required criminal background checks, in accordance with 42 CFR Part 455 Subparts B and E. Provider must submit information related to ownership and control of subcontractors or wholly owned

suppliers within thirty-five (35) calendar days of a request for such information in accordance with 42 CFR 455.105. Additionally, Provider must cooperate with the Department for submission of fingerprints upon a request from the Department or CMS in accordance with 42 CFR 455.434.

3.20 Cultural Competency and Access. Provider shall participate in United's and the State's efforts to promote the delivery of services in a culturally competent manner to all Covered Persons, including those with limited English proficiency, physical or mental disabilities, diverse cultural and ethnic backgrounds, and regardless of gender, sexual orientation or gender identity, and shall provide interpreter services in a Covered Person's primary language and for the hearing impaired for all appointments and emergency services. Provider shall provide information to Covered Persons regarding treatment options and alternatives, as well as information on complaints and appeals, in a manner appropriate to the Covered Person's condition and ability to understand.

Provider shall provide physical access, reasonable accommodations, and accessible equipment for Covered Persons with physical or mental disabilities.

- **3.21 Marketing.** As required under State or federal law or the applicable State Contract, any marketing materials developed and distributed by Provider as related to the performance of the Agreement must be submitted to United to submit to the State Program for prior approval.
- **3.22 Fraud, Waste and Abuse Prevention.** Provider shall cooperate fully with United's policies and procedures designed to protect program integrity and prevent and detect potential or suspected fraud, waste, and abuse in the administration and delivery of services under the State Contract and shall cooperate and assist the State Program and any other State or federal agency charged with the duty of preventing, identifying, investigating, sanctioning or prosecuting suspected fraud, waste, and abuse in state and/or federal health care programs.

In accordance with United's policies and the Deficit Reduction Act of 2005 (DRA), Provider shall have written policies for its employees, contractors or agents that: (a) provide detailed information about the federal False Claims Act (established under sections 3729 through 3733 of title 31, United States Code), including, if any entity makes or receives annual payments under the State Program of at least \$5,000,000, such entity must establish certain minimum written policies and information communicated through an employee handbook relating to the Federal False Claims Act in accordance with 42 CFR §438.600; (b) cite administrative remedies for false claims and statements (established under chapter 38 of title 31, United States Code) and whistleblower protections under federal and state laws; (c) reference state laws pertaining to civil or criminal penalties for false claims and statements; and (d) with respect to the role of such laws in preventing and detecting fraud, waste, and abuse in federal health care programs (as defined in section 1128B(f)), include as part of such written policies, detailed provisions regarding Provider's policies and procedures for detecting and preventing fraud, waste, and abuse. Provider agrees to train its staff on the aforesaid policies and procedures.

3.23 Data; Reports. Provider shall cooperate with and release to United any information necessary for United to perform its obligations under the State Contract to the extent applicable to Provider in performance of the Agreement, including the timely submission of reports and information required by United, in the format specified by United and the State. Such reports shall include child health check-up reporting, if applicable, as well as complete and accurate encounter data in accordance with the requirements of United and the State. Data must be provided at the frequency and level of detail specified by United or the State. By submitting data to United, Provider represents and attests to United and the state that the data is accurate, complete and

truthful, and upon United's request Provider shall certify in writing, that the data is accurate, complete, and truthful, based on Provider's best knowledge, information and belief.

- 3.24 Encounter Data. Provider agrees to cooperate with United to comply with United's obligation to prepare timely encounter data submissions, reports, and clinical information including, without limitation, child and adolescent health check-up reporting, EPSDT encounters, and cancer screening encounters, as applicable, and such other reporting regarding Covered Services as may be required under the State Contract. Encounter data must be provided within the timeframes specified and in a form that meets United and State requirements. By submitting encounter data to United, Provider represents to United that the data is accurate, complete and truthful, and upon United's request Provider shall certify in writing, that the data is accurate, complete, and truthful, based on Provider's best knowledge, information and belief.
- 3.25 Claims Information. Provider shall promptly submit to United the information needed to make payment and shall identify third party liability coverage, including Medicare and other insurance, and if applicable seek such third party liability payment before submitting claims to United. Provider understands and agrees that each claim Provider submits to United constitutes a certification that the claim is true and accurate to the best of Provider's knowledge and belief and that the Covered Services are 1) Medically Necessary and 2) have been provided to the Covered Person prior to submitting the claim.
- Compliance with Medicaid Laws and Regulations. Provider agrees to abide by the Medicaid 3.26 laws, regulations and program instructions to the extent applicable to Provider in Provider's performance of the Agreement. Provider understands that payment of a claim by United or the State is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, federal requirements on fraud, waste and abuse, disclosure, debarment, termination and exclusion screening), and is conditioned on the Provider's compliance with all applicable conditions of participation in Medicaid. Provider understands and agrees that each claim the Provider submits to United constitutes a certification that the Provider has complied with all applicable Medicaid laws, regulations and program instructions in connection with such claims and the services provided therein. Provider's payment of a claim will be denied if Provider is terminated or excluded from participation in federal healthcare programs. Provider's payment of a claim may be temporarily suspended if the State or United provides notice that a credible allegation of fraud exists and there is a pending investigation. Provider's payment of a claim may also be temporarily suspended or adjusted if the Provider bills a claim with a code that does not match the service provided. United performs coding edit procedures based primarily on National Correct Coding Initiative (NCCI) policies and other nationally recognized and validated policies. Provider agrees that it will provide medical records to United upon its request in order to determine appropriateness of coding. Provider may dispute any temporarily suspended or adjusted payment consistent with the terms of the Agreement.
- **3.27 Insurance Requirements.** As applicable, Provider shall secure and maintain during the term of the Agreement insurance appropriate to the services to be performed under the Agreement. Provider shall submit to United, no less frequently that annually, evidence of Provider's continued professional liability insurance coverage.
- **3.28 Licensure.** Provider represents that it is currently licensed and/or certified under applicable State and federal statutes and regulations and by the appropriate State licensing body or standard-setting agency, as applicable. Provider represents that it is in compliance with all applicable State and federal statutory and regulatory requirements of the Medicaid program and that it is eligible

to participate in the Medicaid program. Provider represents that it does not have a Medicaid provider agreement with the Department that is terminated, suspended, denied, or not renewed as a result of any action of the Department, CMS, HHS, or the Medicaid Fraud Control Unit of the State's Attorney General. Provider shall maintain at all times throughout the term of the Agreement all necessary licenses, certifications, registrations and permits as are required to provide the health care services and/or other related activities delegated to Provider by United under the Agreement. If at any time during the term of the Agreement, Provider is not properly licensed as described in this Section, Provider shall discontinue providing services to Covered Persons. Claims for services performed during any period of noncompliance with these license requirements will be denied.

- 3.29 Clinical Laboratory Improvements Act (CLIA) certification or waiver. As applicable, if Provider performs any laboratory tests on human specimens for the purpose of diagnosis and/or treatment, Provider agrees to acquire and maintain the appropriate CLIA certification or waiver for the type of laboratory testing performed. Provider further agrees to provide a copy of the certification if requested by United. A State authorized license or permit that meets the CLIA requirements may be substituted for the CLIA certificate pursuant to State law. Medicare and Medicaid programs require the applicable CLIA certification or waiver for the type of services performed as a condition of payment. Provider must include the appropriate CLIA certificate or waiver number on claims submitted for payment for laboratory services.
- 3.30 Quality; Utilization Management. Pursuant to any applicable provider manuals and related protocols, or as elsewhere specified under the Agreement, Provider agrees to cooperate with United's quality improvement and utilization review and management activities. This shall include, but not be limited to, participation in any internal and external quality assurance, utilization review, peer review, and grievance procedures established by United or as required under the State Contract to ensure that Covered Persons have due process for their complaints, grievances, appeals, fair hearings or requests for external review of adverse decisions made by United or Provider. Provider shall adhere to the quality assurance and utilization review standards of the State Program and shall monitor quality and initiate corrective action to improve quality consistent with the generally accepted level of care.
- **3.31 Immediate Transfer.** Provider shall cooperate with United in the event an immediate transfer to another primary care physician or Medicaid managed care contractor is warranted if the Covered Person's health or safety is in jeopardy, as may be required under law.
- **3.32 Transition of Covered Persons.** In the event of transitioning Covered Persons from other Medicaid managed care contractors and their provider, Provider shall work with United to ensure quality-driven health outcomes for such Covered Persons to the extent required by the State Contract or otherwise required by law.
- **3.33 Continuity of Care.** Provider shall cooperate with United and provide Covered Persons with continuity of treatment, including coordination of care to the extent required under law and according to the terms of the Agreement, in the event Provider's participation with United terminates during the course of a Covered Person's treatment by Provider, except in the case of adverse reasons on the part of Provider.
- **3.34 Advance Directives. When applicable,** Provider shall comply with the advance directives requirements for hospitals, nursing facilities, providers of home and health care and personal care services, hospices, and HMOs as specified in 42 CFR Part 49, subpart I; 42 CFR § 417.436(d); 42 CFR § 422.128; and 42 CFR 438.3(i).

- **3.35 National Provider ID (NPI).** If applicable, Provider shall obtain a National Provider Identification Number (NPI).
- 3.36 Termination. In the event of termination of the Agreement, Provider shall promptly supply to United all information necessary for the reimbursement of any outstanding Medicaid claims. No termination of the Agreement will be effective unless at least 90 days written notice of such termination has been provided to the Department if United terminates the Agreement. If Provider terminates the Agreement, written notice to the Department is required within 15 days after United receives notice from Provider. Provider agrees that nonpayment by United for goods or services rendered by Provider is not a valid reason for avoiding this notice requirement. Advance notice may not be required if a Covered Person's health is subject to imminent danger. Provider further agrees to provide copies of Provider's medical records pertaining to Covered Persons to United upon request for transfer to a subsequent provider in the event of the termination of the Agreement.
- **3.37 Health Care Acquired/Preventable Conditions.** Provider agrees that no payment shall be made for the provision of medical assistance for health care acquired conditions and other provider preventable conditions as may be identified by the State. As a condition of payment, Provider shall identify and report to United any provider preventable conditions in accordance with 42 CFR §§ 434.6(a)(12), 438, including but not limited to § 438.3(g), and § 447.26.
- **3.38 Assignment.** Provider may not assign the Agreement without United's approval nor without prior written notice to the Department.
- **3.39 Eligibility.** Provider shall verify the eligibility of participants by contacting the State of Maryland's Eligibility Verification System (EVS) pursuant to COMAR 10.09.69.07(L).
- **3.40 Referrals.** If Provider is authorized to make referrals pursuant to the terms of the Agreement, such referrals must be made using the uniform consultation referral form adopted by the Maryland Insurance Administration at COMAR 31.10.12.06.
- **3.41 Non-Discrimination.** Provider will not discriminate against Covered Persons on the basis of race, color, national origin, sex, sexual orientation, gender identity, or disability and will not use any policy or practice that has the effect of discriminating on the basis of race, color, or national origin, sex, sexual orientation, gender identity, or disability.
- **3.42** Covered Services. Provider shall perform Covered Services pursuant to the Agreement and any attached services exhibit(s).
- **3.43 Electronic Visit Verification (EVV).** Provider shall cooperate with State requirements for electronic visit verification for personal care services and home health services, as applicable.
- **3.44 Health Records.** Provider agrees to cooperate with United to maintain and share a health record of all services provided to a Covered Person, as appropriate and in accordance with applicable laws, regulations and professional standards.
- **3.45 Overpayment.** Provider shall to report to United when it has received an overpayment and will return the overpayment to United within 60 calendar days after the date on which the overpayment was identified. Provider will notify United in writing of the reason for the overpayment.

- **3.46 Grievance and Appeals.** Provider is subject to a grievance and appeal system consistent with the requirements of COMAR 10.09.71, as further described in the applicable provider manual, policies and protocols.
- **3.47 Hospitals.** If Provider is a hospital or an entity related to a hospital, Provider must be in compliance with COMAR 10.37.12 (fixed price contracting regulations).

SECTION 4 UNITED REQUIREMENTS

- 4.1 **Prompt Payment.** United shall pay Provider pursuant to the State Contract and applicable State and federal law and regulations, including but not limited to 42 CFR 447.46, 42 CFR 447.45(d)(2), 42 CFR 447.45(d)(3), 42 CFR 447.45(d)(5) and 42 CFR 447.45(d)(6), as applicable and as may be amended from time to time. If a third party liability exists, payment of claims shall be determined in accordance with federal and/or State third party liability law and the terms of the State Contract. Unless United otherwise requests assistance from Provider, United will be responsible for third party collections in accordance with the terms of the State Contract.
- **4.2 No Incentives to Limit Medically Necessary Services.** United shall not structure compensation provided to individuals or entities that conduct utilization management and concurrent review activities so as to provide incentives for the individual or entity to deny, limit, or discontinue Medically Necessary services to any Covered Person.
- **4.3 Provider Discrimination Prohibition.** United shall not discriminate with respect to participation, reimbursement, or indemnification of a provider who is acting within the scope of the provider's license or certification under applicable State law, solely on the basis of such license or certification. United shall not discriminate against Provider for serving high-risk Covered Persons or if Provider specializes in conditions requiring costly treatments. This provision shall not be construed as prohibiting United from limiting a provider's participation to the extent necessary to meet the needs of Covered Persons. This provision also is not intended and shall not interfere with measures established by United that are designed to maintain quality of care practice standards and control costs.
- **4.4 Communications with Covered Persons.** United shall not prohibit or otherwise restrict Provider, when acting within the lawful scope of practice, from advising or advocating on behalf of a Covered Person for the following:
 - i) The Covered Person's health status, medical care, or treatment options, including any alternative treatment that may be self-administered;
 - ii) Any information the Covered Person needs in order to decide among all relevant treatment options;
 - iii) The risks, benefits, and consequences of treatment or non-treatment; or
 - iv) The Covered Person's right to participate in decisions regarding his or her health care, including the right to refuse treatment, and to express preferences about future treatment decisions.

United also shall not prohibit a Provider from advocating on behalf of a Covered Person in any grievance system, utilization review process, or individual authorization process to obtain necessary health care services.

4.5 **Termination, Revocation and Sanctions.** In addition to its termination rights under the Agreement, United shall have the right to revoke any functions or activities United delegates to Provider under the Agreement or impose other sanctions consistent with the State Contract if in United's reasonable judgment Provider's performance under the Agreement is inadequate. United shall also have the right to suspend, deny, refuse to renew or terminate Provider in accordance with the terms of the State Contract and applicable law and regulation.

SECTION 5 OTHER REQUIREMENTS

- 5.1 Compliance with State Contract. All tasks performed under the Agreement shall be performed in accordance with the requirements of the applicable State Contract, as set forth in this Appendix, applicable provider manuals, and protocols, policies and procedures that United has provided or delivered to Provider. The applicable provisions of the State Contract are incorporated into the Agreement by reference. Nothing in the Agreement relieves United of its responsibility under the State Contract. If any provision of the Agreement is in conflict with provisions of the State Contract, the terms of the State Contract shall control and the terms of the Agreement in conflict with those of the State Contract will be considered waived.
- 5.2 Monitoring. United shall perform ongoing monitoring (announced or unannounced) of services rendered by Provider under the Agreement and shall perform periodic formal reviews of Provider according to a schedule established by the State, consistent with industry standards or State managed care organization laws and regulations or requirements under the State Contract. As a result of such monitoring activities, United shall identify to Provider any deficiencies or areas for improvement mandated under the State Contract and Provider and United shall take appropriate corrective action. Provider shall comply with any corrective action plan initiated by United and/or required by the State Program. In addition, Provider shall monitor and report the quality of services delivered under the Agreement and initiate a plan of correction where necessary to improve quality of care, in accordance with that level of care which is recognized as acceptable professional practice in the respective community in which United and Provider practice and/or the performance standards established under the State Contract
- **Enrollment.** The parties acknowledge and agree that the State Program is responsible for enrollment, reenrollment and disenrollment of Covered Persons.
- **No Exclusivity.** Nothing in the Agreement or this Appendix shall be construed as prohibiting or penalizing Provider for contracting with a managed care organization other than United or as prohibiting or penalizing United for contracting with other providers.
- **Delegation.** The parties agree that, prior to execution of the Agreement, United evaluated Provider's ability to perform any duties delegated to Provider under the Agreement. Any delegated duties and reporting responsibilities shall be set forth in the Agreement or other written delegation agreement or addendum between the parties. United shall have the right to revoke any functions or activities United delegates to Provider under the Agreement if in United's reasonable judgment Provider's performance under the Agreement is inadequate.

- 5.6 Compliance with State Program. All tasks performed under the Agreement must be performed in accordance with the requirements of the State Program and HealthChoice Program and applicable state regulations, including, but, not limited to COMAR 10.09.62-10.09.75 concerning access, quality assurance, medical records, and reporting requirements, as well as any other applicable regulations, transmittals, and guidelines issued by the Department in effect at any time during the term of this Agreement. United retains a primary duty to the Department and to Covered Persons to ensure Provider delivers the required services in a manner that is consistent with the requirements of COMAR 10.09.62 10.09.75. If any provision of the Agreement is in conflict with requirements of the State Program or HealthChoice Program, the requirements of the State Program or HealthChoice Program shall control.
- **5.7 Specialty Mental Health System.** Provider shall provide information which is necessary to achieve the purpose of coordinating care and delivering quality health care to Covered Persons to the Administrative Services Organization (ASO) of the Specialty Mental Health System or to any other entity that the Maryland Medicaid Program so directs.
- **5.8 Balanced budget Act.** Provider shall comply with all provisions of the Balanced Budget Act of 1997 that apply to the Agreement, as well as the State Medicaid Director's letters regarding managed care issued or to be issued in the future.
- **5.9 Changes in CMS Law.** Provider shall be subject to any change in federal or State law or regulation, or other policy guidance from the Centers for Medicare and Medicaid Services ("CMS") or the Department that applies to the Agreement. United will provide Provider notice of such changes as the information becomes available to United.