IOWA STATE PROGRAMS

REGULATORY REQUIREMENTS APPENDIX

DOWNSTREAM PROVIDER

THIS IOWA STATE PROGRAMS REGULATORY REQUIREMENTS APPENDIX (this "Appendix") supplements and is made part of the provider agreement (the "Agreement") between OptumRx, Inc. ("Subcontractor") and the provider named in the Agreement ("Provider").

SECTION 1
APPLICABILITY

This Appendix applies with respect to the provision of health care services that Provider provides directly to Covered Persons through Health Plan's (as defined herein) products or benefit plans under the Iowa Medicaid, Iowa Health and Wellness Plan, Healthy and Well Kids in Iowa (hawk-i) and related programs (the "State Program") as governed by the State's designated regulatory agencies. Provider has agreed to provide Covered Services to Covered Persons who receive their coverage pursuant to a contract between the State and Health Plan (the "State Contract" as defined herein). The State Contract and applicable State and federal law require that the provisions contained in this Appendix be part of the Agreement. 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 Subcontractor is required to amend or supplement this Appendix as required or requested by the State to comply with federal or State regulations, Subcontractor 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 Covered Person: An individual who is currently enrolled with Health Plan 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.

2.2 Covered Services: Health care services or products for which a Covered Person is enrolled with Health Plan to receive coverage under the State Contract.

2.3 Department: Iowa Department of Human Services.

2.4 Health Plan: An appropriately licensed entity that has entered into a contract with Subcontractor, either directly or indirectly, under which Subcontractor provides certain administrative services for Health Plan pursuant to the State Contract. For purposes of this Appendix, Health Plan refers to UnitedHealthcare Plan of the River Valley, Inc.

2.5 State: The State of Iowa or its designated regulatory agencies.

2.6 State Contract: Health Plan'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: The Iowa Medicaid, Iowa Health and Wellness Plan, Healthy and Well Kids in Iowa (hawk-i), and related programs. For purposes of this Appendix, State Program may refer to the State agency(ies) responsible for administering the applicable 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 Subcontractor, Health Plan 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:

(a) 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 it to result in: (1) Placing the health of the person (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy, (2) Serious impairment to bodily functions, or (3) Serious dysfunction of any bodily organ or part.

(b) Emergency Services: With respect to a Covered Person, Emergency Services means covered inpatient and outpatient services that are as follows: (1) furnished by a provider qualified to furnish these health services; and (2) needed to evaluate or stabilize an Emergency Medical Condition. No prior authorization is required for Emergency Services.

(c) Medically Necessary or Medical Necessity: Covered Services that are, under the terms and conditions of this Contract, determined through Plan utilization management to be:

(1) Appropriate and necessary for the symptoms, diagnosis or treatment of the condition of the Enrollee;
(2) Provided for the diagnosis or direct care and treatment of the condition of Enrollee enabling the Enrollee to make reasonable progress in treatment;

(3) Within standards of professional practice and given at the appropriate time and in the appropriate setting;
(4) Not primarily for the convenience of the Enrollee, the Enrollee's physician or other Provider; and
(5) The most appropriate level of Covered Services, which can safely be provided.
The fact a service is prescribed does not automatically define the service as Medically Necessary.

"Medically Necessary" or "Medical Necessity" for inpatient hospital services requires that those services furnished in a hospital on an inpatient basis could not, consistent with the provisions of the appropriate medical care, be effectively furnished more economically on an outpatient basis or by an inpatient Provider of a different type. The fact that Provider has prescribed, recommended or approved medical or allied goods, or services does not, in itself, make such care, goods or services Medically Necessary or a Medical Necessity or a Covered Service.

3.2 Medicaid Eligibility. Provider must meet minimum requirements for participation in the State Program. Provider shall meet this requirement by being enrolled with the State of Iowa as a Medicaid provider. Provider must also meet the applicable minimum requirements for Medicaid participation, including enrollment in Medicare, if applicable. Subcontractor and Health Plan will exclude from its network any provider who has been terminated or suspended from the Medicare or Medicaid 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. Provider shall make Covered Services available 24 hours a day, 7 days a week when medically necessary. Subcontractor and/or Health Plan shall regularly monitor Provider's compliance with timely access standards and Provider shall implement appropriate corrective action in the event Provider fails to comply with the appointment wait time requirements under the State Contract.

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 fee-for-service if Provider serves only Medicaid beneficiaries.

3.5 Hold Harmless. Except for any applicable cost-sharing requirements under the State Contract, Provider shall look solely to Subcontractor or Health Plan (as applicable) 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 Subcontractor and Health Plan 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 Subcontractor and Health Plan are 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 Contractor applicable law. Neither the State, the Department nor Covered Persons shall be in any manner liable for the debts and obligations of Subcontractor or Health Plan and under no circumstances shall Subcontractor or Health Plan, 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 Subcontractor or Health Plan 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. Provider agrees to indemnify and hold harmless the State and its officers, appointed and elected officials, board and commission members, employees, volunteers and agents (collectively the "Indemnified Parties"), from any and all costs, expenses, losses, claims, damages, liabilities, settlements and judgments (including, without limitation, the reasonable value of the time spent by the Attorney General's Office, and the costs, expenses and attorneys' fees of other counsel retained by the Indemnified Parties) directly or indirectly related to, resulting from, or arising out of the Agreement, including but not limited to any claims related to, resulting from, or arising out of:

(a) Any breach of the Agreement;
(b) Any negligent, intentional or wrongful act or omission of Provider, or any agent or subcontractor utilized or employed by Provider;
(c) Provider's performance or attempted performance of the Agreement, including that of any agent or subcontractor utilized or employed by Provider;
(d) Any failure by Provider to make all reports, payments and withholdings required by federal and State law with respect to social security, employee income and other taxes, fees or costs required by Provider to conduct business in the State of Iowa; or
(e) Any claim of misappropriation of a trade secret or infringement or violation of any intellectual property rights, proprietary rights or personal rights of any third party, including any claim that any services performed pursuant to the Agreement infringe, violate or misappropriate any patent, copyright, trade secret, trademark, trade dress, mask work, utility design, or other intellectual property right or proprietary right of any third party.

Provider's duties and obligations under this Section shall survive the termination of the an Agreement and shall apply to all acts or omissions taken or made in connection with the performance of the Agreement regardless of the date any potential claim is made or discovered by the Department or any other Indemnified Party. This provision does not apply to a state agency or sub-unit of the Department, as defined by the State, or a public health entity with statutory immunity.

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 Subcontractor and/or Health Plan delegates credentialing to Provider, Subcontractor and/or Health Plan will provide monitoring and oversight and Provider shall ensure that all licensed medical professionals are credentialed in accordance with Subcontractor's, Health Plan'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.

3.9 Subcontracts. If Provider subcontracts or delegates any functions of the Agreement, in accordance with the terms of the Agreement, the subcontract or delegation must include all of the requirements of this Appendix, and applicable requirements of the State Contract. Provider further agrees to promptly amend its agreements with such subcontractors, in the manner requested by Subcontractor or Health Plan, 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. Such records shall be maintained for a period of not less than 7 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 7 years following resolution of such action. Prior approval for the disposal of records must be requested and approved by Subcontractor and Health Plan if the Agreement is continuous. Medical records maintained by Provider shall be legible, signed, dated and maintained as required by law. Provider shall maintain a medical records system which: (i) identifies each medical record by State identification number; (ii) identifies the location of every medical record; (iii) places medical records in a given order and location; (iv) maintains the confidentiality of medical records information and releases the information only in accordance with the State Contract Section 6.1.9.4;(v) maintains inactive medical records in a specific place; (vi) permits effective professional review in medical audit processes; and (vii) facilitates an adequate system for follow-up treatment including monitoring and follow-up of off-site referrals and inpatient stays.

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. Provider must timely provide copies of the requested records to the State, the State's designee, or MFCU within ten (10) business days from the date of the request. If such original documentation is not made available as requested, Provider must provide transportation, lodging and subsistence at no cost, for all State and/or Federal representatives to carry out their audit functions at the principal offices of the Provider or other locations of such records. Additionally, the Provider shall grant the State, the State's designee, or MFCU access during the Provider's regular business hours to examine health service and financial records related to a health service billed to the State Program. The State will notify the Provider no less than twenty-four (24) hours before obtaining access to a health service or financial record, unless the Provider waives the notice. The State shall access records in accordance with 45 C.F.R. Parts 160 through 164.

3.12 Government Audit; Investigations. Provider acknowledges and agrees that the State and the U.S. Department of Health and Human Services or their authorized representatives shall have the right to inspect or otherwise evaluate the quality, appropriateness, and timeliness of services provided under the terms of the State Contract and any other applicable rules. 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. If applicable, Provider shall submit to the Department an audit conducted for that year in accordance with the provisions of OMB Circular A-133.

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 de-identification 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 Subcontractor, Health Plan 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 Subcontractor, Health Plan 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 Subcontractor, Health Plan and the Department to ensure that the breach has been mitigated and reporting requirements, if any, complied with.

3.14 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:

(a) 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; and Americans with Disabilities Act, and their implementing regulations, as may be amended from time to time.

(b) 42 CFR 434 and 42 CFR 438.6, as may be amended from time to time.

(c) 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."

(d) 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

3.15 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 438.6(h), 42 CFR 422.208, and 42 CFR 422.210, as may be amended from time to time. Subcontractor, Health Plan and Provider may not 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.

3.16 Lobbying. Provider agrees to comply with the following requirements related to lobbying:

(a) 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.

(b) Disclosure Form to Report Lobbying: 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.

3.17 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:

(a) excluded from participation in federal health care programs under either Section 1128 or section 1128A of the Social Security Act; or

(b) 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 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 Subcontractor and Health Plan 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 at http://www.oig.hhs.gov/fraud/exclusions.asp. The GSA EPLS/SAM database can be accessed at https://www.sam.gov. Applicable state exclusion databases can be accessed through the State's Medicaid website. Subcontractor and Health Plan will terminate the Agreement immediately and exclude from its network any provider who has been excluded from federal health care programs or terminated from the Medicare or the Medicaid program in any state. Subcontractor and Health Plan may also terminate the Agreement if Provider's owners, agents, or managing employees are found to be excluded on a State or Federal exclusion list.

3.18 Disclosure. Provider shall cooperate with Subcontractor and Health Plan in disclosing information the Department may require related to ownership and control, significant business transactions, and persons convicted of crimes, including any required criminal background checks, in accordance with 42 CFR Part 455 and shall provide information upon request. Provider shall 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. Additionally, Provider shall cooperate with the submission of fingerprints upon a request from the Department or CMS in accordance with 42 CFR 455.434.

3.19 Cultural Competency. Provider shall participate in Subcontractor's, Health Plan'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 and diverse cultural and ethnic backgrounds 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 incorporate in its polices, administration and service practice the value of: (i) honoring members' beliefs; (ii) sensitivity to cultural diversity; and (iii) fostering in staff and providers attitudes and interpersonal communication styles which respect members' cultural backgrounds. Subcontractor and /or Health Plan will have specific policy statements on the above values and communicate them to Provider in order to assist Provider in satisfying this requirement.

3.20 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 Health Plan to submit to the State Program for prior approval.

3.21 Fraud, Waste and Abuse Prevention. Provider shall cooperate fully with Subcontractor's and Health Plan'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 Subcontractor's and Health Plan'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); (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.

3.22 Data; Reports. Provider shall cooperate with and release to Subcontractor and Health Plan any information necessary for Subcontractor and Health Plan 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 Subcontractor and Health Plan. 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 Subcontractor, Health Plan and the State.

3.23 Encounter Data. Provider agrees to cooperate with Subcontractor, Health Plan to comply with Subcontractor's and Health Plan's obligation to prepare 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.

3.24 Claims Information. Provider shall promptly submit to Subcontractor and Health Plan 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 Subcontractor and Health Plan. Provider shall submit a Clean Claim, which does not involve a third party payer, within 180 days of the date of service. Provider understands and agrees that each claim Provider submits to Subcontractor and Health Plan 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.

3.25 Compliance with Medicaid Laws and Regulations. Provider agrees to abide by the Medicaid 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 Subcontractor, Health Plan 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 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 Subcontractor and Health Plan 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 may be temporarily suspended if the State Subcontractor or Health Plan provides notice that a credible allegation of fraud exists and there is a pending investigation.

3.26 Insurance Requirements. Provider shall secure and maintain during the term of the Agreement insurance appropriate to the services to be performed under the Agreement and compliant with the State Contract. Provider shall maintain in full force and effect, with insurance companies licensed by the State of Iowa, at Provider's expense, insurance covering Provider's work during the entire term of the Agreement and any extensions or renewals thereof. The insurance shall, among other things, be occurrence based if available and shall insure against any loss or damage resulting from or related to the performance of the Agreement regardless of the date the claim is filed or expiration of the policy.

Unless otherwise requested by Subcontractor and Health Plan in writing, the insurance required under this Section shall insure against all general liabilities, product liability, personal injury, property damage, and (where applicable) professional liability in the amount specified in the Agreement or as required under the State Contract or applicable State law. In addition, Provider shall ensure it has any necessary workers' compensation and employer liability insurance as required by State law.

Provider shall not permit the insurance coverage required under this Section to be canceled or amended except with the advance written approval of Subcontractor and Health Plan and shall submit evidence of such coverage to Subcontractor and Health Plan upon request. Provider shall also obtain a waiver of any subrogation rights that any of its insurance carriers might have against the State. Such waiver shall be indicated on the certificates of insurance coverage. This provision does not apply to self-insured state agencies or sub-units of the Department.

3.27 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 Subcontractor and/or Health Plan 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.

3.28 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 Subcontractor or Health Plan. 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.

3.29 Quality; Utilization Management. Pursuant to any applicable provider manuals and related protocols, or as elsewhere specified under the Agreement, Provider agrees to cooperate with Subcontractor and Health Plan'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 Subcontractor and Health Plan 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 Subcontractor, Health Plan 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.

3.30 Immediate Transfer. Provider shall cooperate with Subcontractor and Health Plan 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.

3.31 Transition of Covered Persons. In the event of transitioning Covered Persons from other Medicaid managed care contractors and their provider, Provider shall work with Subcontractor and Health Plan to ensure quality-driven health outcomes for such Covered Persons to the extent required by the State Contract or otherwise required by law.

3.32 Continuity of Care. Provider shall cooperate with Subcontractor and Health Plan 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 Subcontractor and Health Plan terminates during the course of a Covered Person's treatment by Provider, except in the case of adverse reasons on the part of Provider.

3.33 Advance Directives. 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, and 42 CFR § 417.436(d).

3.34 National Provider ID (NPI). If applicable, Provider shall obtain a National Provider Identification Number (NPI).

3.35 Termination. In the event of termination of the Agreement, Provider shall promptly supply to Subcontractor and Health Plan all information necessary for the reimbursement of any outstanding Medicaid claims.

3.36 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 Subcontractor and Health Plan any provider preventable conditions in accordance with 42 CFR Part 438, including but not limited to 438.6(f)(2)(i

3.37 Certification of Compliance with Pro-Children Act of 1994. Provider certifies that it will comply with the requirements of Public Law 103-227, Part C Environmental Tobacco Smoke, also known as the Pro-Children Act of 1994 (the "Act"), to the extent applicable to Provider in performance of the Agreement. This Act requires that smoking not be permitted in any portion of any indoor facility owned or leased or contracted by an entity and used routinely or regularly for the provision of health, day care, early childhood development services, education or library services to children under the age of eighteen (18), if the services are funded by federal programs either directly or through State or local governments, by federal grant, contract, loan or loan guarantee. Federal programs include grants, cooperative agreements, loans or loan guarantees and contracts. The law also applies to children's services that are provided in indoor facilities that are constructed, operated or maintained with such federal funds. The law does not apply to children's services provided in private residences; portions of facilities used for inpatient drug or alcohol treatment; service providers whose sole source of applicable federal funds is Medicare or Medicaid; or facilities (other than clinics) where WIC coupons are redeemed. Failure to comply with the provisions of the law may result in the imposition of a civil monetary penalty of up to $1,000 for each violation and/or the imposition of an administrative compliance order on the responsible party. Provider shall include this provision in all subcontracts that contain provisions for children's services. Such subcontractors shall certify compliance accordingly.

3.38 Repayment Obligation. In the event that any State and/or federal funds are deferred and/or disallowed as a result of any audits of Provider, or expended by Provider in violation of the laws applicable to the expenditure of such funds, Provider shall be liable to the Department for the full amount of any claim disallowed and for all related penalties incurred.

3.39 Conflict of Interest. Provider represents, warrants, and covenants that no relationship exists or will exist during the Agreement period that is a conflict of interest for Provider. No employee, officer or agent of Provider shall participate in the selection or in the award or administration of a subcontract if a conflict of interest, real or apparent, exists. The provisions of Iowa Code chapter 68B shall apply to the Agreement.

3.40 Immunity from Liability. Provider acknowledges and agrees that the State, the Department, and all their employees, agents, successors, and assigns are immune from liability and suit for or from Provider's activities involving third parties and arising from the Agreement.

3.41 Relationship of the Parties. Provider acknowledges and agrees that performance of the Agreement does not create an employment or agency relationship with the State, the Department, or any other agency, division or department of the State simply by virtue of the services performed under the Agreement.

SECTION 4
SUBCONTACTOR AND HEALTH PLAN REQUIREMENTS

4.1 Prompt Payment. Subcontractor or Health Plan (as applicable) 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 Subcontractor or Health Plan otherwise requests assistance from Provider, Subcontractor and Health Plan 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. Subcontractor and Health Plan 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. Subcontractor and Health Plan 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. Subcontractor and Health Plan 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 Subcontractor and Health Plan 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 Subcontractor and Health Plan that are designed to maintain quality of care practice standards and control costs.

4.4 Communications with Covered Persons. Subcontractor and Health Plan 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:

(a) The Covered Person's health status, medical care, or treatment options, including any alternative treatment that may be self-administered;

(b) Any information the Covered Person needs in order to decide among all relevant treatment options;

(c) The risks, benefits, and consequences of treatment or non-treatment; or

(d) 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.

Subcontractor and Health Plan 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 the termination rights under the Agreement, Subcontractor and Health Plan shall have the right to revoke any functions or activities Subcontractor and Health Plan delegates to Provider under the Agreement or impose other sanctions consistent with the State Contract if in Subcontractor's and Health Plan's reasonable judgment Provider's performance under the Agreement is inadequate. Subcontractor and Health Plan 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
ADDITIONAL PROVIDER REQUIREMENTS FOR SPECIFIC ACTIVITIES

5.1 Nursing Facility Requirements. Provider shall:

(a) promptly notify Subcontractor and/or Health Plan of a Covered Person's admission or request for admission to the nursing facility as soon as the nursing facility has knowledge of such admission or request for admission;

(b) notify Subcontractor and/or Health Plan immediately if the nursing facility is considering discharging a Covered Person and to consult with the Covered Person's care coordinator;

(c) notify Covered Person and/or the Covered Person's representative (if applicable) in writing prior to discharge in accordance with State and Federal requirements;

(d) notify Subcontractor and/or Health Plan of any change in a Covered Person's medical or functional condition that could impact the Covered Person's level of care eligibility for the currently authorized level of nursing facility services;

(e) comply with federal Preadmission Screening and Resident Review (PASRR) requirements to provide or arrange to provide specialized services and all applicable Iowa law governing admission, transfer and discharge policies; and

(f) if the nursing facility is involuntarily decertified by the State or CMS, the Agreement shall automatically be terminated in accordance with federal requirements.

5.2 Home and Community-Based Services (HCBS) Provider Requirements. Provider shall:

(a) provide at least thirty (30) days advance notice to Subcontractor and/or Health Plan when the HCBS provider is no longer willing or able to provide services to a Covered Person and to cooperate with the Covered Person's care coordinator to facilitate a seamless transition to alternate providers;

(b) in the event that a HCBS provider change is initiated for a Covered Person, regardless of any other provision in the Agreement, the transferring HCBS provider shall continue to provide services to the Covered Person in accordance with the Covered Person's plan of care until the Covered Person has been transitioned to a new provider, as determined by Subcontractor and/or Health Plan, or as otherwise directed by Subcontractor and/or Health Plan, which may exceed thirty (30) days from the date of notice to Subcontractor and/or Health Plan;

(c) immediately report any deviations from a Covered Person's service schedule to the Covered Person's care coordinator;

(d) comply with the critical incident reporting requirements as described in State Contract Section 10.4.2; and

(e) comply with all child and dependent adult abuse reporting requirements.

5.3 Long Term Services and Supports (LTSS) Provider Requirements. As applicable, LTSS Provider's service delivery site or services shall meet all applicable requirements of Iowa law and have the necessary and current licenses, certification, accreditation, and/or designation approval per State requirements. When individuals providing LTSS are not required to be licensed, accredited or certified, the Provider shall ensure, based on applicable State licensure rules and/or program standards, that individual is appropriately educated, trained, qualified, and competent to perform their job responsibilities. In addition, the LTSS Provider shall ensure that all required criminal history record checks and child and dependent adult abuse background checks are conducted for individuals who are not licensed/accredited by a board that conducts background checks. Specifically, the Provider shall ensure criminal history checks and child and dependent adult background checks are conducted for self-direction service providers such as Consumer Directed Attendant Care (CDAC) and Consumer Choices Options (CCO) employees. Each of the State's 1915(c) and 1915(i) HCBS waivers, delineate the minimum provider qualifications for each covered service and the Provide shall meet these qualification requirements.

SECTION 6
OTHER REQUIREMENTS

6.1 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 Subcontractor and Health Plan 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 Subcontractor and Health Plan 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.

6.2 Monitoring. Subcontractor and/or Health Plan 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, Subcontractor and/or Health Plan shall identify to Provider any deficiencies or areas for improvement mandated under the State Contract and Provider and Subcontractor and/or Health Plan shall take appropriate corrective action. Provider shall comply with any corrective action plan initiated by Subcontractor and/or Health Plan 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 Subcontractor and/or Health Plan and Provider practice and/or the performance standards established under the State Contract.

6.3 Enrollment. The parties acknowledge and agree that the State Program is responsible for enrollment, reenrollment and disenrollment of Covered Persons.

6.4 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 Subcontractor and Health Plan or as prohibiting or penalizing Subcontractor and Health Plan for contracting with other providers.

6.5 Delegation. The parties agree that, prior to execution of the Agreement, Subcontractor and Health Plan 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. Health Plan shall have the right to revoke any functions or activities Subcontractor and Health Plan delegates to Provider under the Agreement if in Subcontractor and Health Plan's reasonable judgment Provider's performance under the Agreement is inadequate.

6.6 State Oversight. The parties acknowledge and agree that the Agreement is subject to the review and approval of the Department. The Department also has the right to request the termination of the Agreement for good cause.