COLORADO MEDICAID AND CHIP REGULATORY REQUIREMENTS APPENDIX DOWNSTREAM PROVIDER

THIS COLORADO MEDICAID AND CHIP 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 ("United") and the party named in the Agreement ("Provider").

SECTION 1 APPLICABILITY

This Appendix applies to benefit plans sponsored, issued or administered by United under the State's Medicaid program, CHIP program and, as applicable, benefit plans for other state-based healthcare programs (the "State Program") as governed by the State's designated 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.

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 Covered Service** means health care service or product for which a Customer is enrolled with United to receive coverage under the State Program.
- **2.2 Medicaid Agency** or Agency means the single State agency of administering or supervising the administration of the State Program.
- **2.3 State** is the State of Colorado.
- **2.4 State Contract** is the contract between United and the Medicaid Agency for the purpose of providing and paying for Covered Services to Customers enrolled in the State Program.

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 Program requirements for the provision of Covered Services. Provider's decisions affecting the

delivery of acute or chronic care services to Customers shall be made on an individualized basis and in accordance with the following definitions:

- i) **Emergency Medical Condition** means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in any of the following: (a) placing the health of the individual (or with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy; (b) serious impairment to body functions; or (c) serious dysfunction of any body organ or part.
- ii) **Emergency Services** means inpatient and outpatient Covered Services furnished by a provider qualified to furnish those health services and that are needed to evaluate or stabilize an Emergency Medical Condition.
- iii) Medically Necessary or Medical Necessity has the same meaning as contained in 42 C.F.R. § 438.210(a)(5) and as indicated in State statutes and regulations, the State Contract, and other State policy and procedures.
- iv) **Poststabilization Care Services** means covered services, related to an emergency medical condition that are provided after an enrollee is stabilized to maintain the stabilized condition, or, under circumstances described in condition that are provided after an enrollee is stabilized to maintain the stabilized condition, or, under the circumstances described in 42 C.F.R. § 438.114, to improve or resolve the enrollee's condition.
- **3.2 Provider Participation Requirements.** Provider hereby acknowledges and certifies to the best of its knowledge the following:
 - i) State Program Participation. Provider is enrolled as, or has applied to enroll as, a participating provider with the State Program. United may terminate Provider from its State Program Provider network immediately upon notification from the State that Provider cannot be enrolled or has been terminated from the State Program, or the expiration of one 120 day period without enrollment of Provider.
 - ii) Licensure. Provider has 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 and will maintain such necessary licenses, certifications, registrations and permits at all times throughout the term of the Agreement. If at any time during the term of the Agreement, Provider is not in compliance with this Section, Provider shall discontinue providing services to Customers. Additionally, payment will not be made for any items or Covered Services provided during any time period of noncompliance with this Section.
 - iii) Excluded Individuals and Entities. Provider nor any of its employees, principals, nor any providers, subcontractors or consultants or persons with an ownership or controlling interest in the Provider are: (a) 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 b)

excluded from participation in federal health care programs under either 42 U.S.C. §§ 1320a–7 or 1320a–7a. Provider acknowledges and agrees that payment will not be made for any items or Covered Services provided by an excluded individual or entity pursuant to 42 C.F.R. § 1001.1901(b).

- **3.3 Compliance with Law.** Provider shall comply with all federal and State laws and regulations applicable to Provider in performance of the Agreement, including but not limited to, the following:
 - i) Civil Rights. Provider shall comply with Title VI of the Civil Rights Act of 1964; the Age Discrimination Act of 1975; the Rehabilitation Act of 1973; Title IX of the Education Amendments of 1972; Titles II and III of the Americans with Disabilities Act; and section 1557 of the Patient Protection and Affordable Care Act (see 42 CFR 438.3; 42 CFR 438.100(d)).
 - **Lobbying.** Provider certifies to the best of Provider's knowledge and belief, pursuant to 31 U.S.C. § 1352 and 45 C.F.R. § 93.100 et seq. 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.
 - **Medicaid Laws and Regulations.** Provider agrees to abide by all federal and state Medicaid laws, regulations and State Program requirements, including but not limited to:
 - a. 5 C.F.R. § 900.601 et seq., Administration of the Standards for a Merit System of Personnel Administration.
 - b. The following HHS Regulations in 45 C.F.R. subtitle A:
 - i. 45 C.F.R. § 16.1 et seq., Procedures of the Departmental Appeals Board;
 - ii. 45 C.F.R. § 75.1 et seq., Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards;
 - iii. 45 C.F.R. § 80.1 et seq., Nondiscrimination Under Programs Receiving Federal Assistance Through the Department of Health and Human Services: Effectuation of Title VI of the Civil Rights Act of 1964;
 - iv. 45 C.F.R. § 81.1 et seq., Practice and Procedure for Hearings Under 45 C.F.R. § 80.1 et seq.;
 - v. 45 C.F.R. § 84.1 et seq., Nondiscrimination on the Basis of Handicap in Programs and Activities Receiving or Benefiting from Federal Financial Assistance.
 - c. **Availability of Services.** Provider will comply with 42 C.F.R. § 438.206 and any applicable State Program and provider manual regulations and requirements

related to availability of services to Customers including, but not limited to, meeting State Program and provider manual standards for timely access to care and services, taking into account the urgency of the need for services. Additionally, Provider shall offer hours of operation that are no less than the hours of operation offered to commercial beneficiaries or comparable to Medicaid fee-for-service beneficiaries, 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. In addition, Provider will provide physical access, reasonable accommodations and accessible equipment for Customers with physical or mental disabilities.

- d. **Claims Information.** As indicated in the provider manual, 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.
- e. **Continuity of Care.** Provider shall cooperate with United and provide Customers 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 Customer's treatment by Provider, except in the case of adverse reasons on the part of Provider.
- f. Cultural Competency and Access. Provider shall participate in United's and the State's efforts to efforts to promote the delivery of services in a culturally competent manner to all enrollees, including those with limited English proficiency and diverse cultural and ethnic backgrounds, disabilities, and regardless of sex, and shall provide interpreter services in a Customer's primary language and for the hearing impaired for all appointments and emergency services. Provider shall provide information to Customers regarding treatment options and alternatives, as well as information on complaints and appeals, in a manner appropriate to the Customer's condition and ability to understand. Provider shall provide physical access, reasonable accommodations, and accessible equipment for Customers with physical or mental disabilities.
- g. **Data; Reports.** Provider agrees to cooperate with and release to United any information necessary for United to comply with the State Contract and federal and state law, to the extent applicable to Provider in performance of the Agreement. Such information includes timely submission of reports including child health check-up reporting, EPSDT encounters, and cancer screening encounters, if applicable, as well as complete and accurate encounter data in accordance with the requirements of United and 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.
- h. **Fraud, Waste, and Abuse.** 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. Further, when Provider t has received an overpayment, Provider will return the overpayment to United within 60 calendar days after the date on which the overpayment was identified, and to notify United in writing of the reason for the overpayment.

- i. 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.
- j. Hold Harmless. Provider will accept, as payment in full, the amounts paid by United to Provider for Covered Services to Customers, plus any deductible, coinsurance or copayment required to be paid by the Customer, and will hold Customers harmless in the event that United cannot or will not pay for such Covered Services. If a service is not a Covered Services, prior to providing the service, Provider shall inform the Customer the service is not a Covered Service and have the Customer acknowledge the information. If the Customer still requests the service, Provider shall obtain such acknowledgement in writing prior to rendering the service. If United determines a Customer 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.
- k. **Marketing.** Provider will comply with 42 C.F.R. § 438.104 and any applicable State Program guidance and regulations related to marketing materials including, but not limited to, seeking approval from the Medicaid Agency prior to distributing any marketing materials to Customers.

- 1. **Physician Incentive Plans.** If Provider participates in a physician incentive program ("PIP"), Provider must comply with the requirements set forth in 42 C.F.R. §§ 422.208 and 422.210, including but not limited to the following: a) Provider will not make specific payment, directly or indirectly, to a physician or physician group as an inducement to reduce or limit Medically Necessary services furnished to any Customer; and b) if the PIP places Provider at substantial financial risk for services that Provider does not furnish itself, Provider must have stop-loss protection in accordance with 42 C.F.R. § 422.208(f).
- m. **Preventable Conditions.** No payment will be made by United to a Provider for provider preventable conditions, as identified in the State Program. Provider shall identify and report to United any provider preventable conditions in accordance with 42 C.F.R. §§ 434.6(a)(12)(i) and (ii) and 42 C.F.R. § 447.26(d).
- n. **Privacy; Confidentiality.** Provider shall safeguard Customer privacy and confidentiality including, but not limited to, the privacy and confidentiality of any information that identifies a particular Customer and shall comply with all federal and state laws and State Program requirements regarding confidentiality and disclosure of medical records or other health and enrollment information.
- o. Quality; Utilization Management. 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 provider manual and related protocols to ensure that Customers 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.
- p. **Records.** 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 Customers. Medical records and supporting management systems shall include all pertinent information related to the medical management of each Customer. 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.

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 Customers. Provider shall provide immediate access to facilities, records and supportive materials pertinent to the State Contract for State or Federal fraud investigators.

- iv) Stark Law and the Anti-Kickback Statute. 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 (see, 42 U.S.C. 1395nn; 42 U.S.C. 1320a–7b; 42 C.F.R. § 411.350).
- **3.4** Requirements for Specific Provider Types. The following provisions apply to certain provider types as indicated:
 - i) 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 C.F.R. §§ 417.436(d), 422.128, and 438.3(j).
 - ii) 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.
 - **iii) Electronic Visit Verification (EVV).** Provider shall cooperate with State requirements for electronic visit verification for personal care services and home health services, as applicable.
 - **Long-Term Services and Supports (LTSS) Providers.** Any LTSS Covered Services under the State Contract that could be authorized through a waiver under section 1915(c) of the Social Security Act (the "Act") or a State Program amendment authorized through sections 1915(i) or 1915(k) of the Act must be delivered in settings consistent with 42 C.F.R. § 441.301(c)(4).
- **3.5 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.

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 C.F.R. § 447.46. 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.
- **4.3 Provider Discrimination Prohibition.** United will not discriminate in the participation, reimbursement, or indemnification of any provider who is acting within the scope of his or her license or

certification under applicable State law, solely on the basis of that license or certification. In addition, United will not discriminate against providers that serve high-risk populations or specialize in conditions that require costly treatment. This provision shall not be construed as prohibiting United from limiting a provider's participation to the extent necessary to meet the needs of Customers. 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 Provider-Customer Communications. United may not prohibit, or otherwise restrict, Provider when acting within the lawful scope of practice, from advising or advocating on behalf of a Customer for the following: (i) the Customer's health status, medical care, or treatment options, including any alternative treatment that may be self-administered; (ii) any information the Customer needs in order to decide among all relevant treatment options; (iii) the risks, benefits, and consequences of treatment or non-treatment; or (iv) the Customer'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 Customer in any grievance system, utilization review process, or individual authorization process to obtain necessary health care services.

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. The provisions of the State Contract applicable to Provider 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.
- **5.3 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
- **5.4 Delegation.** Any delegated duties and reporting responsibilities shall be set forth in the Agreement or other written delegation agreement or addendum between the parties.
- **5.5 Regulatory Amendment.** United may unilaterally amend this Appendix to comply with applicable laws and regulations and the requirements of applicable regulatory authorities including, but not limited to, Medicaid Agency. Unless such laws, regulations, or regulatory authority(ies) direct otherwise, the signature of Provider will not be required in order for the amendment to take effect.

SECTION 6 STATE SPECIFIC REQUIREMENTS

- **6.1 Medically Necessary or Medical Necessity.** In addition to Section 3.1(iii) and as required by the State Contract, Medically Necessary or Medical Necessity shall be defined as described in 10 CCR 2505-10 § 8.076.1.8.
- **6.2 Confidentiality.** In addition to section 3.3(iii)(n) above, Provider shall advise its employees and subcontractors, if any, that they are subject to the confidentiality requirements. Except for purposes directly connected with administration of the Agreement, no information about or obtained from any Customer shall be disclosed in a form identifiable with the Customer without prior written consent of the Customer, as applicable, or, if such Customer is a minor, without the written consent of such minor's parent or guardian.
- **6.3** Records and Audits. In addition to section 3.3(iii)(i) and 3.3(iii)(p) above, if an audit by or on behalf of the federal and/or state government has begun but is not completed at the end of the ten (10) year period, the materials shall be retained until the resolution of the audit finding.
- **6.4 Untrue or Misleading Information.** Provider shall not knowingly provide untrue or misleading information, as defined at sections 10-16-413(1)(a)-(c), C.R.S., regarding the State Program, other Medicaid Managed care organizations, State Program eligibility to Customers.
- **6.5 Customer Rights.** Provider shall ensure that the Customer has the rights set forth in 42 C.F.R. section 438.100(b)(2), including but not limited to the right to be free from any form of restraint or seclusion used as a means of coercion, discipline, convenience or retaliation, consistent with 42 C.F.R., section 438.100.(b)(2)(v).
- **6.6 Customer Understanding.** In addition to section 3.3 (iii)(f) above, if the Customer cannot understand the Provider's explanation of the Customer's medical condition, recommended treatment, risk(s) of the treatment, expected results and reasonable medical alternatives, the explanation shall be provided to the Customer's biological, adoptive or foster parent, guardian or designated client representative, and documented in the Customer's medical record.
- **6.7 Certification.** Regarding Lobbying, in addition to section 3.3 (ii), if any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of an agency, a member of Congress, an officer or employee of Congress or an employee of a member of Congress in connection with this Federal Contract, grant, loan, or cooperative agreement, Provider shall complete and submit Standard Form LLL, "Disclosure Form to Report Lobbying", in accordance with its instructions.

Provider shall require that the language of this certification be included in the award documents for subawards at all tiers (including subgrants and Contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of the certification is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.

Provider shall include, without modification, the above certification in any it may enter into.	subcontract to the Agreement