MASSACHUSETTS GOVERNMENT PROGRAMS

REGULATORY REQUIREMENTS APPENDIX

DOWNSTREAM PROVIDER

THIS MASSACHUSETTS GOVERNMENT PROGRAMS REGULATORY REQUIREMENTS APPENDIX (this "Appendix") supplements and is made part of the provider agreement (the "Agreement") between Ear Professionals International Corporation d/b/a EPIC Hearing Healthcare and d/b/a UnitedHealthcare Hearing ("Subcontractor") and the party 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 Massachusetts Medicaid, One Care or MassHealth Senior Care Options (each, a "State Program" and collectively, the "State Programs" as further defined below) as governed by the State's designated regulatory agencies. This Appendix also applies to the Medicare program for Dual Eligible Covered Persons (as defined below). 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 and as requested by Health Plan, 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 **Centralized Enrollee Record:** A centralized and comprehensive record documenting each Covered Person's medical, functional, and social status, and containing information relevant to maintaining and promoting each Covered Person's general health and well being, as well as clinical information concerning illnesses and chronic medical conditions.

2.2 **CMS Contract:** The contract between the Centers for Medicare & Medicaid Services ("CMS") and Health Plan for the provision of Medicare benefits pursuant to the Medicare Advantage Program under Title XVIII, Part C of the Social Security Act.

2.3 **Cost Sharing:** Those costs, if any, under a Covered Person's benefit plan that are the responsibility of the Covered Person, including deductibles, coinsurance, and copayments. Cost Sharing may also be referred to as patient expenses or other similar term under the Agreement. Cost Sharing is not permitted at all under the SCO Program.

2.4 **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. For purposes of this Appendix, "Covered Person" may include both Dual Eligible Covered Persons and MassHealth Standard Covered Persons.

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

2.6 **Department:** The Massachusetts Executive Office of Health and Human Services (EOHHS).

2.7 **Dual Eligible Covered Person:** A Covered Person who is eligible for both Medicaid and Medicare.

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 **MassHealth Standard Covered Person:** A Covered Person who is eligible only for MassHealth Standard (Medicaid). MassHealth Standard is comprehensive health insurance, including long-term-care, for low-income Massachusetts residents, including eligible parents with children under 19 years of age, pregnant women, children up to 19 years of age, the elderly, and disabled individuals.

2.10 **Medicaid:** A program authorized by Title XIX of the federal Social Security Act, and jointly financed by the federal and State governments and administered by the State.

2.11 **One Care**: A demonstration project among CMS, the State and managed care organizations for the coordination and delivery of covered Medicare, Medicaid and expanded services for Medicare-Medicaid enrollees in the Commonwealth of Massachusetts.

2.12 **Primary Care:** The provision of coordinated, comprehensive medical services on both a first-contact and a continuous basis to a Covered Person. The provision of Primary Care incorporates an initial medical history intake, medical diagnosis and treatment, communication of information about illness prevention, health maintenance, and referral services.

2.13 **Primary Care Provider ("PCP"):** A practitioner of primary care selected by or assigned to the Covered Person and responsible for providing and coordinating the Covered Person's health care needs, including the initiation and monitoring of referrals for specialty services when required. Primary Care Providers may be nurse practitioners or physicians who are board certified or eligible for certification in one of the following specialties: family practice, internal medicine, general practice, OB/GYN, or geriatrics and who is able and willing to meet all of the PCP requirements under the applicable State Contract.

2.14 **State Contract(s):** Health Plan's contract with the Massachusetts Executive Office of Health and Human Services for the purpose of providing and paying for Covered Services to Covered Persons enrolled in one or more State Programs.

2.15 **SCO Program:** The MassHealth Senior Care Options program, a program of medical, health and support services covered under Title XIX or Title XVIII of the Social Security Act. For purposes of this Appendix, SCO Program may refer to the State agency(ies) responsible for administering the SCO Program.

2.16 **State:** The Commonwealth of Massachusetts or its designated regulatory agencies.

2.17 **State Program(s):** The Commonwealth of Massachusetts Medicaid, One Care and SCO 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 Programs, through contractual requirements and federal and State statutes and regulations, requires the Agreement to contain certain conditions that Health Plan, Subcontractor and Provider agree to undertake, which include the following:

3.1 **Definitions.** Provider shall follow the applicable State Program'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 or Emergency Condition: A medical condition, whether physical or mental, that manifests itself by acute symptoms of sufficient severity (including severe pain) that, in the absence of prompt medical attention, a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in: (1) 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; (2) serious impairment to bodily functions; or (3) serious dysfunction of any bodily organ or part. An Emergency Condition may not be limited on the basis of lists of diagnoses or symptoms.

(b) Emergency Services: Covered inpatient and outpatient services, including behavioral health services, that are furnished to a Covered Person by a provider qualified to furnish such services and that are needed to evaluate or stabilize a Covered Person's

Emergency Medical Condition. Emergency Services include post-stabilization services provided after an Emergency Medical Condition is stabilized in order to maintain the stabilized condition or to improve or resolve the Covered Person's condition. The attending emergency physician, or the provider actually treating the Covered Person, is responsible for determining when the Covered Person is sufficiently stabilized for transfer.

(c) Medically Necessary: A service is "Medically Necessary" if:

(i) It is reasonably calculated to prevent, diagnose, prevent the worsening of, alleviate, correct, or cure conditions in the Covered Person that endanger life, cause suffering or pain, cause physical deformity or malfunction, threaten to cause or to aggravate a handicap, or result in illness or infirmity or otherwise medically necessary under 42 U.S.C. § 1395y or MassHealth regulations at 130 CMR 450.204; and

(ii) There is no other medical service or site of service, comparable in effect, available, and suitable for the Covered Person requesting the service, that is more conservative or less costly. Services that are less costly include, but are not limited to, health care reasonably known by the provider or identified by Subcontractor or Health Plan pursuant to a prior authorization request to be available to the Covered Person through sources described in 130 CMR 450.317(C), 503.007, or 517.007.

(iii) Medically Necessary services must be of a quality that meets professionally recognized standards of health care, and must be substantiated by records including evidence of such medical necessity and quality. A provider must make those records, including medical records, available to Subcontractor, Health Plan and the MassHealth agency upon request.

(iv) A provider's opinion or clinical determination that a service is not Medically Necessary does not constitute an action by Subcontractor, Health Plan or the MassHealth agency.

(v) Any regulatory or contractual exclusion from payment of experimental or unproven services refers to any service for which there is insufficient authoritative evidence that such service is reasonably calculated to have the effect described in subsection (c)(i) above.

(d) **Urgent Care:** Medical services required promptly to prevent impairment of health due to symptoms that do not constitute an Emergency Condition, but that are the result of an unforeseen illness, injury, or condition for which medical services are immediately required. Urgent Care is appropriately provided in a clinic, physician's office, or in a hospital emergency department if a clinic or physician's office is inaccessible. Urgent Care does not include Primary Care services or services provided to treat an Emergency Condition.

3.2 **Medicaid Participation.** Provider must be enrolled with the State as a provider, as applicable to participate in Subcontractor's or Health Plan's Medicaid 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 from the Medicare, Medicaid or CHIP program in any state, as identified in the CMS Termination Notification Database, pursuant to the 21st Century Cures Act section 5005(a).

3.3 **Access to Services.** Provider shall provide for timely access to Covered Person appointments, and shall provide flexibility in scheduling as necessary to accommodate Covered Persons with disabilities, in accordance with the appointment availability requirements established under the applicable State Contract, as set forth in the provider manual. Provider shall not close or otherwise limit its acceptance of Covered Persons as patients unless the same limitations apply to all commercially insured patients. Provider shall not refuse to provide services to any Covered Person because that Covered Person has missed appointments or has an outstanding debt with Provider from a time prior to his or her enrollment in the State Program. If a Covered Person has missed appointments, Provider shall work with United to assist that Covered Persons in keeping his or her future appointments.

3.4 **Hold Harmless.**

(a) Covered Persons and the Department. Except for pharmacy co-payments, Provider shall not seek or accept payment from any Covered Person for any Covered Service rendered, nor shall Provider have any claim against or seek payment from the Department for any Covered Service rendered to a Covered Person. Instead, Provider shall look solely to Subcontractor or Health Plan for payment with respect to Covered Services rendered to Covered Persons. Furthermore, Provider shall not maintain any action at law or in equity against any Covered Person or the Department to collect any sums that are owed by Subcontractor or Health Plan under the State Contract for any reason, even in the event that the Subcontractor or Health Plan fails to pay for or becomes insolvent or otherwise breaches the terms and conditions of the Agreement or any other Agreement entered into by Subcontractor. This provision shall survive any termination of the Agreement, including breach of the Agreement due to insolvency.

(b) Cost Sharing. Provider's obligation to hold Covered Persons harmless, as set forth in subsection (a) above, includes a prohibition against charging Covered Persons coinsurance, co-payments, deductibles, financial penalties, or any other amount in full or in part for any service provided under the SCO Program.

(c) Dual Eligible Covered Persons. Provider agrees that in no event, including but not limited to, non-payment by the State Medicaid agency or other applicable regulatory authority, other State source, or breach by Subcontractor of the Agreement, shall Provider bill, charge, collect a deposit from, seek compensation, remuneration or reimbursement from, or have any recourse against any Dual Eligible Covered Person, person acting on behalf of the Dual Eligible Covered Person, or Subcontractor or Health Plan (unless notified otherwise) for Medicare Part A and B Cost Sharing. Instead, Provider will

either: (a) accept payment made by or on behalf of Subcontractor as payment in full; or (b) bill the appropriate State source for such Cost Sharing amount.

(d) Outstanding Debt. Provider shall not refuse to provide Covered Services to Dual Eligible Covered Persons due to any outstanding debts accrued for services rendered prior to the Dual Eligible Covered Person's eligibility for Covered Services.

(e) Continuity of Care. In the event of Subcontractor's or Health Plan's insolvency or other cessation of operations or termination of the applicable State Contract or CMS Contract, Provider shall continue to provide Covered Services to Covered Persons for the later of: the period for which a premium has been paid to Health Plan on behalf of the Covered Person; or, in the case of Covered Persons who are hospitalized as of such period or date, the Covered Person's discharge.

3.5 **Hours of Operation.** Provider shall offer hours of operation that are no less than the hours of operation offered to commercial enrollees or comparable to Medicaid fee-for-service enrollees. As applicable, Provider will make Covered Services available 24 hours a day, 7 days a week when medically necessary.

3.6 **Referrals Prohibited.** 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.

3.7 **Record Keeping.**

(a) Maintenance. Provider shall maintain, in an accurate and timely manner, adequate medical, financial and administrative records related to the services rendered by Provider under the Agreement, including but not limited to Covered Person medical records and other health and enrollment information. Such records shall be maintained for a period of not less than ten (10) years from the close of the applicable State Contract, or such other period as required by law. If records are under review or audit, they must be retained until the review or audit is complete.

(b) Access to Records.

(i) Provider shall make all books and records pertaining to the goods and services provided under the terms of the Agreement available for inspection, examination or copying by the Department and CMS and their agents, designees or contractors. Provider shall also make such books and records available to the Department and CMS (and their agents, designees or contractors) or any other authorized representatives of the Commonwealth of Massachusetts or the United States Government, or their designees or contractors, at such times, places and in such manner as such entities may reasonably request for the purposes of financial or medical audits, inspections, and examinations.

(ii) Provider further agrees that the Secretary of the U.S. Department of Health and Human Services (DHHS) or his or her designee, the Governor of

Massachusetts or his or her designee, and the State Auditor or his or her designee have the right, at reasonable times and upon reasonable notice, to examine the books, records, and other compilations of data of Provider that pertain to: (i) the ability of Health Plan to bear the risk of potential financial losses; (ii) services performed under the applicable State Contract; or (iii) determinations of amounts payable under the applicable State Contract and/or the Agreement.

(iii) Provider further acknowledges and agrees that U.S. Department of Health and Human Services (DHHS), the Comptroller General, and their designees have the right to inspect, evaluate, and audit any pertinent books, contracts, medical records, patient care documentation, and other records and information belonging to Provider that relate to the CMS or State Contracts.

(iv) For purposes of the above activities, Provider shall make available its premises, physical facilities and equipment, records relating to Covered Persons, and any additional relevant information that the Department or CMS may require, in a manner that meets Department and CMS record maintenance requirements.

(v) The audit and inspection rights set forth in this section shall extend through the later of ten (10) years from the final date of the applicable State Contract period in effect at the time the records were created or the date of completion of any audit, or longer in certain instances described in the applicable Medicare Advantage regulations, in accordance with State and federal requirements.

(vi) Provider also shall ensure that medical information is released pursuant to court orders or subpoenas and that Covered Persons have timely access to medical records and information that pertain to them, in accordance with applicable law.

(c) Subcontractor and Health Plan Access to Records. Provider shall grant Subcontractor and Health Plan or its designee(s) such audit, evaluation, and inspection rights identified in subsection 3.6(b) as are necessary for Subcontractor or Health Plan to comply with its obligations under the CMS and applicable State Contracts. Whenever possible, Subcontractor and Health Plan will give Provider reasonable notice of the need for such audit, evaluation or inspection, and will conduct such audit, evaluate or inspection at a reasonable time and place. Provider shall submit medical records of Covered Persons to Subcontractor and/or Health Plan (as applicable) as may be requested, within the timeframes specified, for the purpose of (i) CMS audits of risk adjustment data and (ii) for other purposes medical records from providers are used by Subcontractor and Health Plan, as specified by CMS. Provision of medical records must be in the manner consistent with HIPAA privacy statute and regulations.

3.8 **Government Audit; Investigations.** Provider acknowledges and agrees that the Department, the Office of Inspector General, the Comptroller General, the U.S. Department of Health and Human Services (DHHS) and the Centers for Medicare and Medicaid Services (CMS) or their authorized representatives or their designees shall have the right to inspect or

otherwise evaluate the quality, appropriateness, and timeliness of services provided under the terms of the applicable 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 **Confidentiality.** Provider shall comply with all applicable provisions of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), and associated implementing regulations at 45 CFR Parts 160, 162 and 164, as may be amended from time to time. Provider shall safeguard Covered Person privacy and confidentiality, including but not limited to the privacy and confidentiality of any information that identifies a particular Covered Person, in accordance with applicable federal and State laws and regulations regarding the confidentiality of Covered Person records and information, including but not limited to 42 CFR §438.224, 42 CFR Part 431, Subpart F, M.G.L. c. 66A, and, if applicable M.G.L. c. 123 §36, as may be amended from time to time.

3.10 **Compliance with Laws.** The Agreement and this Appendix shall be governed by and construed in accordance with all laws, regulations and contractual obligations incumbent upon Subcontractor and Health Plan, including but not limited to all applicable requirements specified in the applicable State Contract. Provider shall comply with all applicable federal and Medicare laws, regulations and CMS instructions and State and local laws, rules and regulations, including but not limited to the following, to the extent applicable to Provider in performance of the Agreement:

(a) Federal laws and regulations designed to prevent or ameliorate fraud, waste and abuse, including but not limited to applicable provisions of federal criminal law, the False Claims Act (31 U.S.C. §3729 et seq.), and the anti-kickback statute (§1128B of the Social Security Act).

(b) 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; Section 504 of the Rehabilitation Act of 1973 (U.S.C. 794); Americans with Disabilities Act (ADA) (28 CFR 35.130), section 1557 of the Patient Protection and Affordable Care Act, and their implementing regulations, as may be amended from time to time.

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

(d) 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."

(e) 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.

(f) The Emergency Medical Treatment and Labor Act (EMTALA) codified at §1867 of the Social Security Act, as well as the accompanying regulations in 42 CFR §489.24 and related requirements at 42 CFR 489.20(l), (m), (q), and (r).

3.11 **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.

3.12 **Physician Incentive Plans**. In the event Provider participates in a physician incentive plan ("PIP") under the Agreement, Provider agrees that such PIP must comply with all applicable requirements governing PIPs, including but not limited to 42 CFR Parts 417, 422, 434, 438 and 1003, as may be amended from time to time. Neither Subcontractor, Health Plan, nor Provider may make a specific payment directly or indirectly under a PIP to a physician or physician group as an inducement to reduce or limit Medically Necessary services furnished to an individual Covered Person. PIPs must not contain provisions that provide incentives, monetary or otherwise, for the withholding of Medically Necessary care. Provider shall maintain adequate and appropriate stop-loss protection in accordance with 42 CFR Part 417 if incentive arrangements with Provider place Provider at substantial financial risk for services it does not provide.

3.13 **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, retention and exclusion of providers,

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

3.14 **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.

3.15 **Excluded Individuals.** By signing the Agreement, Provider certifies to the best of Provider's knowledge and belief that neither it nor any of its principals, nor any providers, subcontractors or consultants with whom Provider contracts for the provision of 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 non-procurement 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 its employees and contractors to determine whether any of them have been debarred or 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. Provider shall immediately report to 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. Federal and State exclusion databases must be reviewed monthly to ensure that no employee or contractor has been excluded. Subcontractor must exclude from its network any provider who has been excluded from the Medicare, Medicaid or CHIP program in any state.

3.16 **Disclosure.** Provider must be screened and enrolled into the State's Medicaid or CHIP program, as applicable, and submit disclosures to Department on ownership and control, significant business transactions, and persons convicted of crimes in accordance with 42 CFR Part 455 and shall provide such 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 information. 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.

3.17 **Cultural Competency and Access.** Provider shall participate in Subcontractor's, Health Plan's and the Department's efforts to promote the delivery of services in a culturally competent manner to all Covered Persons, including those with limited English proficiency, physical or mental disabilities, and diverse cultural and ethnic backgrounds, and regardless of gender, sexual orientation or gender identity, and shall provide interpreter services in a Covered Person's primary language and for the hearing impaired for all appointments and emergency services. Provider shall provide information to Covered Persons regarding treatment options and alternatives 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.

3.18 **Outreach.** As required under the State Contracts, any outreach materials for Covered Persons or potential Covered Persons that are developed or distributed by Provider on behalf of Subcontractor and Health Plan must be submitted to Subcontractor for prior approval by Health Plan and the Department before use.

3.19 **Fraud and Abuse.** 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, abuse and waste in the administration and delivery of services under the State Contracts and shall cooperate and assist the Department, the Office of the Attorney General's Medicaid Fraud Control Unit, the Office of the State Auditor's Bureau of Special Investigations, and any other State or federal agency charged with the duty of preventing, identifying, investigating, sanctioning or prosecuting suspected fraud, abuse or waste in state and/or federal health care programs. Such cooperation shall include, but not be limited to, providing at no charge, prompt access and copies of any documents and other available information determined necessary by such agencies to carry out their responsibilities regarding

Medicaid fraud and abuse, maintaining the confidentiality of any such investigations, and making knowledgeable staff available at no charge to support any investigation, court, or administrative proceeding. Provider will immediately notify Subcontractor and Health Plan if it receives or identifies any information that gives Provider reason to suspect that a Covered Person or a provider has engaged in fraud as defined under 42 CFR Part 455.2. In the event of suspected fraud, no further contact shall be initiated with the Covered Person or provider on that specific matter without Subcontractor's, Health Plan's and the Department's approval.

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.

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

3.21 **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's and Health Plan's quality assessment, performance improvement and utilization review and management activities, which shall be tailored to the nature and type of services subcontracted. 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 or Health Plan or as required under the applicable State Contract to ensure quality control for the health care provided, including but not limited to the accessibility of Medically Necessary health care, and 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 Programs and shall monitor quality and initiate corrective action to improve quality consistent with the generally accepted level of care. Provider is not required to indemnify Subcontractor or Health Plan for any expenses or liabilities incurred in connection with any claim or action brought against Subcontractor or Health Plan based on Subcontractor's or Health Plan's management decisions, utilization review provisions or other policies, guidelines or actions except, to the extent, such claim or action is as a result of Provider's fault or negligence.

3.22 **Outstanding Claim Information.** In the event of termination of the Agreement, Provider shall promptly supply to Subcontractor and/or Health Plan (as applicable) all information necessary for the reimbursement of any outstanding Medicaid claims.

3.23 **Assignment and Delegation.** Provider acknowledges and agrees that assignment or delegation of the Agreement is prohibited unless prior written approval is obtained from Subcontractor. If, with Subcontractor's approval, Provider subcontracts or delegates any functions of the Agreement, the subcontract or delegation must include all of the requirements of this Appendix and applicable requirements of the State Contracts. 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 delegated or subcontracted.

3.24 **Payment.** Provider shall accept Subcontractor's and/or Health Plan's payment as payment in full for services provided under the Agreement and shall not bill Covered Persons, the Department or CMS for such services or hold any of the above liable for any fees that are the obligation of Subcontractor or Health Plan. Provider shall hold harmless the Department, CMS and Covered Persons in the event that Subcontractor or Health Plan cannot or will not pay for services performed by Provider pursuant to the Agreement. Furthermore, Provider shall not bill Covered Persons for missed appointments or refuse to provide services to Covered Persons who have missed appointments.

3.25 **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 Department. 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).

3.26 **Notification to Primary Care Provider (PCP).** As applicable, Provider shall notify the Covered Person's PCP of any screening or treatment of Covered Services, including Emergency Services.

3.27 **Centralized Enrollee Record.** As applicable, Provider shall comply with Subcontractor's and Health Plan's policies and statutory and regulatory requirements applicable to the Centralized Enrollee Record and other Covered Person medical records. This shall include, at a minimum, compliance with all federal and State legal requirements as they pertain to the confidentiality of Covered Person records (as further set forth in Section 3.8 of this Appendix) and all confidentiality protections established by Subcontractor or Health Plan. Provider shall make appropriate and timely entries in the Centralized Enrollee Record describing the care provided, diagnoses determined, medications prescribed, and treatment plans developed (as applicable). The documentation included in the Centralized Enrollee Record must be consistent with current professional standards and be current, detailed, and organized in a manner that permits effective patient care and quality review. If Provider is a PCP, Provider shall be responsible for maintaining the Centralized Enrollee Record for Covered Persons residing in the community. Nursing home Providers will be responsible for maintaining the

Centralized Enrollee Record for Covered Persons who reside in such nursing home. Additional requirements for the Centralized Enrollee Record are set forth in the provider manual.

3.28 **Health Information Exchange.** As applicable in performance of the services under the Agreement, Provider will leverage national standards-based statewide health information exchanges and cooperate with Subcontractor and Health Plan to ensure effective linkages of clinical and management information systems. As applicable, a single electronic medical record shall be utilized to manage communication and information regarding referrals, transitions and care delivered outside of the primary care site of service.

3.29 **Data Requirements.** Provider must provide to Subcontractor or Health Plan and/or the Department all information the Department requires under the applicable State Contract related to the performance of Provider's responsibilities, including encounter data, as well as non-medical information for the purposes of research and evaluation, and any information the Department requires to comply with all applicable federal and State laws and regulations. Such data must include, but isn't limited to, information pertaining to (a) substance use disorders, (b) births to Covered Persons, (c) clinical assessment and outcomes data, and (d) provider incentives. As applicable, Provider shall submit to Subcontractor or Health Plan all risk adjustment data as defined in 42 CFR 422.310(a). Provider shall send to Subcontractor or Health Plan all risk adjustment data and other Medicare Advantage program-related information as may be requested by Health Plan, within the timeframes specified and in a form that meets Medicare Advantage program requirements. By submitting data to Subcontractor or Health Plan, Provider represents, and upon Subcontractor's request shall certify in writing, that the data is accurate, complete, and truthful, based on Provider's best knowledge, information and belief.

3.30 **Identifier.** If Provider is a physician, Provider must obtain and provide to Subcontractor or Health Plan a unique identifier in accordance with the system established under 42 U.S.C. § 1320d-2(b).

3.31 **Conflicts of Interest.** Provider may not, for the duration of the Agreement, have any interest that will conflict, as determined by the Department, with the performance of services under the applicable State Contract or that may otherwise be anticompetitive.

3.32 **Submission of Information.** Provider shall submit all management and clinical data required by Subcontractor or Health Plan in a format compatible with Subcontractor's and/or Health Plan's information systems.

3.33 **Minority Business Enterprises.** Provider shall promptly notify Subcontractor or Health Plan if it is currently, or at any time during the term of the Agreement becomes, certified as a Minority Business Enterprise by the Massachusetts State Office of Minority and Women Business Assistance.

3.34 **Licensure.** Provider shall maintain throughout the Agreement all appropriate license(s), certification(s) and/or accreditation necessary to perform its obligations under the Agreement and shall continually meet all applicable State and federal requirements for the provision of the services Provider provides under the Agreement. Provider shall immediately report to

Subcontractor or Health Plan the loss, suspension or restriction of any license(s), certification(s) and/or accreditation necessary for Provider to perform its obligations under the Agreement.

3.35 **Policies and Procedures.** Provider shall cooperate and comply with Subcontractor's and Health Plan's policies and procedures.

3.36 **State and Federal Funds.** Provider acknowledges and agrees that Subcontractor or Health Plan receives State and federal payments under the State Contracts and CMS Contract and that payments Provider receives from or on behalf of Subcontractor or Health Plan are, in whole or in part, from State and federal funds. Provider is therefore subject to certain laws that are applicable to individuals and entities receiving State and federal funds.

3.37 **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.

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

3.39 **Termination.** Neither United nor Provider has the right to terminate the Agreement without cause. If the Agreement is terminated with cause, Subcontractor or Health Plan will provide a written statement to Provider of the reason or reasons for the termination with cause. In the event of termination of the Agreement, Provider shall promptly supply to Subcontractor or Health Plan all information necessary for the reimbursement of any outstanding Medicaid claims and shall assist with transitioning Covered Persons' medical records and other relevant information as directed by Subcontractor, Health Plan or that Covered Person.

3.40 **Offshoring.** Unless previously authorized by Subcontractor or Health Plan in writing, all services provided pursuant to the Agreement that are subject to this Appendix must be performed within the United States, the District of Columbia, or the United States territories.

3.41 **Liability Insurance.** Provider shall maintain liability protection sufficient to protect itself against any losses arising from any claims, including, at a minimum, works' compensation insurance, comprehensive liability insurance, and property damage insurance.

SECTION 4
ADDITIONAL PROVIDER REQUIREMENTS FOR SPECIFIC ACTIVITIES

4.1. **Primary Care Provider (PCP) Responsibilities.** The PCP must serve as the Covered Person's initial and most important point of interaction within the Subcontractor or Health Plan network. As such, PCP responsibilities include the following, as further described in the provider manual:

(a) Serving as the Covered Person's Primary Care Provider;

(b) Making referrals for specialty care and other Medically Necessary services, both in- and out-of-plan;

(c) Coordinating and implementing an individualized care plan for the Covered Person; and

(d) Delivering team-based integrated primary and behavioral health Covered Services to Covered Persons and coordinate care with other providers, including the assembly of an interdisciplinary care team, as appropriate.

SECTION 5
HEALTH PLAN AND SUBCONTRACTOR REQUIREMENTS

5.1 **Payments to Provider.** Subcontractor or Health Plan (as applicable) shall pay Provider on a timely basis as set forth in the Agreement, the applicable State Contract and applicable State and federal law and regulations, including but not limited to 42 U.S.C. 1396u-2(f) and 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. Unless a different timeframe is set forth in the Agreement, Subcontractor or Health Plan (as applicable) will pay 90% of claims from physicians in an individual or group practice which can be processed without obtaining additional information from the physician or from a third party within ninety (90) days of the date of receipt of the claim. 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 applicable State Contract. Unless Subcontractor or Health Plan (as applicable) otherwise requests assistance from Provider, Subcontractor or Health Plan will be responsible for third party collections in accordance with the terms of the applicable State Contract.

5.2 **Provider Discrimination.** Neither Health Plan nor Subcontractor shall 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. This provision shall not be construed as prohibiting Health Plan and 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 that are designed to maintain quality of care practice standards and control costs consistent with Health Plan's responsibilities under the applicable State Contract.

5.3 **Provider / Covered Person Communications.** Neither Health Plan nor Subcontractor shall prohibit or otherwise restrict Provider, when acting within the lawful scope of Provider's licensure and practice, from advising or advocating on behalf of a Covered Person who is Provider's patient 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;

(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) Providing information to such Covered Person pertaining to the provisions, terms or requirements of the State Program or the method by which Provider is compensated by Subcontractor or Health Plan for Covered Services.

(f) Notwithstanding the foregoing, neither Health Plan nor Subcontractor is required to provide, reimburse for, or provide coverage of a counseling or referral service if Health Plan or Subcontractor objects to the service on moral or religious grounds; provided, however, that Health Plan or Subcontractor furnishes information about such services to the Department, Covered Persons and potential Covered Persons in accordance with the requirements of the applicable State Contract.

5.4 **High Risk Persons.** Health Plan and Subcontractor shall not discriminate against Provider for serving high-risk Covered Persons or if Provider specializes in conditions requiring costly treatments.

5.5 **No Incentives to Limit Medically Necessary Services.** Health Plan and Subcontractor 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. Additionally, Health Plan and Subcontractor will ensure that all behavioral health authorization and utilization management activities are in compliance with 42 U.S.C. 1396u-2(b)(8).

SECTION 6
OTHER REQUIREMENTS

6.1 **Government Contracts.**

(a) **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, the Guide to the Senior Care Options Program for MassHealth Providers

distributed by the Department, and applicable provider manual(s), protocols, policies and procedures that Health Plan or Subcontractor has provided, delivered or made available 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 legal responsibilities under the applicable State Contract; Health Plan remains fully responsible for meeting all terms and requirements of the State Contract. If any provision of the Agreement or this Appendix is in conflict with provisions of the applicable State Contract, the terms of the State Contract shall control and the terms of the Agreement or this Appendix in conflict with those of the State Contract will be considered waived.

(b) **CMS Contract.** Provider also shall perform the services set forth in the Agreement in a manner consistent with and in compliance with Health Plan's contractual obligations under the CMS Contract.

6.2 **Accountability; Delegated Activities.** Provider acknowledges and agrees that Health Plan oversees and is accountable to the Department and CMS for any functions and responsibilities described in the applicable State Contract, the CMS Contract and applicable State and federal regulations, including those that Subcontractor may delegate to Provider or others. If Health Plan and Subcontractor have delegated any of its functions and responsibilities under the State Contracts or CMS Contract to Provider pursuant to the Agreement, the following shall apply in addition to the other provisions of this Appendix:

(a) Provider shall perform those delegated activities specified in the Agreement, if any, and shall comply with any reporting responsibilities as set forth in the Agreement.

(b) If Subcontractor has delegated to Provider any activities related to the credentialing of health care providers, Provider must comply with all applicable CMS and State Program requirements for credentialing, including but not limited to the requirement that the credentials of medical professionals must either be reviewed by Subcontractor or the credentialing process must be reviewed, pre-approved and audited on an ongoing basis by Subcontractor and/or Health Plan.

(c) If Subcontractor has delegated to Provider the selection of health care providers to be participating providers in Subcontractor's network for the State Program, Subcontractor retains the right to approve, suspend or terminate the participation status of such health care providers.

(d) Provider acknowledges and agrees that Subcontractor shall perform ongoing monitoring of Provider's performance of any delegated activities and the quality of care provided to Covered Persons, and shall perform annual formal reviews of Provider and according to any other schedule established by the Department, consistent with industry standards or State managed care organization laws and regulations, federal law and the applicable State Contract. As a result of such monitoring activities, Subcontractor shall identify to Provider any deficiencies or areas for improvement mandated under the State Contract and Subcontractor and Provider shall take appropriate corrective action. Provider shall comply with any corrective action plan required by Subcontractor or Health Plan. 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 Provider practice and/or the performance standards established under the applicable State Contract. Provider acknowledges and agrees that if the Department identifies to Health Plan and Subcontractor a deficiency in the performance of Provider, and Subcontractor does not successfully implement an approved corrective action plan, the Department may require Subcontractor to contract with a different provider deemed satisfactory by the Department.

(e) In addition to its termination rights under the Agreement, Subcontractor shall have the right to revoke any or all activities and reporting requirements delegated to Provider under the Agreement or impose other sanctions consistent with the applicable State Contract if in Subcontractor's and/the Department, CMS or Health Plan's reasonable judgment determine that Provider has not performed satisfactorily. Provider shall cooperate with Subcontractor and Health Plan in the transition of any delegated activities or reporting requirements that have been revoked by Subcontractor and/or Health Plan.

6.3 **Conflicts of Laws.** Provider acknowledges and agrees that Massachusetts general law or Massachusetts regulation will prevail if there is a conflict with the state law or state regulation where Provider is based.

6.4 **Independent Contractor Relationship.** Provider, its employees, subcontractors, and any other of its agents shall, in the performance of the Agreement, act in an independent capacity and not as officers or employees of the federal government, the State, the Department, or CMS.