HAWAII STATE PROGRAMS
REGULATORY REQUIREMENTS APPENDIX

DOWNSTREAM PROVIDER

THIS HAWAII 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 State of Hawaii QUEST Integration program ("QI") ("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 contracts 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 and as requested by the Health Plan, Provider agrees that Subcontractor shall be permitted to 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 State Program, the definitions shall have the meaning set forth under the State Program.

2.1 Agreement: An executed contract between Subcontractor and Provider for the provision of Covered Services to persons enrolled in the Hawaii State Program.

2.2 Clean Claim: A claim that can be processed without obtaining additional information from Provider or Provider's designated representative. Clean Claims include claims with errors originating in the State's claims system, but do not include claims submitted by Provider if Provider is under investigation for fraud or abuse, or claims under review for medical necessity.

2.3 Covered Person: An individual who is currently enrolled with Health Plan or Payer for the provision of services under the State Program. A Covered Person may also be referred to as an Enrollee, Member or Customer under the Agreement.

2.4 Covered Services: Health care services, benefits or products to which a Covered Person is entitled under Hawaii's State Program pursuant to the State Contract.

2.5 Department of Human Services or DHS: The administrative agency within the executive department of Hawaii State government. DHS includes the Med- QUEST Division ("MQD").

2.6 Early and Periodic Screening, Diagnostic and Treatment ("EPSDT"): A mandated program under Title XIX of the Social Security Act that provides services for children up to age 21 years that emphasizes the importance of prevention through early screening for medical, dental and behavioral health conditions and timely diagnosis and treatment of conditions that are detected. The State covers all services under Title XIX of the Social Security Act that are included in Section 1905 (a) of the Social Security Act, when medically needed, to correct or ameliorate defects and physical and mental illness and conditions discovered as a result of EPSDT screening.

2.7 Financial Relationship: A direct or indirect ownership or investment interest (including an option or nonvested interest) in any entity. This direct or indirect interest may be in the form of equity, debt, or other means and includes an indirect ownership or investment interest no matter how many levels removed from a direct interest, or a compensation management with an entity.

2.8 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 Insurance Company.

2.9 Med-QUEST Division or MQD: The division within DHS that has the responsibility for administering the State Program.

2.10 Primary Care Provider or PCP: A provider who is licensed in Hawaii and is 1) a physician, either a Doctor of Medicine ("M.D.") or a Doctor of Osteopathy ("D.O.") and must generally be a family practitioner, general practitioner, general internist, pediatrician or obstetrician/gynecologist (for women, especially pregnant women) or geriatrician; 2) an advanced practice registered nurse with prescriptive authority or 3) a licensed physician assistant recognized by the state Board of Medical Examiners as a licensed physician assistant. PCPs have the responsibility for supervising, coordinating and providing initial and primary care to Covered Persons and for initiating referrals and maintaining the continuity of care of Covered Persons.

2.11 QUEST Integration Program ("QI"): The Hawaii capitated managed care program that provides health care benefits, including acute and long-term services and supports, to individuals, families, and children, both non-aged, blind, or disabled (non-ABD) individuals and aged, blind, or disabled (ABD) individuals, with household income up to a specified federal poverty level (FPL).

2.12 State: The State of Hawaii or its designated regulatory agencies.

2.13 State Contract: Health Plan's contract(s) with the State for the purpose of providing and paying for Covered Services to Covered Persons enrolled in the QI Program ("State Contract").

2.14 State Program. The QI program offered by the State of Hawaii ("State Program"). For purposes of this Appendix, State Program may refer to the State agency(ies) responsible for administering the State Program.

2.15 VFC Program: The Vaccines for Children Program, a federally funded program that replaces public and private vaccines for Medicaid children under the age of nineteen (19).

SECTION 3
PROVIDER REQUIREMENTS

3.1 Covered Service Definitions. Provider shall follow the applicable State Contract provisions and Provider Manual for the coverage 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: A medical condition manifesting itself by sudden onset of symptoms of sufficient severity (including severe pain) 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 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, serious impairments of bodily functions, or serious dysfunction of any bodily organ or part. An emergency medical condition shall not be defined on the basis of lists of diagnoses or symptoms.

(b) Emergency Services: Any covered inpatient and outpatient services furnished by a provider that is qualified to furnish services and that are needed to evaluate or stabilize an Emergency Medical Condition.

(c) Medical Necessity: As defined in Hawaii Revised Statutes ("HRS") 432E-1.4, for health interventions that the health plans are required to cover within the specified categories, a health intervention is medically necessary if it is recommended by the treating physician or treating licensed health care provider, is approved by health plan's medical director or physician designee, and is:

(i) For the purpose of treating a medical condition;

(ii) The most appropriate delivery or level of service, considering potential benefits and harms to the patient;

(iii) Known to be effective in improving health outcomes; provided that:

a. Effectiveness is determined first by scientific evidence;

b. If no scientific evidence exists, then by professional standards of care; and

c. If no professional standards of care exist or if they exist but are outdated or contradictory, then by expert opinion; and

(iv) Cost-effective for the medical condition being treated compared to alternative health interventions, including no intervention. For purposes of this paragraph, cost-effective shall not necessarily mean the lowest price.

For purposes of this Section:

"Cost-effective" means a health intervention where the benefits and harms relative to the costs represent an economically efficient use of resources for patients with the medical condition being treated through the health intervention; provided that the characteristics of the individual patient shall be determinative when applying this criterion to an individual case.

"Effective" means a health intervention that may reasonably be expected to produce the intended results and to have expected benefits that outweigh potential harmful effects.

"Health intervention" means an item or service delivered or undertaken primarily to treat a medical condition or to maintain or restore functional ability. A health intervention is defined not only by the intervention itself, but also by the medical condition and patient indications for which it is being applied. New interventions for which clinical trials have not been conducted and effectiveness has not been scientifically established shall be evaluated on the basis of professional standards of care or expert opinion. For existing interventions, scientific evidence shall be considered first and, to the greatest extent possible, shall be the basis for determinations of medical necessity. If no scientific evidence is available, professional standards of care shall be considered. If professional standards of care do not exist or are outdated or contradictory, decisions about existing interventions shall be based on expert opinion. Giving priority to scientific evidence shall not mean that coverage of existing interventions shall be denied in the absence of conclusive scientific evidence. Existing interventions may meet the definition of medical necessity in the absence of scientific evidence if there is a strong conviction of effectiveness and benefit expressed through up-to-date and consistent professional standards of care, or in the absence of such standards, convincing expert opinion.

"Health outcomes" means outcomes that affect health status as measured by the length or quality of a patient's life, primarily as perceived by the patient.

"Medical condition" means a disease, illness, injury, genetic or congenital defect, pregnancy, or a biological or psychological condition that lies outside the range of normal, age-appropriate human variation.

"Physician designee" means a physician or other health care practitioner designated to assist in the decision-making process who has training and credentials at least equal to the treating licensed health care provider.

"Scientific evidence" means controlled clinical trials that either directly or indirectly demonstrate the effect of the intervention on health outcomes. If controlled clinical trials are not available, observational studies that demonstrate a causal relationship between the intervention and the health outcomes may be used. Partially controlled observational studies and uncontrolled clinical serious may be suggestive, but do not by themselves demonstrate a causal relationship unless the magnitude of the effect observed exceeds anything that could be explained either by the natural history of the medical condition or potential experimental biases.

"Treat" means to prevent, diagnose, detect, provide medical care, or palliate.

"Treating licensed health care provider" means a licensed health care provider who has personally evaluated the patient.

3.2 Medicaid or CHIP Participation. Provider must be enrolled with the State as a Medicaid or CHIP provider, as applicable to participate in Health Plan's Medicaid or CHIP network. Upon notification from the State that Provider's enrollment has been denied or terminated, Subcontractor and Health Plan must terminate Provider immediately and will notify affected Covered Persons that Provider is no longer participating in the network. Subcontractor and Health Plan will exclude from its network any provider who is on the State's exclusion list or 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 including without limitation, access to emergency care, and appointments for preventive care, urgent care, routine sick care, well care, or specialty services.

3.4 Hold Harmless. Except for applicable cost-sharing requirements under the State Contract, Provider shall look solely to Health Plan or Subcontractor for payment of Covered Services provided to Covered Persons pursuant to the Agreement and the State Contract. The State and Covered Persons shall bear no liability for Health Plan or Subcontractor's failure or refusal to pay valid claims of subcontractors or Providers for Covered Services and Provider shall hold the State, the U.S. Department of Health and Human Services ("DHHS") and Covered Persons harmless in the event that Health Plan or Subcontractor cannot or will not pay for such Covered Services. In accordance with 42 Code of Federal Regulations ("CFR") Section 447.15, as may be amended from time to time, the Covered Person is not liable to Provider for any services for which Health Plan or Subcontractor is liable and as specified under the State's

relevant health insurance or managed care statutes, rules or administrative agency guidance. In addition, Provider agrees to the following:

a) Provider shall not require any copayment or cost sharing for Covered Services provided under the Agreement unless expressly permitted under the State Contract.

b) If Provider has collected payment from a Covered Person (including a family member) in excess of the cost-sharing, Provider shall refund such payment to the Covered Person upon notification of the Covered Person's eligibility for Covered Services.

c) Provider shall be prohibited from charging Covered Persons a 'no show' fee for missed appointments for Covered Services.

d) In the case of newborns, Provider shall not look to any individual or entity other than Health Plan or Subcontractor or an available commercial health plan, if applicable, for any payment owed to Provider related to the newborn.

e) Provider shall accept Health Plan or Subcontractor's payment in full and cannot charge the Covered Person for any cost of a Covered Service whether or not the Covered Service was paid for by Health Plan or Subcontractor;

f) The State and Covered Persons shall bear no liability for Covered Services provided to a Covered Person for which the State does not pay Health Plan or Subcontractor;

g) The State and Covered Persons shall bear no liability for services provided to a Covered Person for which Health Plan, Subcontractor or the State does not pay the individual or provider that furnishes the services under a contractual, referral or other arrangement to the extent that the payments are in excess of the amount that the Covered Person would owe if Health Plan or Subcontractor provided the services directly; and

h) If Provider fails to follow Health Plan or Subcontractor's procedures which results in nonpayment, Provider may not bill the Covered Person.

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

3.5 Hours of Operation. 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. As applicable, Provider will make Covered Services available 24 hours a day, 7 days a week when medically necessary.

3.6 Services. Provider shall accept all Covered Persons for treatment, unless Provider applies to Health Plan or Subcontractor for a waiver of this requirement, and shall perform those services set forth in the Agreement, which shall also describe how the services performed by Provider are accessed by Covered Persons. Provider shall not segregate Covered Persons in any way from other persons receiving services, except for health and safety reasons.

3.7 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.

3.8 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 Covered Persons. Provider shall also comply with the following requirements related to maintenance and retention of records:

(a) In accordance with HRS §§ 622-51 and 622-58, Provider shall retain records and reports relating to the State Contract, including medical records and reports of services provided to Covered Persons, for a minimum of 10 years after the last date of entry in the records. For minors, records must be preserved and maintained during the period of minority plus a minimum of 10 years after the age of majority. If records are under review or audit, they must be retained a minimum of 10 years following resolution of the action.

(b) Provider shall provide copies of medical records to requesting Covered Persons and allow such records to be amended as specified in 45 CFR Part 164. Provider shall coordinate with Health Plan or Subcontractor in transferring medical records (or copies) when a Covered Person changes Primary Care Providers.

(c) Provider acknowledges and agrees that CMS, the State Medicaid Fraud Control Unit and DHS (including DHS personnel and its contracted personnel) or their respective designee will have the right to inspect, evaluate, and audit any pertinent books, financial records, medical records, documents, papers, and records of any provider involving financial transactions related to this contract and for the monitoring of quality of care being rendered with or without the specific consent of the Covered Person, so long as access to the records is required to perform the duties of the State Contract and to administer the State Program. Provider shall comply with Health Plan standards that provide prompt access to medical records whether electronic or paper.

(d) 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.

3.9 Privacy. Provider 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, as may be amended from time to time; Hawaii Administrative Rules ("HAR") §17-1702; §346-10 HRS; HRS §334-5, HRS Chapter 577A, 42 CFR Part 434 and 42 CFR Section 438.6 (if Applicable), as may be amended from time to time.

Provider shall notify United and DHS of any breach of confidential information related to Covered Persons within two (2) business days 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 DHS with a written investigation report within thirty (30) calendar days of the discovery. Provider shall work with United and DHS to ensure that the breach has been mitigated and reporting requirements, if any, complied with.

3.10 Compliance with Law. Provider shall provide services without regard to race, color, creed, ancestry, sex, including gender identity or expression, sexual orientation, religion, health status, income status, or physical or mental disability, and 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; 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.

(b) 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."

(c) All applicable sections of HAR, and Medicaid requirements for licensing, certification, and recertification.

(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 DHS and the appropriate Regional Office of the Environmental Protection Agency.

3.11 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 438.3, 42 CFR 422.208, and 42 CFR 422.210, as may be amended from time to time. Health Plan, Subcontractor or 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 services that are of Medical Necessity 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.

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

3.13 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. If the value of the Agreement exceeds $100,000, Provider agrees to complete and submit to Health Plan or Subcontractor the certification required under 31 United States Code ("USC") Section 1352 and 45 CFR Part 93.

(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.

3.14 Excluded Individuals and Entities. Provider represents that neither it nor any of its principals, employees, providers, subcontractors, 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, who are providing items or services that are significant and material to Provider's obligations under the Agreement is:

(a) excluded from participation by the Department of Health and Human Services (DHHS), Office of Inspector General (OIG) under either Section 1128 or Section 1128A of the Social Security Act, or excluded from participation by the DHS in the State Program; 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 is obligated to screen all employees, contractors, and/or subcontractors initially and on an ongoing monthly basis as required under 42 CFR §1001.1901(b) to determine whether any of them have been excluded from participation in Medicare, Medicaid, CHIP, or any Federal Health Care Programs (as defined in Section 1128B(f) of the Social Security Act). Provider shall not employ or contract with an individual or entity that has been excluded to provide items or Covered Services 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 any state or federal exclusion lists. Provider shall immediately report to Health Plan and Subcontractor any exclusion information discovered. Provider acknowledges and agrees that 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. 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. Subcontractor 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 Medicaid program in any state. Subcontractor may also terminate the Agreement if Provider's owners, agents, or managing employees are found to be excluded on the state or federal exclusion list.

Provider shall cooperate with Health Plan and Subcontractor and comply with all disclosure requirements identified in accordance with 42 CFR Part 455, Subpart B and the State Contract within thirty-five (35) days of the date on a request by Health Plan, Subcontractor, or DHS.

3.15 Information to Covered Persons. Provider shall provide information to Covered Persons regarding treatment options, including the option of no treatment, in a culturally-competent manner and shall ensure that individuals with disabilities have effective communications in making decisions regarding treatment options, pursuant to the requirements of the applicable State Contract or as otherwise may be required by law. Provider shall offer access to auxiliary aids and services at no cost for members living with disabilities and will document the offer and provision of auxiliary aids as applicable.

3.16 Marketing. All marketing materials developed and intending to be distributed by Provider related to the State Program, Health Plan, Subcontractor, or performance of the Agreement must be submitted to Health Plan to submit to the State for prior approval and reference either QI or Medicaid.

3.17 Fraud, Waste and Abuse. Provider shall cooperate fully with 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 Contracts and shall cooperate and assist MQD and any other State or federal agency charged with the duty of preventing, identifying, investigating, sanctioning or prosecuting suspected fraud, waste or abuse in State and/or federal health care programs. Such cooperation shall include providing, upon request, information, access to records, and access to interviews.

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), 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.

3.18 Termination. In the event of termination of the Agreement, Provider shall promptly supply to Subcontractor all information necessary for the reimbursement of any outstanding State Program claims.

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

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

3.21 Encounter Data. Provider shall cooperate with Subcontractor to comply with Health Plan's obligation to prepare encounter data submissions, reports, and clinical information

required under the State Contract including, without limitation, all 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 applicable State Contract. Provider agrees to submit complete and accurate encounter data on a monthly basis and any and all medical records to support encounter data upon request from Subcontractor or Health Plan with or without the specific consent of the Covered Person, DHS, or its designee for the purpose of validating encounters. Provider shall certify claim and encounter submissions to Subcontractor as accurate and complete. Provider shall provide medical or access to medical records to Subcontractor and Health Plan and the DHS or its designee, within sixty (60) days of a request. Refusal to provide medical records, access to medical records, or inability to produce the medical records to support the claim or encounter, shall result in recovery of payment.

3.22 Non-Covered Services. With respect to payment for non-covered services or for self-referrals by a Covered Person without following Health Plan or Subcontractor procedures, Provider may not bill a Covered Person directly unless Provider has informed the Covered Person of the costs for such non-covered services prior to rendering such services and has obtained the Covered Person's prior written, signed consent agreeing to pay for such services on a completed Advance Beneficiary Notice of Non-coverage, which includes the cost of the procedure and payment terms, provided however, if Provider fails to follow Health Plan or Subcontractor's procedures which results in nonpayment, Provider may not bill the Covered Person. The form of such written consent shall comply with any requirements of the State Contract and all applicable laws or regulations.

3.23 Cultural Competency and Access. 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, or physical or mental disabilities, and diverse cultural and ethnic backgrounds, disabilities, 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.

3.24 Transition of Covered Persons. In the event of transitioning Covered Persons to or from other Medicaid managed care contractors and their providers, Provider shall work with Health Plan and Subcontractor to ensure quality-driven health outcomes for such Covered Persons to the extent required by the applicable State Contract or otherwise required by law, and shall cooperate in all aspects with providers of other health plans to assure maximum health outcomes for Covered Persons.

3.25 Insurance Requirements. Provider shall maintain during the term of the Agreement, as applicable, general liability insurance and professional liability insurance as necessary to protect Covered Persons, Health Plan and Subcontractor. Such comprehensive general liability

insurance and professional liability insurance shall provide coverage in an amount established by United pursuant to the Agreement or as required under the State Contract. If Provider is transporting Covered Persons, Provider shall also secure and maintain automobile insurance as required under the State Contract or state law.

3.26 EPSDT Requirements. If Provider will be offering EPSDT services, Provider shall comply with all EPSDT requirements under the State Contract.

3.27 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 specified in 42 CFR Part 489, subpart I, and 42 CFR § 417.436(d).

3.28 Refund of Payment. Provider shall refund any payment received from a Covered Person, resident or family member of a Covered Person (in excess of share of cost) on behalf of the Covered Person for the prior coverage period.

3.29 Annual Cost Reports. If applicable, Provider shall submit annual cost reports to the MQD.

3.30 Third Party Liability. Provider shall comply with Health Plan and Subcontractor's policies and procedures regarding third party liability, shall report third party liability to, and shall seek reimbursement from all other liable third parties to the limit of legal liability.

3.31 Claim submissions. Provider shall comply with the requirements of the Agreement, the State Contract and Health Plan's policies and procedures as specified in the Administrative Guide and other applicable manuals for requirements related to the submission of claims and billing and coding requirements.

3.32 Vaccines to Children. If Provider will be providing vaccines to children, Provider shall enroll and complete appropriate forms for the VFC program.

3.33 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.

3.34 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, and 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 Subcontractor or Health Plan, to meet any additional State Program requirements that may apply to the services.

3.35 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, 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 Subcontractor and/or 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 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, Subcontractor or Health Plan 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. Subcontractor and/or Health Plan 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 Subcontractor and/or Health Plan 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.

3.36 Disclosure. Provider must be screened and enrolled into the State's Medicaid or CHIP program, as applicable, and submit disclosures to the 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.

3.37 Electronic Visit Verification (EVV). Provider shall cooperate with State requirements for electronic visit verification for personal care services and home health services, as applicable.

3.38 Data; Reports. Provider shall cooperate with and release to Subcontractor and/or Health Plan any information necessary for Subcontractor and/or 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/or Health Plan, in the format specified by Subcontractor, Health Plan and/or 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 Subcontractor and/or Health Plan and the State. Data must be provided at the frequency and level of detail specified by Subcontractor,

Health Plan or the State. By submitting data to Subcontractor and/or Health Plan, Provider represents and attests to Subcontractor, Health Plan and the State that the data is accurate, complete and truthful, and upon Subcontractor's and/or Health Plan's request Provider shall certify in writing, that the data is accurate, complete, and truthful, based on Provider's best knowledge, information and belief.

3.39 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 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.

3.40 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.

3.41 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 Health Records. Provider agrees to cooperate with Subcontractor and/or Health Plan 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.

3.43 Overpayment. Provider shall report to Subcontractor and/or Health Plan when it has received an overpayment and will return the overpayment to Subcontractor and/or Health Plan within 60 calendar days after the date on which the overpayment was identified. Provider will notify Subcontractor and/or Health Plan in writing of the reason for the overpayment.

SECTION 4
ADDITIONAL PROVIDER REQUIREMENTS FOR PCP Providers

4.1 Agreements with Primary Care Providers. In addition to the other requirements of this Appendix, if Provider is serving as a PCP (including specialists acting as PCP) Provider shall:

(a) Be responsible for supervising, coordinating, and providing all primary care to each assigned Covered Person;

(b) Coordinate and initiate referrals for specialty care;

(c) Maintain continuity of each Covered Person's healthcare and maintain the Covered Person's health record;

(d) Have and maintain admission and treatment privileges in a minimum of one (1) general acute care hospital that is in Health Plan's network and on the island of service. For the island of Hawaii this means that the PCP shall have and maintain admission and treatment privileges in one (1) general acute care hospital in either East Hawaii or West Hawaii, depending on which is closer. If a PCP (including specialists acting as PCPs) with an ambulatory practice does not have admission and treatment privileges with at least one (1) acute care hospital, the PCP must have a written arrangement with at least one (1) other provider with admission and treatment privileges at an acute care hospital within Health Plan's network. Health Plan or Subcontractor shall validate the PCPs arrangement and take appropriate steps to ensure arrangements are satisfactory prior to PCP patient assignment.

SECTION 5
HEALTH PLAN AND SUBCONTRACTOR REQUIREMENTS

5.1 Prompt Payment. Health Plan or Subcontractor shall pay Provider pursuant to the State Contract and applicable State 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. Provider shall comply with Health Plan and Subcontractor's billing and coding requirements as set forth in this Appendix, applicable provider manuals, and protocols, policies and procedures that Health Plan or Subcontractor has provided or delivered to Provider. Provider shall submit Clean Claims within 12 months of, (a) the date the Covered Person receives the Covered Service, or (b) in the case of a claim involving a coordination of benefits, the date of the primary/secondary payer's explanation of benefits. Ninety percent (90%) of Clean Claims for payment shall be paid within thirty (30) days of the date of receipt of such claims. Ninety-nine percent (99%) of Clean Claims shall be paid within ninety (90) days of the date of receipt of such claims. These timeframes shall apply unless an alternative payment schedule is agreed to in writing by Health Plan or Subcontractor and Provider and approved by DHS. Health Plan and Subcontractor shall pay interest (according to the interest rate provided by DHS) for all Clean Claims that are not paid within the required time

frames. 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 otherwise requests assistance from Provider, Health Plan or Subcontractor will be responsible for third party collections in accordance with the terms of the State Contract.

5.2 Non-Discrimination Against Providers. Health Plan or Subcontractor 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. Health Plan or Subcontractor 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 Health Plan or Subcontractor 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 Health Plan or Subcontractor that are designed to maintain quality of care practice standards and control costs.

5.3 Communication with Covered Persons. Health Plan or Subcontractor shall not prohibit or otherwise restrict Provider, from acting within the lawful scope of practice, or 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 or non-treatment options that may not reflect Health Plan or Subcontractor's position, may not be a Covered Service, or 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;

(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; or

(e) The Covered Person's right to obtain necessary healthcare services in any grievance system or utilization review process, or individual authorization process.

SECTION 6
OTHER REQUIREMENTS

6.1 Compliance with the 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 Health Plan or Subcontractor 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 Health Plan of its responsibility under the State Contracts. 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. As required under the State Contract, Health Plan or Subcontractor shall perform ongoing monitoring of Provider and shall perform periodic formal reviews of Provider consistent with the requirements of State and federal law and the State Contract. As a result of such monitoring activities, Health Plan and Subcontractor shall identify to Provider any deficiencies or areas for improvement mandated under the State Contract and Provider shall take appropriate corrective action.

6.3 State Approval. Health Plan, Subcontractor and Provider acknowledge that the Agreement is subject to the approval of DHS in accordance with the terms of the State Contracts and applicable State law.

6.4 NCQA Accreditation. As applicable in the performance of the Agreement, Provider is subject to all applicable accreditation standards (e.g., National Committee for Quality Assurance ("NCQA") accreditation), as may be set forth in the Agreement and any applicable attachments thereto.

6.5 Health Care-Acquired/Preventable Conditions. Health Plan, Subcontractor and Provider acknowledge and agree that Health Plan and Subcontractor is prohibited from making payments to Provider for the provision of medical assistance for health care-acquired conditions and other provider-preventable conditions as may be identified by DHS. As a condition of payment, Provider shall identify and report to Subcontractor and Health Plan any provider preventable conditions in accordance with 42 CFR §§ 434.6(a) (12), 438, including but not limited to § 438.3g, and § 447.26.

6.6 Termination and Sanctions. Provider shall comply with all corrective action plans initiated by Health Plan, Subcontractor or the State. In addition to other termination rights under the Agreement and this Appendix,

(a) Health Plan and Subcontractor shall have the right to revoke any functions or activities that delegates to Provider under the Agreement or impose other sanctions consistent with the State Contract if in Health Plan and/or Subcontractor's reasonable judgment Provider's performance under the Agreement is inadequate; and

(b) Health Plan shall immediately comply if the DHS requires that it remove Provider from its network if: (1) the Provider fails to meet or violates any State or federal laws, rules, or regulations; or (2) the Provider's performance is deemed inadequate by the State based upon accepted community or professional standards.