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CHANGE TITLE: TRICARE PROGRAM; CLARIFICATION OF BENEFIT COVERAGE OF DURABLE EQUIPMENT AND ORDERING OR PRESCRIBING DURABLE EQUIPMENT; CLARIFICATION OF BENEFIT COVERAGE OF ASSISTIVE TECHNOLOGY DEVICES UNDER THE EXTENDED CARE HEALTH OPTION PROGRAM

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Assistant Secretary of Defense (Health Affairs). An authority of the Assistant Secretary of Defense (Health Affairs) includes any person designated by the Assistant Secretary to exercise the authority involved.

Assistive technology devices. Equipment that generally does not treat an underlying injury, illness, disease or their symptoms. Assistive technology devices are authorized only under the Extended Care Health Option (ECHO). Assistive technology devices help an ECHO beneficiary overcome or remove a disability and are used to increase, maintain, or improve the functional capabilities of an individual. Assistive technology devices may include non-medical devices but do not include any structural alterations (e.g., permanent structure of wheelchair ramps or alterations to street curbs) service animals (e.g., Seeing Eye dogs, hearing/handicapped assistance animals, etc.) or specialized equipment and devices whose primary purpose is to enable the individual to engage in sports or recreational events. Assistive technology devices are authorized only under coverage criteria determined by the Director, TRICARE Management Activity to assist in the reduction of the disabling effects of a qualifying condition for individuals eligible to receive benefits under the ECHO program, as provided in Sec. 199.5.

Attending physician. The physician who has the primary responsibility for the medical diagnosis and treatment of the patient. A consultant or an assistant surgeon, for example, would not be an attending physician. Under very extraordinary circumstances, because of the presence of complex, serious, and multiple, but unrelated, medical conditions, a patient may have more than one attending physician concurrently rendering medical treatment during a single period of time. An attending physician also may be a teaching physician.

Augmentative communication device (ACD). A voice prosthesis as determined by the Secretary of Defense to be necessary because of significant conditions resulting from trauma, congenital anomalies, or disease. Also referred to as Speech Generating Device.

Authorized provider. A hospital or institutional provider, physician, or other individual professional provider, or other provider of services or supplies specifically authorized to provide benefits under CHAMPUS in Sec. 199.6 of this part.

Automobile liability insurance. Automobile liability insurance means insurance against legal liability for health and medical expenses resulting from personal injuries arising from operation of a motor vehicle. Automobile liability insurance includes:

- (1) Circumstances in which liability benefits are paid to an injured party only when the insured party's tortious acts are the cause of the injuries; and
- (2) Uninsured and underinsured coverage, in which there is a third-party tortfeasor who caused the injuries (i.e., benefits are not paid on a no-fault basis), but the insured party is not the tortfeasor.

Backup hospital. A hospital which is otherwise eligible as a CHAMPUS institutional provider and which is fully capable of providing emergency care to a patient who develops complications beyond the scope of services of a given category of CHAMPUS-authorized freestanding institutional provider and which is accessible from the site of the CHAMPUS-authorized freestanding institutional provider within an average transport time acceptable

for the types of medical emergencies usually associated with the type of care provided by the freestanding facility.

Balance billing. A provider seeking any payment, other than any payment relating to applicable deductible and cost sharing amounts, from a beneficiary for CHAMPUS covered services for any amount in excess of the applicable CHAMPUS allowable cost or charge.

Bariatric Surgery. Surgical procedures performed to treat co-morbid conditions associated with morbid obesity. Bariatric surgery is based on two principles:

- (1) Divert food from the stomach to a lower part of the digestive tract where the normal mixing of digestive fluids and absorption of nutrients cannot occur (i.e., Malabsorptive surgical procedures); or
- (2) Restrict the size of the stomach and decrease intake (i.e., Restrictive surgical procedures).

Basic program. The primary medical benefits authorized under chapter 55 of title 10 U.S. Code, and set forth in Sec. 199.4 of this part.

Beneficiary. An individual who has been determined to be eligible for CHAMPUS benefits, as set forth in Sec. 199.3 of this part.

Beneficiary liability. The legal obligation of a beneficiary, his or her estate, or responsible family member to pay for the costs of medical care or treatment received. Specifically, for the purposes of services and supplies covered by CHAMPUS, beneficiary liability includes any annual deductible amount, cost-sharing amounts, or, when a provider does not submit a claim on a participating basis on behalf of the beneficiary, amounts above the CHAMPUS-determined allowable cost or charge. Beneficiary liability also includes any expenses for medical or related services and supplies not covered by CHAMPUS.

Birthing center. A health care provider which meets the applicable requirements established by Sec. 199.6(b) of this part.

Birthing room. A room and environment designed and equipped to provide care, to accommodate support persons, and within which a woman with a low-risk, normal, full-term pregnancy can labor, deliver and recover with her infant.

Brace. An orthopedic appliance or apparatus (an orthosis) used to support, align, or hold parts of the body in correct position. For the purposes of CHAMPUS, it does not include orthodontic or other dental appliances.

CAHs. A small facility that provides limited inpatient and outpatient hospital services primarily in rural areas and meets the applicable requirements established by Sec. 199.6(b)(4)(xvi).

Capped Rate. The maximum per diem or all-inclusive rate that CHAMPUS will allow for care.

Case management. Case management is a collaborative process which assesses, plans, implements, coordinates, monitors, and evaluates the options and services required to meet an individual's health needs, using communication and available resources to promote quality, cost effective outcomes.

Case managers. A licensed registered nurse, licensed clinical social worker, licensed psychologist or licensed physician who has a minimum of two (2) years case management experience.

Case-mix index. Case-mix index is a scale that measures the relative difference in resources intensity among different groups receiving home health services.

Certified nurse-midwife. An individual who meets the applicable requirements established by Sec. 199.6(c) of this part.

Certified psychiatric nurse specialist. A licensed, registered nurse who meets the criteria in Sec. 199.6(c)(3)(iii)(G).

CHAMPUS DRG-Based Payment System. A reimbursement system for hospitals which assigns prospectively-determined payment levels to each DRG based on the average cost of treating all CHAMPUS patients in a given DRG.

CHAMPUS fiscal intermediary. An organization with which the Director, OCHAMPUS, has entered into a contract for the adjudication and processing of CHAMPUS claims and the performance of related support activities.

CHAMPUS Health Benefits Advisors (HBAs). Those individuals located at Uniformed Services medical facilities (on occasion at other locations) and assigned the responsibility for providing CHAMPUS information, information concerning availability of care from the Uniformed Services direct medical care system, and generally assisting beneficiaries (or sponsors). The term also includes "Health Benefits Counselor" and "CHAMPUS Advisor."

Chemotherapy. The administration of approved antineoplastic drugs for the treatment of malignancies (cancer) via perfusion, infusion, or parenteral methods of administration.

Child. An unmarried child of a member or former member, who meets the criteria (including age requirements) in Sec. 199.3 of this part.

Chiropractor. A practitioner of chiropractic (also called chiropraxis); essentially a system of therapeutics based upon the claim that disease is caused by abnormal function of the nerve system. It attempts to restore normal function of the nerve system by manipulation and treatment of the structures of the human body, especially those of the spinal column.

NOTE: Services of chiropractors are not covered by CHAMPUS.

Christian science nurse. An individual who has been accredited as a Christian Science Nurse by the Department of Care of the First Church of Christ, Scientist, Boston, Massachusetts, and listed (or eligible to be listed) in the Christian Science Journal at the time the service is provided. The duties of Christian Science nurses are spiritual and are

nonmedical and nontechnical nursing care performed under the direction of an accredited Christian Science practitioner. There exist two levels of Christian Science nurse accreditation:

- (i) Graduate Christian Science nurse. This accreditation is granted by the Department of Care of the First Church of Christ, Scientist, Boston, Massachusetts, after completion of a 3-year course of instruction and study.
- (ii) Practical Christian Science nurse. This accreditation is granted by the Department of Care of the First Church of Christ, Scientist, Boston, Massachusetts, after completion of a 1-year course of instruction and study.

Christian Science practitioner. An individual who has been accredited as a Christian Science Practitioner for the First Church, Scientist, Boston, Massachusetts, and listed (or eligible to be listed) in the Christian Science Journal at the time the service is provided. An individual who attains this accreditation has demonstrated results of his or her healing through faith and prayer rather than by medical treatment. Instruction is executed by an accredited Christian Science teacher and is continuous.

Christian Science sanatorium. A sanatorium either operated by the First Church of Christ, Scientist, or listed and certified by the First Church of Christ, Scientist, Boston, Massachusetts.

Chronic medical condition. A medical condition that is not curable, but which is under control through active medical treatment. Such chronic conditions may have periodic acute episodes and may require intermittent inpatient hospital care. However, a chronic medical condition can be controlled sufficiently to permit generally continuation of some activities of persons who are not ill (such as work and school).

Chronic renal disease (CRD). The end stage of renal disease which requires a continuing course of dialysis or a kidney transplantation to ameliorate uremic symptoms and maintain life.

Clinical psychologist. A psychologist, certified or licensed at the independent practice level in his or her state, who meets the criteria in Sec. 199.6(c)(3)(iii)(A).

Clinical social worker. An individual who is licensed or certified as a clinical social worker and meets the criteria listed in Sec. 199.6.

Clinically Meaningful Endpoints. As used the definition of reliable evidence in this paragraph (b) and Sec. 199.4(g)(15), the term clinically meaningful endpoints means objectively measurable outcomes of clinical interventions or other medical procedures, expressed in terms of survival, severity of illness or condition, extent of adverse side effects, diagnostic capability, or other effect on bodily functions directly associated with such results.

Collateral visits. Sessions with the patient's family or significant others for purposes of information gathering or implementing treatment goals.

Combined daily charge. A billing procedure by an inpatient facility that uses an inclusive flat rate covering all professional and ancillary charges without any itemization.

Complications of pregnancy. One of the following, when commencing or exacerbating during the term of the pregnancy:

- (i) Caesarean delivery; hysterotomy.
- (ii) Pregnancy terminating before expiration of 26 weeks, except a voluntary abortion.
- (iii) False labor or threatened miscarriage.
- (iv) Nephritis or pyelitis of pregnancy.
- (v) Hyperemesis gravidarum.
- (vi) Toxemia.
- (vii) Aggravation of a heart condition or diabetes.
- (viii) Premature rupture of membrane.
- (ix) Ectopic pregnancy.
- (x) Hemorrhage.
- (xi) Other conditions as may be determined by the Director, OCHAMPUS, or a designee.

Confinement. That period of time from the day of admission to a hospital or other institutional provider, to the day of discharge, transfer, or separation from the facility, or death. Successive admissions also may qualify as one confinement provided not more than 60 days have elapsed between the successive admissions, except that successive admissions related to a single maternity episode shall be considered one confinement, regardless of the number of days between admissions.

Conflict of Interest. Includes any situation where an active duty member (including a reserve member while on active duty) or civilian employee of the United States Government, through an official federal position, has the apparent or actual opportunity to exert, directly or indirectly, any influence on the referral of CHAMPUS beneficiaries to himself or herself or others with some potential for personal gain or appearance of impropriety. For purposes of this part, individuals under contract to a Uniformed Service may be involved in a conflict of interest situation through the contract position.

Congenital anomaly. A condition existing at or from birth that is a significant deviation from the common form or norm and is other than a common racial or ethnic feature. For purposes of CHAMPUS, congenital anomalies do not include anomalies relating to teeth (including malocclusion or missing tooth buds) or structures supporting the teeth, or to any form of hermaphroditism or sex gender confusion. Examples of congenital anomalies are harelip, birthmarks, webbed fingers or toes, or such other conditions that the Director, OCHAMPUS, or a designee, may determine to be congenital anomalies.

NOTE: Also refer to Sec. 199.4(e)(7) of this part.

Consultation. A deliberation with a specialist physician or dentist requested by the attending physician primarily responsible for the medical care of the patient, with respect to the diagnosis or treatment in any particular case. A consulting physician or dentist may perform a limited examination of a given system or one requiring a complete diagnostic history and examination. To qualify as a consultation, a written report to the attending physician of the findings of the consultant is required.

NOTE: Staff consultations required by rules and regulations of the medical staff of a hospital or other institutional provider do not qualify as consultation.

Consultation appointment. An appointment for evaluation of medical symptoms resulting in a plan for management which may include elements of further evaluation, treatment and follow-up evaluation. Such an appointment does not include surgical intervention or other invasive diagnostic or therapeutic procedures beyond the level of very simply office procedures, or basic laboratory work but rather provides the beneficiary with an authoritative opinion.

Consulting physician or dentist. A physician or dentist, other than the attending physician, who performs a consultation.

Conviction. For purposes of this part, "conviction" or "convicted" means that (1) a judgment of conviction has been entered, or (2) there has been a finding of guilt by the trier of fact, or (3) a plea of guilty or a plea of *nolo contendere* has been accepted by a court of competent jurisdiction, regardless of whether an appeal is pending.

Coordination of benefits. The coordination, on a primary or secondary payer basis, of the payment of benefits between two or more health care coverages to avoid duplication of benefit payments.

Corporate services provider. A health care provider that meets the applicable requirements established by Sec. 199.6(f).

Cosmetic, reconstructive, or plastic surgery. Surgery that can be expected primarily to improve the physical appearance of a beneficiary, or that is performed primarily for psychological purposes, or that restores form, but does not correct or improve materially a bodily function.

Cost-share. The amount of money for which the beneficiary (or sponsor) is responsible in connection with otherwise covered inpatient and outpatient services (other than the annual fiscal year deductible or disallowed amounts) as set forth in Secs. 199.4(f) and 199.5(b) of this part. Cost-sharing may also be referred to as "co-payment."

Custodial care. The term "custodial care" means treatment or services, regardless of who recommends such treatment or services or where such treatment or services are provided, that:

- (1) Can be rendered safely and reasonably by a person who is not medically skilled; or
- (2) Is or are designed mainly to help the patient with the activities of daily living.

Days. Calendar days.

Deceased member. A person who, at the time of his or her death, was an active duty member of a Uniformed Service under a call or order that did not specify a period of 30 days or less.

Deceased reservist. A reservist in a Uniformed Service who incurs or aggravates an injury, illness, or disease, during, or on the way to or from, active duty training for a period of 30 days or less or inactive duty training and dies as a result of that specific injury, illness or disease.

Deceased retiree. A person who, at the time of his or her death, was entitled to retired or retainer pay or equivalent pay based on duty in a Uniformed Service. For purposes of this part, it also includes a person who died before attaining age 60 and at the time of his or her death would have been eligible for retired pay as a reservist but for the fact that he or she was not 60 years of age, and had elected to participate in the Survivor Benefit Plan established under 10 U.S.C. chapter 73.

Deductible. Payment by a beneficiary of the first \$50 of the CHAMPUS-determined allowable costs or charges for otherwise covered outpatient services or supplies provided in any one fiscal year; or for a family, the aggregate payment by two or more beneficiaries who submit claims of the first \$100.

Deductible certificate. A statement issued to the beneficiary (or sponsor) by a CHAMPUS fiscal intermediary certifying to deductible amounts satisfied by a CHAMPUS beneficiary for any applicable fiscal year.

Defense Enrollment Eligibility Reporting System (DEERS). An automated system maintained by the Department of Defense for the purpose of:

- (1) Enrolling members, former members and their dependents, and
- (2) Verifying members', former members' and their dependents' eligibility for health care benefits in the direct care facilities and for CHAMPUS.

Dental care. Services relating to the teeth and their supporting structures.

Dentist. Doctor of Dental Medicine (D.M.D.) or Doctor of Dental Surgery (D.D.S.) who is licensed to practice dentistry by an appropriate authority.

Dependent. Individuals whose relationship to the sponsor (including NATO members who are stationed in or passing through the United States on official business when authorized) leads to entitlement to benefits under this part. (See Sec. 199.3 of this part for specific categories of dependents).

Deserter or desertion status. A service member is a deserter, or in a desertion status, when the Uniformed Service concerned has made an administrative determination to that effect, or the member's period of unauthorized absence has resulted in a court-martial conviction of desertion. Administrative declarations of desertion normally are made when a member has been an unauthorized absentee for over 30 days, but particular circumstances may result in

an earlier declaration. Entitlement to CHAMPUS benefits ceases as of 12:01 a.m. on the day following the day the desertion status is declared. Benefits are not to be authorized for treatment received during a period of unauthorized absence that results in a court-martial conviction for desertion. Dependent eligibility for benefits is reestablished when a deserter is returned to military control and continues, even though the member may be in confinement, until any discharge is executed. When a deserter status is later found to have been determined erroneously, the status of deserter is considered never to have existed, and the member's dependents will have been eligible continuously for benefits under CHAMPUS.

Diagnosis-Related Groups (DRGs). Diagnosis-related groups (DRGs) are a method of dividing hospital patients into clinically coherent groups based on the consumption of resources. Patients are assigned to the groups based on their principal diagnosis (the reason for admission, determined after study), secondary diagnoses, procedures performed, and the patient's age, sex, and discharge status.

Diagnostic admission. An admission to a hospital or other authorized institutional provider, or an extension of a stay in such a facility, primarily for the purpose of performing diagnostic tests, examinations, and procedures.

Director. The Director of the TRICARE Management Activity or Director, Office of CHAMPUS. Any references to the Director, Office of CHAMPUS, or OCHAMPUS, shall mean the Director, TRICARE Management Activity. Any reference to Director shall also include any person designated by the Director to carry out a particular authority. In addition, any authority of the Director may be exercised by the Assistant Secretary of Defense (Health Affairs).

Director, OCHAMPUS. An authority of the Director, OCHAMPUS includes any person designated by the Director, OCHAMPUS to exercise the authority involved.

Director, TRICARE Management Activity. This term includes the Director, TRICARE Management Activity, the official sometimes referred to in this part as the Director, Office of CHAMPUS (or OCHAMPUS), or any designee of the Director, TRICARE Management Activity or the Assistant Secretary of Defense for Health Affairs who is designated for purposes of an action under this part.

Doctor of Dental Medicine (D.M.D.). A person who has received a degree in dentistry, that is, that department of the healing arts which is concerned with the teeth, oral cavity, and associated structures.

Doctor of Medicine (M.D.). A person who has graduated from a college of allopathic medicine and who is entitled legally to use the designation M.D.

Doctor of Osteopathy (D.O.). A practitioner of osteopathy, that is, a system of therapy based on the theory that the body is capable of making its own remedies against disease and other toxic conditions when it is in normal structural relationship and has favorable environmental conditions and adequate nutrition. It utilizes generally accepted physical, medicinal, and surgical methods of diagnosis and therapy, while placing chief emphasis on the importance of normal body mechanics and manipulative methods of detecting and correcting faulty structure.

Domiciliary care. The term “domiciliary care” means care provided to a patient in an institution or homelike environment because:

- (1) Providing support for the activities of daily living in the home is not available or is unsuitable; or
- (2) Members of the patient’s family are unwilling to provide the care.

Donor. An individual who supplies living tissue or material to be used in another body, such as a person who furnishes a kidney for renal transplant.

Double coverage. When a CHAMPUS beneficiary also is enrolled in another insurance, medical service, or health plan that duplicates all or part of a beneficiary’s CHAMPUS benefits.

Double coverage plan. The specific insurance, medical service, or health plan under which a CHAMPUS beneficiary has entitlement to medical benefits that duplicate CHAMPUS benefits in whole or in part. Double coverage plans do not include:

- (i) Medicaid.
- (ii) Coverage specifically designed to supplement CHAMPUS benefits.
- (iii) Entitlement to receive care from the Uniformed Services medical facilities;
- (iv) Entitlement to receive care from Veterans Administration medical care facilities; or
- (v) Part C of the Individuals with Disabilities Education Act for services and items provided in accordance with Part C of the IDEA that are medically or psychologically necessary in accordance with the Individual Family Service Plan and that are otherwise allowable under the CHAMPUS Basic Program or the Extended Care Health Option (ECHO).

Dual Compensation. Federal Law (5 U.S.C. 5536) prohibits active duty members or civilian employees of the United States Government from receiving additional compensation from the government above their normal pay and allowances. This prohibition applies to CHAMPUS cost-sharing of medical care provided by active duty members or civilian government employees to CHAMPUS beneficiaries.

Duplicate equipment. An item of durable equipment, durable medical equipment, or assistive technology items, as defined in this section that serves the same purpose that is served by an item of durable equipment, durable medical equipment, or assistive technology item previously cost-shared by TRICARE. For example, various models of stationary oxygen concentrators with no essential functional differences are considered duplicate equipment, whereas stationary and portable oxygen concentrators are not considered duplicates of each other because the latter is intended to provide the user with mobility not afforded by the former. Also, a manual wheelchair and electric wheelchair, both of which otherwise meet the definition of durable equipment or durable medical equipment, would not be considered duplicates of each other if each is found to provide an appropriate level of mobility. For the purpose of this Part, durable equipment, durable medical equipment, or assistive technology items that are essential in providing a fail-safe in-home life support system or that replace in-

like-kind an item of equipment that is not serviceable due to normal wear, accidental damage, a change in the beneficiary's condition, or has been declared adulterated by the U.S. FDA, or is being or has been recalled by the manufacturer is not considered duplicate equipment.

Durable equipment. Equipment that--

- (1) Is a medically necessary item, which can withstand repeated use;
- (2) Is primarily and customarily used to serve a medical purpose; and
- (3) Is generally not useful to an individual in the absence of an illness or injury. It includes durable medical equipment as defined in Sec. 199.2, wheelchairs, iron lungs, and hospital beds. It does not include equipment (including wheelchairs) used or designed primarily for use in sports or recreational activities.

Durable medical equipment. Durable equipment that is medically appropriate to--

- (1) Improve, restore, or maintain the function of a malformed, diseased, or injured body part or can otherwise minimize or prevent the deterioration of the beneficiary's function or condition; or
- (2) Maximize the beneficiary's function consistent with the beneficiary's physiological or medical needs.

Economic interest. (1) Any right, title, or share in the income, remuneration, payment, or profit of a CHAMPUS-authorized provider, or of an individual or entity eligible to be a CHAMPUS-authorized provider, resulting, directly or indirectly, from a referral relationship; or any direct or indirect ownership, right, title, or share, including a mortgage, deed of trust, note, or other obligation secured (in whole or in part) by one entity for another entity in a referral or accreditation relationship, which is equal to or exceeds 5 percent of the total property and assets of the other entity.

(2) A referral relationship exists when a CHAMPUS beneficiary is sent, directed, assigned or influenced to use a specific CHAMPUS-authorized provider, or a specific individual or entity eligible to be a CHAMPUS-authorized provider.

(3) An accreditation relationship exists when a CHAMPUS-authorized accreditation organization evaluates for accreditation an entity that is an applicant for, or recipient of CHAMPUS-authorized provider status.

Emergency inpatient admission. An unscheduled, unexpected, medically necessary admission to a hospital or other authorized institutional provider for treatment of a medical condition meeting the definition of medical emergency and which is determined to require immediate inpatient treatment by the attending physician.

Entity. For purposes of Sec. 199.9(f)(1), "entity" includes a corporation, trust, partnership, sole proprietorship or other kind of business enterprise that is or may be eligible to receive reimbursement either directly or indirectly from CHAMPUS.

Essential Access Community Hospital (EACH). A hospital that is designated by the Centers for Medicare and Medicaid Services (CMS) as an EACH and meets the applicable requirements established by Sec. 199.14(a)(7)(vi).

Extended Care Health Option (ECHO). The TRICARE program of supplemental benefits for qualifying active duty family members as described in Sec. 199.5.

External Partnership Agreement. The External Partnership Agreement is an agreement between a military treatment facility commander and a CHAMPUS authorized institutional provider, enabling Uniformed Services health care personnel to provide otherwise covered medical care to CHAMPUS beneficiaries in a civilian facility under the Military-Civilian Health Services Partnership Program. Authorized costs associated with the use of the facility will be financed through CHAMPUS under normal cost-sharing and reimbursement procedures currently applicable under the basic CHAMPUS.

External Resource Sharing Agreement. A type External Partnership Agreement, established in the context of the TRICARE program by agreement of a military medical treatment facility commander and an authorized TRICARE contractor. External Resource Sharing Agreements may incorporate TRICARE features in lieu of standard CHAMPUS features that would apply to standard External Partnership Agreements.

Extramedical individual providers of care. Individuals who do counseling or nonmedical therapy and whose training and therapeutic concepts are outside the medical field, as specified in Sec. 199.6 of this part.

Extraordinary physical or psychological condition. A complex physical or psychological clinical condition of such severity which results in the beneficiary being homebound as defined in this section.

Facility charge. The term "facility charge" means the charge, either inpatient or outpatient, made by a hospital or other institutional provider to cover the overhead costs of providing the service. These costs would include building costs, i.e. depreciation and interest; staffing costs; drugs and supplies; and overhead costs, i.e., utilities, housekeeping, maintenance, etc.

Former member. A retiree, deceased member, deceased retiree, or deceased reservist in certain circumstances (see section 199.3 for additional information related to certain deceased reservists' dependents' eligibility). Under conditions specified under Sec. 199.3 of this part, former member may also include a member of the Uniformed Services who has been discharged from active duty (or, in some cases, full-time National Guard duty), whether voluntarily or involuntarily, under other than adverse conditions and qualifies for CHAMPUS benefits under the Transitional Assistance Management Program or the Continued Health Care Benefit Program.

Former spouse. A former husband or wife of a Uniformed Service member or former member who meets the criteria as set forth in Sec. 199.3(b)(2)(ii) of this part.

Fraud. For purposes of this part, fraud is defined as (1) a deception or misrepresentation by a provider, beneficiary, sponsor, or any person acting on behalf of a provider, sponsor, or beneficiary with the knowledge (or who had reason to know or should have known) that the deception or misrepresentation could result in some unauthorized CHAMPUS benefit to self

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or some other person, or some unauthorized CHAMPUS payment, or (2) a claim that is false or fictitious, or includes or is supported by any written statement which asserts a material fact which is false or fictitious, or includes or is supported by any written statement that (a) omits a material fact and (b) is false or fictitious as a result of such omission and (c) is a statement in which the person making, presenting, or submitting such statement has a duty to include such material fact. It is presumed that, if a deception or misrepresentation is established *and* a CHAMPUS claim is filed, the person responsible for the claim had the requisite knowledge. This presumption is rebuttable only by substantial evidence. It is further presumed that the provider of the services is responsible for the actions of all individuals who file a claim on behalf of the provider (for example, billing clerks); this presumption may only be rebutted by clear and convincing evidence.

Freestanding. Not “institution-affiliated” or “institution-based.”

Full-time course of higher education. A complete, progressive series of studies to develop attributes such as knowledge, skill, mind, and character, by formal schooling at a college or university, and which meets the criteria set out in Sec. 199.3 of this part. To qualify as full-time, the student must be carrying a course load of a minimum of 12 credit hours or equivalent each semester.

General staff nursing service. All nursing care (other than that provided by private duty nurses) including, but not limited to, general duty nursing, emergency room nursing, recovery room nursing, intensive nursing care, and group nursing arrangements performed by nursing personnel on the payroll of the hospital or other authorized institution.

Good faith payments. Those payments made to civilian sources of medical care who provided medical care to persons purporting to be eligible beneficiaries but who are determined later to be ineligible for CHAMPUS benefits. (The ineligible person usually possesses an erroneous or illegal identification card.) To be considered for good faith payments, the civilian source of care must have exercised reasonable precautions in identifying a person claiming to be an eligible beneficiary.

Habilitation. The provision of functional capacity, absent from birth due to congenital anomaly or developmental disorder, which facilitates performance of an activity in the manner, or within the range considered normal, for a human being.

Handicap. For the purposes of this part, the term “handicap” is synonymous with the term “disability.”

High-risk pregnancy. A pregnancy is high-risk when the presence of a currently active or previously treated medical, anatomical, physiological illness or condition may create or increase the likelihood of a detrimental effect on the mother, fetus, or newborn and presents a reasonable possibility of the development of complications during labor or delivery.

Homebound. A beneficiary’s condition is such that there exists a normal inability to leave home and, consequently, leaving home would require considerable and taxing effort. Any absence of an individual from the home attributable to the need to receive health care treatment--including regular absences for the purpose of participating in therapeutic, psychosocial, or medical treatment in an adult day-care program that is licensed or certified by a state, or accredited to furnish adult day-care services in the--state shall not disqualify an

individual from being considered to be confined to his home. Any other absence of an individual from the home shall not disqualify an individual if the absence is infrequent or of relatively short duration. For purposes of the preceding sentence, any absence for the purpose of attending a religious service shall be deemed to be an absence of infrequent or short duration. Also, absences from the home for non-medical purposes, such as an occasional trip to the barber, a walk around the block or a drive, would not necessarily negate the beneficiary's homebound status if the absences are undertaken on an infrequent basis and are of relatively short duration. An exception is made to the above homebound definitional criteria for beneficiaries under the age of 18 and those receiving maternity care. The only homebound criteria for these special beneficiary categories is written certification from a physician attesting to the fact that leaving the home would place the beneficiary at medical risk. In addition to the above, absences, whether regular or infrequent, from the beneficiary's primary residence for the purpose of attending an educational program in a public or private school that is licensed and/or certified by a state, shall not negate the beneficiary's homebound status.

Home health discipline. One of six home health disciplines covered under the home health benefit (skilled nursing services, home health aide services, physical therapy services, occupational therapy services, speech-language pathology services, and medical social services).

Home health market basket index. An index that reflects changes over time in the prices of an appropriate mix of goods and services included in home health services.

Hospice care. Hospice care is a program which provides an integrated set of services and supplies designed to care for the terminally ill. This type of care emphasizes palliative care and supportive services, such as pain control and home care, rather than cure-oriented services provided in institutions that are otherwise the primary focus under CHAMPUS. The benefit provides coverage for a humane and sensible approach to care during the last days of life for some terminally ill patients.

Hospital, acute care (general and special). An institution that meets the criteria as set forth in Sec. 199.6(b)(4)(i) of this part.

Hospital, long-term (tuberculosis, chronic care, or rehabilitation). An institution that meets the criteria as set forth in Sec. 199.6(b)(4)(iii) of this part.

Hospital, psychiatric. An institution that meets the criteria as set forth in Sec. 199.6(b)(4)(ii) of this part.

Illegitimate child. A child not recognized as a lawful offspring; that is, a child born of parents not married to each other.

Immediate family. The spouse, natural parent, child and sibling, adopted child and adoptive parent, stepparent, stepchild, grandparent, grandchild, stepbrother and stepsister, father-in-law, mother-in-law of the beneficiary, or provider, as appropriate. For purposes of this definition only, to determine who may render services to a beneficiary, the step-relationship continues to exist even if the marriage upon which the relationship is based terminates through divorce or death of one of the parents.

Independent laboratory. A freestanding laboratory approved for participation under Medicare and certified by the Health Care Financing Administration.

Infirmaries. Facilities operated by student health departments of colleges and universities to provide inpatient or outpatient care to enrolled students. When specifically approved by the Director, OCHAMPUS, or a designee, a boarding school infirmary also is included.

Initial determination. A formal written decision on a CHAMPUS claim, a request for benefit authorization, a request by a provider for approval as an authorized CHAMPUS provider, or a decision disqualifying or excluding a provider as an authorized provider under CHAMPUS. Rejection of a claim or a request for benefit or provider authorization for failure to comply with administrative requirements, including failure to submit reasonably requested information, is not an initial determination. Responses to general or specific inquiries regarding CHAMPUS benefits are not initial determinations.

In-out surgery. Surgery performed in the outpatient department of a hospital or other institutional provider, in a physician's office or the office of another individual professional provider, in a clinic, or in a "freestanding" ambulatory surgical center which does not involve a formal inpatient admission for a period of 24 hours or more.

Inpatient. A patient who has been admitted to a hospital or other authorized institution for bed occupancy for purposes of receiving necessary medical care, with the reasonable expectation that the patient will remain in the institution at least 24 hours, and with the registration and assignment of an inpatient number or designation. Institutional care in connection with in and out (ambulatory) surgery is not included within the meaning of inpatient whether or not an inpatient number or designation is made by the hospital or other institution. If the patient has been received at the hospital, but death occurs before the actual admission occurs, an inpatient admission exists as if the patient had lived and had been formally admitted.

Institution-affiliated. Related to a CHAMPUS-authorized institutional provider through a shared governing body but operating under a separate and distinct license or accreditation.

Institution-based. Related to a CHAMPUS-authorized institutional provider through a shared governing body and operating under a common license and shared accreditation.

Institutional provider. A health care provider which meets the applicable requirements established by Sec. 199.6(b) of this part.

Intensive care unit (ICU). A special segregated unit of a hospital in which patients are concentrated by reason of serious illness, usually without regard to diagnosis. Special lifesaving techniques and equipment regularly and immediately are available within the unit, and patients are under continuous observation by a nursing staff specially trained and selected for the care of this type patient. The unit is maintained on a continuing rather than an intermittent or temporary basis. It is not a postoperative recovery room nor a postanesthesia room. In some large or highly specialized hospitals, the ICUs may be further refined for special purposes, such as for respiratory conditions, cardiac surgery, coronary care, burn care, or neurosurgery. For the purposes of CHAMPUS, these specialized units would be considered ICUs if they otherwise conformed to the definition of an ICU.

Intern. A graduate of a medical or dental school serving in a hospital in preparation to being licensed to practice medicine or dentistry.

Internal Partnership Agreement. The Internal Partnership Agreement is an agreement between a military treatment facility commander and a CHAMPUS-authorized civilian health care provider which enables the use of civilian health care personnel or other resources to provide medical care to CHAMPUS beneficiaries on the premises of a military treatment facility under the Military-Civilian Health Services Partnership Program. These internal agreements may be established when a military treatment facility is unable to provide sufficient health care services for CHAMPUS beneficiaries due to shortages of personnel and other required resources.

Internal Resource Sharing Agreement. A type of Internal Partnership Agreement, established in the context of the TRICARE program by agreement of a military medical treatment facility commander and authorized TRICARE contractor. Internal Resource Sharing Agreements may incorporate TRICARE features in lieu of standard CHAMPUS features that would apply to standard Internal Partnership Agreements.

Item, Service, or Supply. Includes (1) any item, device, medical supply, or service claimed to have been provided to a beneficiary (patient) and listed in an itemized claim for CHAMPUS payment or a request for payment, or (2) in the case of a claim based on costs, any entry or omission in a cost report, books of account, or other documents supporting the claim.

Laboratory and pathological services. Laboratory and pathological examinations (including machine diagnostic tests that produce hard-copy results) when necessary to, and rendered in connection with medical, obstetrical, or surgical diagnosis or treatment of an illness or injury, or in connection with well-baby care.

Legitimized child. A formerly illegitimate child who is considered legitimate by reason of qualifying actions recognized in law.

Licensed practical nurse (L.P.N.). A person who is prepared specially in the scientific basis of nursing; who is a graduate of a school of practical nursing; whose qualifications have been examined by a state board of nursing; and who has been authorized legally to practice as an L.P.N. under the supervision of a physician.

Licensed vocational nurse (L.V.N.) A person who specifically is prepared in the scientific basis or nursing; who is a graduate of a school of vocational nursing; whose qualifications have been examined by a state board of nursing; and who has been authorized legally to practice as a L.V.N. under the supervision of a physician.

Long-term hospital care. Any inpatient hospital stay that exceeds 30 days.

Low-risk pregnancy. A pregnancy is low-risk when the basis for the ongoing clinical expectation of a normal uncomplicated birth, as defined by reasonable and generally accepted criteria of maternal and fetal health, is documented throughout a generally accepted course of prenatal care.

Major life activity. Breathing, cognition, hearing, seeing, and age appropriate ability essential to bathing, dressing, eating, grooming, speaking, stair use, toilet use, transferring, and walking.

Marriage and family therapist, certified. An extramedical individual provider who meets the requirements outlined in Sec. 199.6.

Maternity care. Care and treatment related to conception, delivery, and abortion, including prenatal and postnatal care (generally through the 6th post-delivery week), and also including treatment of the complications of pregnancy.

Medicaid. Those medical benefits authorized under Title XIX of the Social Security Act provided to welfare recipients and the medically indigent through programs administered by the various states.

Medical. The generally used term which pertains to the diagnosis and treatment of illness, injury, pregnancy, and mental disorders by trained and licensed or certified health professionals. For purposes of CHAMPUS, the term "medical" should be understood to include "medical, psychological, surgical, and obstetrical," unless it is specifically stated that a more restrictive meaning is intended.

Medical emergency. The sudden and unexpected onset of a medical condition or the acute exacerbation of a chronic condition that is threatening to life, limb, or sight, and requires immediate medical treatment or which manifests painful symptomatology requiring immediate palliative efforts to alleviate suffering. Medical emergencies include heart attacks, cardiovascular accidents, poisoning, convulsions, kidney stones, and such other acute medical conditions as may be determined to be medical emergencies by the Director, OCHAMPUS, or a designee. In the case of a pregnancy, a medical emergency must involve a sudden and unexpected medical complication that puts the mother, the baby, or both, at risk. Pain would not, however, qualify a maternity case as an emergency, nor would incipient birth after the 34th week of gestation, unless an otherwise qualifying medical condition is present. Examples of medical emergencies related to pregnancy or delivery are hemorrhage, ruptured membrane with prolapsed cord, placenta previa, abruptio placenta, presence of shock or unconsciousness, suspected heart attack or stroke, or trauma (such as injuries received in an automobile accident).

Medical supplies and dressings (consumables). Necessary medical or surgical supplies (exclusive of durable medical equipment) that do not withstand prolonged, repeated use and that are needed for the proper medical management of a condition for which benefits are otherwise authorized under CHAMPUS, on either an inpatient or outpatient basis. Examples include disposable syringes for a diabetic, colostomy sets, irrigation sets, and ace bandages.

Medically or psychologically necessary. The frequency, extent, and types of medical services or supplies which represent appropriate medical care and that are generally accepted by qualified professionals to be reasonable and adequate for the diagnosis and treatment of illness, injury, pregnancy, and mental disorders or that are reasonable and adequate for well-baby care.

Medically or psychologically necessary preauthorization. A pre (or prior) authorization for payment for medical/surgical or psychological services based upon criteria that are

generally accepted by qualified professionals to be reasonable for diagnosis and treatment of an illness, injury, pregnancy, and mental disorder.

Medicare. These medical benefits authorized under Title XVIII of the Social Security Act provided to persons 65 or older, certain disabled persons, or persons with chronic renal disease, through a national program administered by the DHHS, Health Care Financing Administration, Medicare Bureau.

Member. A person on active duty in a Uniformed Service under a call or order that does not specify a period of 30 days or less. (For CHAMPUS cost-sharing purposes only, a former member who received a dishonorable or bad-conduct discharge or was dismissed from a Uniformed Service as a result of a court-martial conviction for an offense involving physical or emotional abuse or was administratively discharged as a result of such an offense is considered a member).

Mental disorder. For purposes of the payment of CHAMPUS benefits, a mental disorder is a nervous or mental condition that involves a clinically significant behavioral or psychological syndrome or pattern that is associated with a painful symptom, such as distress, and that impairs a patient's ability to function in one or more major life activities. Additionally, the mental disorder must be one of those conditions listed in the DSM-III.

Mental health therapeutic absence. A therapeutically planned absence from the inpatient setting. The patient is not discharged from the facility and may be away for periods of several hours to several days. The purpose of the therapeutic absence is to give the patient an opportunity to test his or her ability to function outside the inpatient setting before the actual discharge.

Missing in action (MIA). A battle casualty whose whereabouts and status are unknown, provided the absence appears to be involuntary and the service member is not known to be in a status of unauthorized absence.

NOTE: Claims for eligible CHAMPUS beneficiaries whose sponsor is classified as MIA are processed as dependents of an active duty service member.

Morbid obesity. A body mass index (BMI) equal to or greater than 40 kilograms per meter squared (kg/m²), or a BMI equal to or greater than 35 kg/m² in conjunction with high-risk co-morbidities, which is based on the guidelines established by the National Heart, Lung and Blood Institute on the Identification and Management of Patients with Obesity.

NOTE: Body mass index is equal to weight in kilograms divided by height in meters squared.

Most-favored rate. The lowest usual charge to any individual or third-party payer in effect on the date of the admission of a CHAMPUS beneficiary.

Natural childbirth. Childbirth without the use of chemical induction or augmentation of labor or surgical procedures other than episiotomy or perineal repair.

Naturopath. A person who practices naturopathy, that is, a drugless system of therapy making use of physical forces such as air, light, water, heat, and massage.

NOTE: Services of a naturopath are not covered by CHAMPUS.

NAVCARE clinics. Contractor owned, staffed, and operated primary clinics exclusively serving uniformed services beneficiaries pursuant to contracts awarded by a Military Department.

No-fault insurance. No-fault insurance means an insurance contract providing compensation for health and medical expenses relating to personal injury arising from the operation of a motor vehicle in which the compensation is not premised on whom may have been responsible for causing such injury. No-fault insurance includes personal injury protection and medical payments benefits in cases involving personal injuries resulting from operation of a motor vehicle.

Nonavailability statement. A certification by a commander (or a designee) of a Uniformed Services medical treatment facility, recorded on DEERS, generally for the reason that the needed medical care being requested by a non-TRICARE Prime enrolled beneficiary cannot be provided at the facility concerned because the necessary resources are not available in the time frame needed.

Nonparticipating provider. A hospital or other authorized institutional provider, a physician or other authorized individual professional provider, or other authorized provider that furnished medical services or supplies to a CHAMPUS beneficiary, but who did not agree on the CHAMPUS claim form to participate or to accept the CHAMPUS-determined allowable cost or charge as the total charge for the services. A nonparticipating provider looks to the beneficiary or sponsor for payment of his or her charge, not CHAMPUS. In such cases, CHAMPUS pays the beneficiary or sponsor, not the provider.

North Atlantic Treaty Organization (NATO) member. A military member of an armed force of a foreign NATO nation who is on active duty and who, in connection with official duties, is stationed in or passing through the United States. The foreign NATO nations are Belgium, Canada, Denmark, France, Federal Republic of Germany, Greece, Iceland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Turkey, and the United Kingdom.

Not-for-profit entity. An organization or institution owned and operated by one or more nonprofit corporations or associations formed pursuant to applicable state laws, no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

Occupational therapist. A person who is trained specially in the skills and techniques of occupational therapy (that is, the use of purposeful activity with individuals who are limited by physical injury or illness, psychosocial dysfunction, developmental or learning disabilities, poverty and cultural differences, or the aging process in order to maximize independence, prevent disability, and maintain health) and who is licensed to administer occupational therapy treatments prescribed by a physician.

Off-label use of a drug or device. A use other than an intended use for which the prescription drug, biologic or device is legally marketed under the Federal Food, Drug, and Cosmetic Act or the Public Health Services Act. This includes any use that is not included in the approved labeling for an approved drug, licensed biologic, approved device or combination product; any use that is not included in the cleared statement of intended use

for a device that has been determined by the Food and Drug Administration (FDA) to be substantially equivalent to a legally marketed predicate device and cleared for marketing; and any use of a device for which a manufacturer or distributor would be required to seek pre-market review by the FDA in order to legally include that use in the device's labeling.

Official formularies. A book of official standards for certain pharmaceuticals and preparations that are not included in the U.S. Pharmacopeia.

Optometrist (Doctor of Optometry). A person trained and licensed to examine and test the eyes and to treat visual defects by prescribing and adapting corrective lenses and other optical aids, and by establishing programs of exercises.

Oral surgeon (D.D.S. or D.M.D.). A person who has received a degree in dentistry and who limits his or her practice to oral surgery, that is, that branch of the healing arts that deals with the diagnosis and the surgical correction and adjunctive treatment of diseases, injuries, and defects of the mouth, the jaws, and associated structures.

Orthopedic shoes. Shoes prescribed by an orthopedic surgeon to effect changes in foot or feet position and alignment and which are not an integral part of a brace.

Other allied health professionals. Individual professional providers other than physicians, dentists, or extramedical individual providers, as specified in Sec. 199.6 of this part.

Other special institutional providers. Certain specialized medical treatment facilities, either inpatient or outpatient, other than those specifically defined, that provide courses of treatment prescribed by a doctor of medicine or osteopathy; when the patient is under the supervision of a doctor of medicine or osteopathy during the entire course of the inpatient admission or the outpatient treatment; when the type and level of care and services rendered by the institution are otherwise authorized in this Regulation; when the facility meets all licensing or other certification requirements that are extant in the jurisdiction in which the facility is located geographically; which is accredited by the Joint Commission on Accreditation if an appropriate accreditation program for the given type of facility is available; and which is not a nursing home, intermediate facility, halfway house, home for the aged, or other institution of similar purpose.

Outpatient. A patient who has not been admitted to a hospital or other authorized institution as an inpatient.

Ownership or control interest. For purposes of Sec. 199.9(f)(1), a "person with an ownership or control interest" is anyone who

- (1) Has directly or indirectly a 5 percent or more ownership interest in the entity; or
- (2) Is the owner of a whole or part interest in any mortgage, deed of trust, note, or other obligation secured (in whole or in part) by the entity or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property and assets of the entity; or
- (3) Is an officer or director of the entity if the entity is organized as a corporation; or

(4) Is a partner in the entity if the entity is organized as a partnership.

Partial hospitalization. A treatment setting capable of providing an interdisciplinary program of medical therapeutic services at least 3 hours per day, 5 days per week, which may embrace day, evening, night and weekend treatment programs which employ an integrated, comprehensive and complementary schedule of recognized treatment approaches. Partial hospitalization is a time-limited, ambulatory, active treatment program that offers therapeutically intensive, coordinated, and structured clinical services within a stable therapeutic environment. Partial hospitalization is an appropriate setting for crisis stabilization, treatment of partially stabilized mental health disorders, and a transition from an inpatient program when medically necessary. Such programs must enter into a participation agreement with CHAMPUS, and be accredited and in substantial compliance with the standards of the Mental Health Manual of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) (formerly known as the Consolidated Standards).

Participating provider. A CHAMPUS-authorized provider that is required, or has agreed by entering into a CHAMPUS participation agreement or by act of indicating "accept assignment" on the claim form, to accept the CHAMPUS-allowable amount as the maximum total charge for a service or item rendered to a CHAMPUS beneficiary, whether the amount is paid for fully by CHAMPUS or requires cost-sharing by the CHAMPUS beneficiary.

Part-time or intermittent home health aide and skilled nursing services. Part-time or intermittent means skilled nursing and home health aide services furnished any number of days per week as long as they are furnished (combined) less than 8 hours each day and 28 or fewer hours each week (or, subject to review on a case-by-case basis as to the need for care, less than 8 hours each day and 35 or fewer hours per week).

Party to a hearing. An appealing party or parties and CHAMPUS.

Party to the initial determination. Includes CHAMPUS and also refers to a CHAMPUS beneficiary and a participating provider of services whose interests have been adjudicated by the initial determination. In addition, a provider who has been denied approval as an authorized CHAMPUS provider is a party to that initial determination, as is a provider who is disqualified or excluded as an authorized provider under CHAMPUS, unless the provider is excluded based on a determination of abuse or fraudulent practices or procedures under another federal or federally funded program. See Sec. 199.10 for additional information concerning parties not entitled to administrative review under the CHAMPUS appeals and hearing procedures.

Pastoral counselor. An extramedical individual provider who meets the requirements outlined in Sec. 199.6.

Pharmaceutical Agent. Drugs, biological products, and medical devices under the regulatory authority of the Food and Drug Administration.

Pharmacist. A person who is trained specially in the scientific basis of pharmacology and who is licensed to prepare and sell or dispense drugs and compounds and to make up prescriptions ordered by a physician.

Physical medicine services or physiatry services. The treatment of disease or injury by physical means such as massage, hydrotherapy, or heat.

Physical therapist. A person who is trained specially in the skills and techniques of physical therapy (that is, the treatment of disease by physical agents and methods such as heat, massage, manipulation, therapeutic exercise, hydrotherapy, and various forms of energy such as electrotherapy and ultrasound), who has been authorized legally (that is, registered) to administer treatments prescribed by a physician and who is entitled legally to use the designation "Registered Physical Therapist." A physical therapist also may be called a physiotherapist.

Physician. A person with a degree of Doctor of Medicine (M.D.) or Doctor of Osteopathy (D.O.) who is licensed to practice medicine by an appropriate authority.

Physician in training. Interns, residents, and fellows participating in approved postgraduate training programs and physicians who are not in approved programs but who are authorized to practice only in a hospital or other institutional provider setting, e.g., individuals with temporary or restricted licenses, or unlicensed graduates of foreign medical schools.

Podiatrist (Doctor of Podiatry or Surgical Chiropody). A person who has received a degree in podiatry (formerly called chiropody), that is, that specialized field of the healing arts that deals with the study and care of the foot, including its anatomy, pathology, and medical and surgical treatment.

Preauthorization. A decision issued in writing, or electronically by the Director, TRICARE Management Activity, or a designee, that TRICARE benefits are payable for certain services that a beneficiary has not yet received. The term prior authorization is commonly substituted for preauthorization and has the same meaning.

Prescription drugs and medicines. Drugs and medicines which at the time of use were approved for commercial marketing by the U.S. Food and Drug Administration, and which, by law of the United States, require a physician's or dentist's prescription, except that it includes insulin for known diabetics whether or not a prescription is required. Drugs grandfathered by the Federal Food, Drug and Cosmetic Act of 1938 may be covered under CHAMPUS as if FDA approved. Prescription drugs and medicines may also be referred to as "pharmaceutical agents".

NOTE: The fact that the U.S. Food and Drug Administration has approved a drug for testing on humans would not qualify it within this definition.

Preventive care. Diagnostic and other medical procedures not related directly to a specific illness, injury, or definitive set of symptoms, or obstetrical care, but rather performed as periodic health screening, health assessment, or health maintenance.

Primary caregiver. An individual who renders to a beneficiary services to support the activities of daily living (as defined in Sec. 199.2) and specific services essential to the safe management of the beneficiary's condition.

Primary payer. The plan or program whose medical benefits are payable first in a double coverage situation.

PRIMUS clinics. Contractor owned, staffed, and operated primary care clinics exclusively serving uniformed services beneficiaries pursuant to contracts awarded by a Military Department.

Private room. A room with one bed that is designated as a private room by the hospital or other authorized institutional provider.

Profound hearing loss (adults). An “adult” (a spouse as defined in section 32 CFR 199.3(b) of this part of a member of the Uniformed Services on active duty for more than 30 days) with a hearing threshold of:

- (1) 40 dB HL or greater in one or both ears when tested at 500, 1,000, 1,500, 2,000, 3,000, or 4,000Hz; or
- (2) 26 dB HL or greater in one or both ears at any three or more of those frequencies; or
- (3) A speech recognition score less than 94 percent.

Profound hearing loss (children). A “child” (an unmarried child of an active duty member who otherwise meets the criteria (including age requirements) in 32 CFR 199.3 of this part) with a 26dB HL or greater hearing threshold level in one or both ears when tested in the frequency range at 500, 1,000, 2,000, 3,000 or 4,000 Hz.

Progress notes. Progress notes are an essential component of the medical record wherein health care personnel provide written evidence of ordered and supervised diagnostic tests, treatments, medical procedures, therapeutic behavior and outcomes. In the case of mental health care, progress notes must include: the date of the therapy session; length of the therapy session; a notation of the patient’s signs and symptoms; the issues, pathology and specific behaviors addressed in the therapy session; a statement summarizing the therapeutic interventions attempted during the therapy session; descriptions of the response to treatment, the outcome of the treatment, and the response to significant others; and a statement summarizing the patient’s degree of progress toward the treatment goals. Progress notes do not need to repeat all that was said during a therapy session but must document a patient contact and be sufficiently detailed to allow for both peer review and audits to substantiate the quality and quantity of care rendered.

Prosthetic or Prosthetic device (prosthesis). A prosthetic or prosthetic device (prosthesis) determined by the Secretary of Defense to be necessary because of significant conditions resulting from trauma, congenital anomalies, or diseases.

Prosthetic supplies. Supplies that are necessary for the effective use of a prosthetic or prosthetic device.

Provider. A hospital or other institutional provider, a physician, or other individual professional provider, or other provider of services or supplies as specified in Sec. 199.6 of this part.

Provider exclusion and suspension. The terms “exclusion” and “suspension”, when referring to a provider under CHAMPUS, both mean the denial of status as an authorized provider, resulting in items, services, or supplies furnished by the provider not being

reimbursed, directly or indirectly, under CHAMPUS. The terms may be used interchangeably to refer to a provider who has been denied status as an authorized CHAMPUS provider based on (1) a criminal conviction or civil judgment involving fraud, (2) an administrative finding of fraud or abuse under CHAMPUS, (3) an administrative finding that the provider has been excluded or suspended by another agency of the Federal Government, a state, or a local licensing authority, (4) an administrative finding that the provider has knowingly participated in a conflict of interest situation, or (5) an administrative finding that it is in the best interests of the CHAMPUS or CHAMPUS beneficiaries to exclude or suspend the provider.

Provider termination. When a provider's status as an authorized CHAMPUS provider is ended, other than through exclusion or suspension, based on a finding that the provider does not meet the qualifications, as set forth in Sec. 199.6 of this part, to be an authorized CHAMPUS provider.

Psychiatric emergency. A psychiatric inpatient admission is an emergency when, based on a psychiatric evaluation performed by a physician (or other qualified mental health care professional with hospital admission authority), the patient is at immediate risk of serious harm to self or others as a result of a mental disorder and requires immediate continuous skilled observation at the acute level of care.

Public facility. A public authority or entity legally constituted within a State (as defined in this section) to administer, control or perform a service function for public health, education or human services programs in a city, county, or township, special district, or other political subdivision, or such combination of political subdivisions or special districts or counties as are recognized as an administrative agency for a State's public health, education or human services programs, or any other public institution or agency having administrative control and direction of a publicly funded health, education or human services program.

Public facility adequacy. An available public facility shall be considered adequate when the Director, OCHAMPUS, or designee, determines that the quality, quantity, and frequency of an available service or item otherwise allowable as a CHAMPUS benefit is sufficient to meet the beneficiary's specific disability related need in a timely manner.

Public facility availability. A public facility shall be considered available when the public facility usually and customarily provides the requested service or item to individuals with the same or similar disability related need as the otherwise equally qualified CHAMPUS beneficiary.

Qualified accreditation organization. A not-for-profit corporation or a foundation that:

- (1) Develops process standards and outcome standards for health care delivery programs, or knowledge standards and skill standards for health care professional certification testing, using experts both from within and outside of the health care program area or individual specialty to which the standards are to be applied;
- (2) Creates measurable criteria that demonstrate compliance with each standard;
- (3) Publishes the organization's standards, criteria and evaluation processes so that they are available to the general public;

- (4) Performs on-site evaluations of health care delivery programs, or provides testing of individuals, to measure the extent of compliance with each standard;
- (5) Provides on-site evaluation or individual testing on a national or international basis;
- (6) Provides to evaluated programs and tested individuals time-limited written certification of compliance with the organization's standards;
- (7) Excludes certification of any program operated by an organization which has an economic interest, as defined in this section, in the accreditation organization or in which the accreditation organization has an economic interest;
- (8) Publishes promptly the certification outcomes of each program evaluation or individual test so that it is available to the general public; and
- (9) Has been found by the Director, OCHAMPUS, or designee, to apply standards, criteria, and certification processes which reinforce CHAMPUS provider authorization requirements and promote efficient delivery of CHAMPUS benefits.

Radiation therapy services. The treatment of diseases by x-ray, radium, or radioactive isotopes when ordered by the attending physician.

Rare Diseases. TRICARE/CHAMPUS defines a rare disease as any disease or condition that has a prevalence of less than 200,000 persons in the United States.

Referral. The act or an instance of referring a CHAMPUS beneficiary to another authorized provider to obtain necessary medical treatment. Under CHAMPUS, only a physician may make referrals.

Registered nurse. A person who is prepared specially in the scientific basis of nursing, who is a graduate of a school of nursing, and who is registered for practice after examination by a state board of nurse examiners or similar regulatory authority, who holds a current, valid license, and who is entitled legally to use the designation R.N.

Rehabilitation. The reduction of an acquired loss of ability to perform an activity in the manner, or within the range considered normal, for a human being.

Rehabilitative therapy. Any rehabilitative therapy that is necessary to improve, restore, or maintain function, or to minimize or prevent deterioration of function, of a patient and prescribed by a physician.

Reliable evidence. (1) As used in Sec. 199.4(g)(15), the term reliable evidence means only:

- (i) Well controlled studies of clinically meaningful endpoints, published in refereed medical literature.
- (ii) Published formal technology assessments.
- (iii) The published reports of national professional medical associations.

(iv) Published national medical policy organization positions; and

(v) The published reports of national expert opinion organizations.

(2) The hierarchy of reliable evidence of proven medical effectiveness, established by (1) through (5) of this paragraph, is the order of the relative weight to be given to any particular source. With respect to clinical studies, only those reports and articles containing scientifically valid data and published in the refereed medical and scientific literature shall be considered as meeting the requirements of reliable evidence. Specifically not included in the meaning of reliable evidence are reports, articles, or statements by providers or groups of providers containing only abstracts, anecdotal evidence or personal professional opinions. Also not included in the meaning of reliable evidence is the fact that a provider or a number of providers have elected to adopt a drug, device, or medical treatment or procedure as their personal treatment or procedure of choice or standard of practice.

Representative. Any person who has been appointed by a party to the initial determination as counsel or advisor and who is otherwise eligible to serve as the counsel or advisor of the party to the initial determination, particularly in connection with a hearing.

Reservist. A person who is under an active duty call or order to one of the Uniformed Services for a period of 30 days or less or is on inactive training.

Resident (medical). A graduate physician or dentist who has an M.D. or D.O. degree, or D.D.S. or D.M.D. degree, respectively, is licensed to practice, and who choose to remain on the house staff of a hospital to get further training that will qualify him or her for a medical or dental specialty.

Residential treatment center (RTC). A facility (or distinct part of a facility) which meets the criteria in Sec. 199.6(b)(4)(v).

Respite care. Respite care is short-term care for a patient in order to provide rest and change for those who have been caring for the patient at home, usually the patient's family.

Retiree. A member or former member of a Uniformed Service who is entitled to retired, retainer, or equivalent pay based on duty in a Uniformed Service.

Routine eye examinations. The services rendered in order to determine the refractive state of the eyes.

Sanction. For purpose of Sec. 199.9, "sanction" means a provider exclusion, suspension, or termination.

Secondary payer. The plan or program whose medical benefits are payable in double coverage situations only after the primary payer has adjudicated the claim.

Semiprivate room. A room containing at least two beds. If a room is designated publicly as a semiprivate accommodation by the hospital or other authorized institutional provider and contains multiple beds, it qualifies as a semiprivate room for the purposes of CHAMPUS.

Serious physical disability. Any physiological disorder or condition or anatomical loss affecting one or more body systems which has lasted, or with reasonable certainty is expected to last, for a minimum period of 12 contiguous months, and which precludes the person with the disorder, condition or anatomical loss from unaided performance of at least one Major Life Activity as defined in this section.

Skilled nursing facility. An institution (or a distinct part of an institution) that meets the criteria as set forth in Sec. 199.6(b)(4)(vi).

Skilled nursing services. Skilled nursing services includes application of professional nursing services and skills by an RN, LPN, or LVN, that are required to be performed under the general supervision/direction of a TRICARE-authorized physician to ensure the safety of the patient and achieve the medically desired result in accordance with accepted standards of practice.

Sole community hospital (SCH). A hospital that is designated by CMS as an SCH and meets the applicable requirements established by Sec. 199.6(b)(4)(xvii).

Spectacles, eyeglasses, and lenses. Lenses, including contact lenses, that help to correct faulty vision.

Speech generating device (SGD). See Augmentative Communication Device.

Sponsor. A member or former member of a Uniformed Service upon whose status his or her dependents' eligibility for CHAMPUS is based. A sponsor also includes a person who, while a member of the Uniformed Services and after becoming eligible to be retired on the basis of years of service, has his or her eligibility to receive retired pay terminated as a result of misconduct involving abuse of a spouse or dependent child. It also includes NATO members who are stationed in or passing through the United States on official business when authorized. It also includes individuals eligible for CHAMPUS under the Transitional Assistance Management Program.

Spouse. A lawful husband or wife, who meets the criteria in Sec. 199.3 of this part, regardless of whether or not dependent upon the member or former member for his or her own support.

State. For purposes of this part, any of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, and each territory and possession of the United States.

State victims of crime compensation programs. Benefits available to victims of crime under the Violent Crime Control and Law Enforcement Act.

Student status. A dependent of a member or former member of a Uniformed Service who has not passed his or her 23rd birthday, and is enrolled in a full-time course of study in an institution of higher learning.

Supervised mental health counselor. An extramedical individual provider who meets the requirements outlined in Sec. 199.6.

Supplemental insurance plan. A health insurance policy or other health benefit plan offered by a private entity to a CHAMPUS beneficiary, that primarily is designed, advertised, marketed, or otherwise held out as providing payment for expenses incurred for services and items that are not reimbursed under CHAMPUS due to program limitations, or beneficiary liabilities imposed by law. CHAMPUS recognizes two types of supplemental plans, general indemnity plans, and those offered through a direct service health maintenance organization (HMO).

- (1) An indemnity supplemental insurance plan must meet all of the following criteria:
 - (i) It provides insurance coverage, regulated by state insurance agencies, which is available only to beneficiaries of CHAMPUS.
 - (ii) It is premium based and all premiums relate only to the CHAMPUS supplemental coverage.
 - (iii) Its benefits for all covered CHAMPUS beneficiaries are predominantly limited to non-covered services, to the deductible and cost-shared portions of the pre-determined allowable charges, and/or to amounts exceeding the allowable charges for covered services.
 - (iv) It provides insurance reimbursement by making payment directly to the CHAMPUS beneficiary or to the participating provider.
 - (v) It does not operate in a manner which results in lower deductibles or cost-shares than those imposed by law, or that waives the legally imposed deductibles or cost-shares.
- (2) A supplemental insurance plan offered by a Health Maintenance Organization (HMO) must meet all of the following criteria:
 - (i) The HMO must be authorized and must operate under relevant provisions of state law.
 - (ii) The HMO supplemental plan must be premium based and all premiums must relate only to CHAMPUS supplemental coverage.
 - (iii) The HMO's benefits, above those which are directly reimbursed by CHAMPUS, must be limited predominantly to services not covered by CHAMPUS and CHAMPUS deductible and cost-share amounts.
 - (iv) The HMO must provide services directly to CHAMPUS beneficiaries through its affiliated providers who, in turn, are reimbursed by CHAMPUS.
 - (v) The HMO's premium structure must be designed so that no overall reduction in the amount of the beneficiary deductibles or cost-shares will result.

Suppliers of portable X-ray services. A supplier that meets the conditions of coverage of the Medicare program, set forth in the Medicare regulations (42 CFR 405.1411 through 405.1416 (as amended)) or the Medicaid program in the state in which the covered service is provided.

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Surgery. Medically appropriate operative procedures, including related preoperative and postoperative care; reduction of fractures and dislocations; injections and needling procedures of the joints; laser surgery of the eye; and those certain procedures listed in Sec. 199.4(c)(2)(i) of this part.

Surgical assistant. A physician (or dentist or podiatrist) who assists the operating surgeon in the performance of a covered surgical service when such assistance is certified as necessary by the attending surgeon, when the type of surgical procedure being performed is of such complexity and seriousness as to require a surgical assistant, and when interns, residents, or other house staff are not available to provide the surgical assistance services in the specialty area required.

Suspension of claims processing. The temporary suspension of processing (to protect the government's interests) of claims for care furnished by a specific provider (whether the claims are submitted by the provider or beneficiary) or claims submitted by or on behalf of a specific CHAMPUS beneficiary pending action by the Director, OCHAMPUS, or a designee, in a case of suspected fraud or abuse. The action may include the administrative remedies provided for in Sec. 199.9 or any other Department of Defense issuance (e.g. DoD issuances implementing the Program Fraud Civil Remedies Act), case development or investigation by OCHAMPUS, or referral to the Department of Defense-Inspector General or the Department of Justice for action within their cognizant jurisdictions.

Teaching physician. A teaching physician is any physician whose duties include providing medical training to physicians in training within a hospital or other institutional provider setting.

Third-party billing agent. Any entity that acts on behalf of a provider to prepare, submit and monitor claims, excluding those entities that act solely as a collection agency.

Third-party payer. Third-payer means an entity that provides an insurance, medical service, or health plan by contract or agreement, including an automobile liability insurance or no fault insurance carrier and a worker's compensation program or plan, and any other plan or program (e.g., homeowners insurance) that is designed to provide compensation or coverage for expenses incurred by a beneficiary for medical services or supplies. For purposes of the definition of "third-party payer," an insurance, medical service, or health plan includes a preferred provider organization, an insurance plan described as Medicare supplemental insurance, and a personal injury protection plan or medical payments benefit plan for personal injuries resulting from the operation of a motor vehicle.

NOTE: TRICARE is secondary payer to all third-party payers. Under limited circumstances described in Sec. 199.8(c)(2) of this part, TRICARE payment may be authorized to be paid in advance of adjudication of the claim by certain third-party payers. TRICARE advance payments will not be made when a third-party provider is determined to be a primary medical insurer under Sec. 199.8(c)(3) of this part.

Timely filing. The filing of CHAMPUS claims within the prescribed time limits as set forth in Sec. 199.7 of this part.

Transitional Assistance Management Program (TAMP). The program established under 10 U.S.C. Sec. 1145(a) and Sec. 199.3(e) of this part.

Treatment plan. A detailed description of the medical care being rendered or expected to be rendered a CHAMPUS beneficiary seeking approval for inpatient benefits for which preauthorization is required as set forth in Sec. 199.4(b) of this part. A treatment plan must include, at a minimum, a diagnosis (either ICD-9-CM or DSM-III); detailed reports of prior treatment, medical history, family history, social history, and physical examination; diagnostic test results; consultant's reports (if any); proposed treatment by type (such as surgical, medical, and psychiatric); a description of who is or will be providing treatment (by discipline or specialty); anticipated frequency, medications, and specific goals of treatment; type of inpatient facility required and why (including length of time the related inpatient stay will be required); and prognosis. If the treatment plan involves the transfer of a CHAMPUS patient from a hospital or another inpatient facility, medical records related to that inpatient stay also are required as a part of the treatment plan documentation.

TRICARE certified mental health counselor. An allied health professional who meets the requirements outlined in Sec. 199.6.

TRICARE Extra plan. The health care option, provided as part of the TRICARE program under Sec. 199.17, under which beneficiaries may choose to receive care in facilities of the uniformed services, or from special civilian network providers (with reduced cost sharing), or from any other CHAMPUS-authorized provider (with standard cost sharing).

TRICARE Hospital Outpatient Prospective Payment System (OPPS). OPPS is a hospital outpatient prospective payment system, based on nationally established APC payment amounts and standardized for geographic wage differences that includes operating and capital-related costs that are directly related and integral to performing a procedure or furnishing a service in a hospital outpatient department.

TRICARE Prime plan. The health care option, provided as part of the TRICARE program under Sec. 199.17, under which beneficiaries enroll to receive all health care from facilities of the uniformed services and civilian network providers (with civilian care subject to substantially reduced cost sharing).

TRICARE program. The program establish under Sec. 199.17.

TRICARE Reserve Select. The program established under 10 U.S.C. 1076d and Sec. 199.24 of this Part.

TRICARE Retired Reserve. The program established to allow members of the Retired Reserve who are qualified for non-regular retirement, but are not yet 60 years of age, as well as certain survivors to qualify to purchase medical coverage equivalent to the TRICARE Standard (and Extra) benefit unless that member is either enrolled in, or eligible to enroll in, a health benefit plan under Chapter 89 of Title 5, United States Code. The program benefits and requirements are set forth in section 25 of this Part.

TRICARE standard plan. The health care option, provided as part of the TRICARE program under Sec. 199.17, under which beneficiaries are eligible for care in facilities of the uniformed services and CHAMPUS under standard rules and procedures.

TRICARE Young Adult. The program authorized by and described in Sec. 199.26 of this part.

Uniform HMO benefit. The health care benefit established by Sec. 199.18.

Uniformed Services. The Army, Navy, Air Force, Marine Corps, Coast Guard, Commissioned Corps of the USPHS, and the Commissioned Corps of the NOAA.

Veteran. A person who served in the active military, naval, or air service, and who was discharged or released therefrom under conditions other than dishonorable.

NOTE: Unless the veteran is eligible for “retired pay,” “retirement pay,” or “retainer pay,” which refers to payments of a continuing nature and are payable at fixed intervals from the government for military service neither the veteran nor his or her dependents are eligible for benefits under CHAMPUS.

Waiver of benefit limits. Extension of current benefit limitations under the Case Management Program, of medical care, services, and/or equipment, not otherwise a benefit under the TRICARE/CHAMPUS program.

Well-child care. A specific program of periodic health screening, developmental assessment, and routine immunization for dependents under six years of age.

Widow or Widower. A person who was a spouse at the time of death of a member or former member and who has not remarried.

Worker’s compensation benefits. Medical benefits available under any worker’s compensation law (including the Federal Employees Compensation Act), occupational disease law, employers liability law, or any other legislation of similar purpose, or under the maritime doctrine of maintenance, wages, and cure.

X-ray services. An x-ray examination from which an x-ray film or other image is produced, ordered by the attending physician when necessary and rendered in connection with a medical or surgical diagnosis or treatment of an illness or injury, or in connection with maternity or well-baby care.

[51 FR 24008, Jul 1, 1986, as amended at 64 FR 46134, Aug 24, 1999; 66 FR 40606, Aug 3, 2001; 66 FR 45172, Aug 28, 2001; 67 FR 18826, Apr 17, 2002; 67 FR 40602, Jun 13, 2002; 68 FR 6618, Feb 10, 2003; 68 FR 23032, Apr 30, 2003; 68 FR 32361, May 30, 2003; 68 FR 44880, Jul 31, 2003; 69 FR 17048, Apr 1, 2004; 69 FR 44946, Jul 28, 2004; 69 FR 51563, Aug 20, 2004; 69 FR 60554, Oct 12, 2004; 70 FR 12802, Mar 16, 2005; 70 FR 61377, Oct 24, 2005; 71 FR 31944, Jun 2, 2006; 71 FR 35532, Jun 21, 2006; 71 FR 47092, Aug 16, 2006; 72 FR 46383, Aug 20, 2007; 73 FR 74964, Dec 10, 2008; 74 FR 44755, Aug 31, 2009; 75 FR 47455, Aug 6, 2010; 75 FR 47458, Aug 6, 2010; 76 FR 8297, Feb 14, 2011; 76 FR 23483, Apr 27, 2011; 77 FR 38178, Jun 27, 2012; 78 FR 12954, Feb 26, 2013; 78 FR 48309, Aug 8, 2013; 79 FR 41641, Jul 17, 2014; **78 FR 78711, Dec 31, 2014**]

EDITORIAL NOTE: For Federal Register citations affecting Sec. 199.2, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

EDITORIAL NOTE: At 66 FR 45172, Aug. 28, 2001, Sec. 199.2, was amended in part by revising the definition of “Director, OCHAMPUS”. However, because of inaccurate amendatory language, this amendment could not be incorporated.

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PART 199.4 - BASIC PROGRAM BENEFITS

(a) **General.** The CHAMPUS Basic Program is essentially a supplemental program to the Uniformed Services direct medical care system. The Basic Program is similar to private insurance programs, and is designed to provide financial assistance to CHAMPUS beneficiaries for certain prescribed medical care obtained from civilian sources.

(1)(i) **Scope of benefits.** Subject to all applicable definitions, conditions, limitations, or exclusions specified in this part, the CHAMPUS Basic Program will cost share medically necessary services and supplies required in the diagnosis and treatment of illness or injury, including maternity care and well-baby care. Benefits include specified medical services and supplies provided to eligible beneficiaries from authorized civilian sources such as hospitals, other authorized institutional providers, physicians, other authorized individual professional providers, and professional ambulance services, prescription drugs, authorized medical supplies, and rental or purchase of durable equipment.

(ii) **Impact of TRICARE program.** The basic program benefits set forth in this section are applicable to the basic CHAMPUS program. In areas in which the TRICARE program is implemented, certain provisions of Sec. 199.17 will apply instead of the provisions of this section. In those areas, the provisions of Sec. 199.17 will take precedence over any provisions of this section with which they conflict.

(2) **Persons eligible for Basic Program benefits.** Persons eligible to receive the Basic Program benefits are set forth in Sec. 199.3 of this part. Any person determined to be an eligible CHAMPUS beneficiary is eligible for Basic Program benefits.

(3) **Authority to act for CHAMPUS.** The authority to make benefit determinations and authorize the disbursement of funds under CHAMPUS is restricted to the Director, OCHAMPUS; designated OCHAMPUS staff; Director, OCHAMPUSEUR; or CHAMPUS fiscal intermediaries. No other persons or agents (such as physicians, staff members of hospitals, or CHAMPUS health benefits advisors) have such authority.

(4) **Status of patient controlling for purposes of cost-sharing.** Benefits for covered services and supplies described in this section will be extended either on an inpatient or outpatient cost-sharing basis in accordance with the status of the patient at the time the covered services and supplies were provided, unless otherwise specifically designated (such as for ambulance service or maternity care). For cost-sharing provisions, refer to paragraph (f) of this section.

(5) **Right to information.** As a condition precedent to the provision of benefits hereunder, OCHAMPUS or its CHAMPUS fiscal intermediaries shall be entitled to receive information from a physician or hospital or other person, institution, or organization (including a local, state, or U.S. Government agency) providing services or supplies to the beneficiary for which claims or requests for approval for benefits are submitted. Such information and records may relate to the attendance, testing, monitoring, or examination or diagnosis of, or treatment rendered, or services and supplies furnished to a beneficiary, and shall be necessary for the accurate and efficient administration of CHAMPUS benefits. Before a determination will be

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made on a request for preauthorization or claim of benefits, a beneficiary or sponsor must provide particular additional information relevant to the requested determination, when necessary. The recipient of such information shall in every case hold such records confidential except when:

- (i) Disclosure of such information is authorized specifically by the beneficiary;
- (ii) Disclosure is necessary to permit authorized governmental officials to investigate and prosecute criminal actions, or
- (iii) Disclosure is authorized or required specifically under the terms of the Privacy Act or Freedom of Information Act (refer to Sec. 199.1(m) of this part).

For the purposes of determining the applicability of and implementing the provisions of Secs. 199.8, 199.11, and 199.12, or any provision of similar purpose of any other medical benefits coverage or entitlement, OCHAMPUS or CHAMPUS fiscal intermediaries may release, without consent or notice to any beneficiary or sponsor, to any person, organization, government agency, provider, or other entity any information with respect to any beneficiary when such release constitutes a routine use published in the Federal Register in accordance with DoD 5400.11-R (Privacy Act (5 U.S.C. 552a)). Before a person's claim of benefits will be adjudicated, the person must furnish to CHAMPUS information that reasonably may be expected to be in his or her possession and that is necessary to make the benefit determination. Failure to provide the requested information may result in denial of the claim.

(6) Physical examinations. The Director, OCHAMPUS, or a designee, may require a beneficiary to submit to one or more medical (including psychiatric) examinations to determine the beneficiary's entitlement to benefits for which application has been made or for otherwise authorized medically necessary services and supplies required in the diagnosis or treatment of an illness or injury (including maternity and well-baby care). When a medical examination has been requested, CHAMPUS will withhold payment of any pending claims or preauthorization requests on that particular beneficiary. If the beneficiary refuses to agree to the requested medical examination, or unless prevented by a medical reason acceptable to OCHAMPUS, the examination is not performed within 90 days of initial request, all pending claims for services and supplies will be denied. A denial of payments for services or supplies provided before (and related to) the request for a physical examination is not subject to reconsideration. The medical examination and required beneficiary travel related to performing the requested medical examination will be at the expense of CHAMPUS. The medical examination may be performed by a physician in a Uniformed Services medical facility or by an appropriate civilian physician, as determined and selected by the Director, OCHAMPUS, or a designee who is responsible for making such arrangements as are necessary, including necessary travel arrangements.

(7) Claims filing deadline. For all services provided on or after January 1, 1993, to be considered for benefits, all claims submitted for benefits must, except as provided in Sec. 199.7, be filed with the appropriate CHAMPUS contractor no later than one year after the services are provided. Unless the requirement is waived, failure to file a claim within this deadline waives all rights to benefits for such services or supplies.

(8) Double coverage and third party recoveries. CHAMPUS claims involving double coverage or the possibility that the United States can recover all or a part of its expenses from

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services or direct supervision of care provided by a physician in training. In order to be considered an attending physician, the teaching physician must:

- (i) Review the patient's history and the record of examinations and tests in the institution, and make frequent reviews of the patient's progress; and
- (ii) Personally examine the patient; and
- (iii) Confirm or revise the diagnosis and determine the course of treatment to be followed; and
- (iv) Either perform the physician's services required by the patient or supervise the treatment so as to assure that appropriate services are provided by physicians in training and that the care meets a proper quality level; and
- (v) Be present and ready to perform any service performed by an attending physician in a nonteaching setting when a major surgical procedure or a complex or dangerous medical procedure is performed; and
- (vi) Be personally responsible for the patient's care, at least throughout the period of hospitalization.

(2) Direct supervision by an attending physician of care provided by physicians in training. Payment on the basis of allowable charges may be made for the professional services rendered to a beneficiary by his/her attending physician when the attending physician provides personal and identifiable direction to physicians in training who are participating in the care of the patient. It is not necessary that the attending physician be personally present for all services, but the attending physician must be on the provider's premises and available to provide immediate personal assistance and direction if needed.

(3) Individual, personal services. A teaching physician may be reimbursed on an allowable charge basis for any individual, identifiable service rendered to a CHAMPUS beneficiary, so long as the service is a covered service and is normally reimbursed separately, and so long as the patient records substantiate the service.

(4) Who may bill. The services of a teaching physician must be billed by the institutional provider when the physician is employed by the provider or a related entity or under a contract which provides for payment to the physician by the provider or a related entity. Where the teaching physician has no relationship with the provider (except for standard physician privileges to admit patients) and generally treats patients on a fee-for-service basis in the private sector, the teaching physician may submit claims under his/her own provider number.

(B) Physicians in training. Physicians in training in an approved teaching program are considered to be "students" and may not be reimbursed directly by CHAMPUS for services rendered to a beneficiary when their services are provided as part of their employment (either salaried or contractual) by a hospital or other institutional provider. Services of physicians in training may be reimbursed on an allowable charge basis only if:

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- (1) The physician in training is fully licensed to practice medicine by the state in which the services are performed, and
- (2) The services are rendered outside the scope and requirements of the approved training program to which the physician in training is assigned.

(d) Other benefits--(1) General. Benefits may be extended for the allowable charge of those other covered services and supplies described in paragraph (d) of this section, which are provided in accordance with good medical practice and established standards of quality by those other authorized providers described in Sec. 199.6. Such benefits are subject to all applicable definitions, conditions, limitations, or exclusions as otherwise may be set forth in this or other chapters of this Regulation. To be considered for benefits under paragraph (d) of this section, the described services or supplies must be prescribed and ordered by a physician. Other authorized individual professional providers acting within their scope of licensure may also prescribe and order these services and supplies unless otherwise specified in paragraph (d) of this section.

(2) Billing practices. To be considered for benefits under paragraph (d) of this section, covered services and supplies must be provided and billed for by an authorized provider as set forth in Sec. 199.6 of this part. Such billing must be itemized fully and described sufficiently, even when CHAMPUS payment is determined under the CHAMPUS DRG-based payment system, so that CHAMPUS can determine whether benefits are authorized by this part. Except for claims subject to the CHAMPUS DRG-based payment system, whenever continuing charges are involved, claims should be submitted to the appropriate CHAMPUS fiscal intermediary at least every 30 days (monthly) either by the beneficiary or sponsor or directly by the provider. For claims subject to the CHAMPUS DRG-based payment system, claims may be submitted only after the beneficiary has been discharged or transferred from the hospital.

(3) Other covered services and supplies--(i) Blood. If whole blood or plasma (or its derivatives) are provided and billed for by an authorized institution in connection with covered treatment, benefits are extended as set forth in paragraph (b) of this section. If blood is billed for directly to a beneficiary, benefits may be extended under paragraph (d) in the same manner as a medical supply.

(ii) Durable equipment--(A) Scope of benefit. (1) Durable equipment, which is for the specific use of the beneficiary and is ordered by an authorized individual professional provider listed in Sec. 199.6(c)(3)(i), (ii) or (iii), acting within his or her scope of licensure shall be covered if the durable equipment meets the definition in Sec. 199.2 and--

(i) Provides the medically appropriate level of performance and quality for the medical condition present and

(ii) Is not otherwise excluded by this part.

(2) Items that may be provided to a beneficiary as durable equipment include:

(i) Durable medical equipment as defined in Sec. 199.2;

(ii) Wheelchairs. A wheelchair, which is medically appropriate to provide basic mobility,

including reasonable additional costs for medically appropriate modifications to accommodate a particular physiological or medical need, may be covered as durable equipment. An electric wheelchair, or TRICARE approved alternative to an electric wheelchair (e.g., scooter) may be provided in lieu of a manual wheelchair when it is medically indicated and appropriate to provide basic mobility. Luxury or deluxe wheelchairs, as described in paragraph (d)(3)(ii)(A)(3) of this section, include features beyond those required for basic mobility of a particular beneficiary are not authorized.

(iii) Iron lungs.

(iv) Hospital beds.

(v) Cardiorespiratory monitors under conditions specified in paragraph (d)(3)(ii)(B) of this section.

(3) Whether a prescribed item of durable equipment provides the medically appropriate level of performance and quality for the beneficiary's condition must be supported by adequate documentation. Luxury, deluxe, immaterial, or non-essential features, which increase the cost of the item relative to a similar item without those features, based on industry standards for a particular item at the time the equipment is prescribed or replaced for a beneficiary, are not authorized. Only the "base" or "basic" model of equipment (or more cost-effective alternative equipment) shall be covered, unless customization of the equipment, or any accessory or item of supply for any durable equipment, is essential, as determined by the Director (or designee), for--

(i) Achieving therapeutic benefit for the patient;

(ii) Making the equipment serviceable; or

(iii) Otherwise assuring the proper functioning of the equipment.

(B) Cardiorespiratory monitor exception. (1) When prescribed by a physician who is otherwise eligible as a CHAMPUS individual professional provider, or who is on active duty with a United States Uniformed Service, an electronic cardiorespiratory monitor, including technical support necessary for the proper use of the monitor, may be cost-shared as durable medical equipment when supervised by the prescribing physician for in-home use by:

(i) An infant beneficiary who has had an apparent life-threatening event, as defined in guidelines issued by the Director, OCHAMPUS, or a designee, or

(ii) An infant beneficiary who is a subsequent or multiple birth biological sibling of a victim of sudden infant death syndrome (SIDS), or

(iii) An infant beneficiary whose birth weight was 1,500 grams or less, or

(iv) An infant beneficiary who is a pre-term infant with pathologic apnea, as defined in guidelines issued by the Director, OCHAMPUS, or a designee, or

(v) Any beneficiary who has a condition or suspected condition designated in guidelines issued by the Director, OCHAMPUS, or a designee, for which the in-home use of the

cardiorespiratory monitor otherwise meets Basic Program requirements.

(2) The following types of services and items may be cost-shared when provided in conjunction with an otherwise authorized cardiorespiratory monitor:

(i) Trend-event recorder, including technical support necessary for the proper use of the recorder.

(ii) Analysis of recorded physiological data associated with monitor alarms.

(iii) Professional visits for services otherwise authorized by this part, and for family training on how to respond to an apparent life threatening event.

(iv) Diagnostic testing otherwise authorized by this part.

(C) Exclusions. Durable equipment, which is otherwise qualified as a benefit is excluded from coverage under the following circumstances:

(1) Durable equipment for a beneficiary who is a patient in a type of facility that ordinarily provides the same type of durable equipment item to its patients at no additional charge in the usual course of providing its services.

(2) Durable equipment, which is available to the beneficiary from a Uniformed Services Medical Treatment Facility.

(D) Basis for reimbursement. (1) Durable equipment may be provided on a rental or purchase basis. Coverage of durable equipment will be based on the price most advantageous to the government taking into consideration the anticipated duration of the medically necessary need for the equipment and current price information for the type of item. The cost analysis must include a comparison of the total price of the item as a monthly rental charge, a lease-purchase price, and a lump-sum purchase price and a provision for the time value of money at the rate determined by the U.S. Department of Treasury. If a beneficiary wishes to obtain an item of durable equipment with deluxe, luxury, immaterial or non-essential features, the beneficiary may agree to accept TRICARE coverage limited to the allowable amount that would have otherwise been authorized for a similar item without those features. In that case, the TRICARE coverage is based upon the allowable amount for the kind of durable equipment normally used to meet the intended purpose (i.e., the standard item least costly). The provider shall not hold the beneficiary liable for deluxe, luxury, immaterial, or non-essential features that cannot be considered in determining the TRICARE allowable costs. However, the beneficiary shall be held liable if the provider has a specific agreement in writing from the beneficiary (or his or her representative) accepting liability for the itemized difference in costs of the durable equipment with deluxe, luxury, or immaterial features and the TRICARE allowable costs for an otherwise authorized item without such features.

(2) In general, repairs of beneficiary owned durable equipment are covered when necessary to make the equipment serviceable and replacement of durable equipment is allowed when the durable equipment is not serviceable because of normal wear, accidental damage or when necessitated by a change in the beneficiary's condition. However, repairs of durable equipment damaged while using the equipment in a manner inconsistent with its

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common use, and replacement of lost or stolen durable equipment are excluded from coverage. In addition, repairs of deluxe, luxury, or immaterial features of durable equipment are excluded from coverage.

(iii) Medical supplies and dressings (consumables). Medical supplies and dressings (consumables) are those that do not withstand prolonged, repeated use. Such items must be related directly to an appropriate and verified covered medical condition of the specific beneficiary for whom the item was purchased and obtained from a medical supply company, a pharmacy, or authorized institutional provider. Examples of covered medical supplies and dressings are disposable syringes for a known diabetic, colostomy sets, irrigation sets, and elastic bandages. An external surgical garment specifically designed for use following a mastectomy is considered a medical supply item.

NOTE: Generally, the allowable charge of a medical supply item will be under \$100. Any item over this amount must be reviewed to determine whether it would not qualify as a DME item. If it is, in fact, a medical supply item and does not represent an excessive charge, it can be considered for benefits under paragraph (d)(3)(iii) of this section.

(iv) Oxygen. Oxygen and equipment for its administration are covered. Benefits are limited to providing a tank unit at one location with oxygen limited to a 30-day supply at any one time. Repair and adjustment of CHAMPUS-purchased oxygen equipment also is covered.

(v) Ambulance. Civilian ambulance service is covered when medically necessary in connection with otherwise covered services and supplies and a covered medical condition. For the purpose of TRICARE payment, ambulance service is an outpatient service (including in connection with maternity care) with the exception of otherwise covered transfers between hospitals which are cost-shared on an inpatient basis. Ambulance transfers from a hospital based emergency room to another hospital more capable of providing the required care will also be cost-shared on an inpatient basis.

NOTE: The inpatient cost-sharing provisions for ambulance transfers only apply to otherwise covered transfers between hospitals, i.e., acute care, general, and special hospitals; psychiatric hospitals; and long-term hospitals.

(A) Ambulance service cannot be used instead of taxi service and is not payable when the patient's condition would have permitted use of regular private transportation; nor is it payable when transport or transfer of a patient is primarily for the purpose of having the patient nearer to home, family, friends, or personal physician. Except as described in paragraph (d)(3)(v)(C)(1) of this section transport must be to the closest appropriate facility by the least costly means.

(B) Vehicles such as medicabs or ambicabs function primarily as public passenger conveyances transporting patients to and from their medical appointments. No actual medical care is provided to the patients in transit. These types of vehicles do not qualify for benefits for the purpose of CHAMPUS payment.

(C) Except as described in paragraph (d)(3)(v)(C)(1)(i) of this section, ambulance services by other than land vehicles (such as a boat or airplane) may be considered only when the pickup point is inaccessible by a land vehicle, or when great distance or other obstacles are

involved in transporting the patient to the nearest hospital with appropriate facilities and the patient's medical condition warrants speedy admission or is such that transfer by other means is contraindicated.

(1) Advanced life support air ambulance and certified advanced life support attendant are covered services for solid organ and stem cell transplant candidates.

(2) Advanced life support air ambulance and certified advanced life support attendant shall be reimbursed subject to standard reimbursement methodologies.

(vi) Drugs and medicines. Drugs and medicines that by United States law require a prescription are also referred to as "legend drugs." Legend drugs are covered when prescribed by a physician or other authorized individual professional provider acting within the scope of the provider's license and ordered or prescribed in connection with an otherwise covered condition or treatment, and not otherwise excluded by TRICARE. This includes Rh immune globulin.

(A) Drugs administered by a physician or other authorized individual professional provider as an integral part of a procedure covered under paragraph (b) or (c) of this section (such as chemotherapy) are not covered under this subparagraph inasmuch as the benefit for the institutional services or the professional services in connection with the procedure itself also includes the drug used.

(B) CHAMPUS benefits may not be extended for drugs not approved by the U.S. Food and Drug Administration for commercial marketing. Drugs grandfathered by the Federal Food, Drug and Cosmetic Act of 1938 may be covered under CHAMPUS as if FDA approved.

(C) Over-the-counter (OTC) drugs (drugs that by United States law do not require a prescription), in general, are not covered. However, insulin is covered for a known diabetic even in states that do not require a prescription for its purchase. In addition, OTC drugs used for smoking cessation are covered when all requirements under the TRICARE smoking cessation program are met as provided in paragraph (e)(30) of this section.

(vii) Prosthetics, prosthetic devices, and prosthetic supplies, as determined by the Secretary of Defense to be necessary because of significant conditions resulting from trauma, congenital anomalies, or disease. Additionally, the following are covered:

(A) Any accessory or item of supply that is used in conjunction with the device for the purpose of achieving therapeutic benefit and proper functioning;

(B) Services necessary to train the recipient of the device in the use of the device;

(C) Repair of the device for normal wear and tear or damage;

(D) Replacement of the device if the device is lost or irreparably damaged or the cost of repair would exceed 60 percent of the cost of replacement.

(viii) Orthopedic braces and appliances. The purchase of leg braces (including attached shoes), arm braces, back braces, and neck braces is covered, orthopedic shoes, arch supports,

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shoe inserts, and other supportive devices for the feet, including special-ordered, custom-made built-up shoes or regular shoes subsequently built up, are not covered.

(ix) Diabetes Self-Management Training (DSMT). A training service or program that educates diabetic patients about the successful self-management of diabetes. It includes the following criteria: Education about self-monitoring of blood glucose, diet, and exercise; an insulin treatment plan developed specifically for the patient who is insulin-dependent; and motivates the patient to use the skills for self-management. The DSMT service or program must be accredited by the American Diabetes Association. Coverage limitations on the provision of this benefit will be as determined by the Director, TRICARE Management Activity, or designee.

(e) Special benefit information--(1) General. There are certain circumstances, conditions, or limitations that impact the extension of benefits and that require special emphasis and explanation. This paragraph (e) sets forth those benefits and limitations recognized to be in this category. The benefits and limitations herein described also are subject to all applicable definitions, conditions, limitations, exceptions, and exclusions as set forth in this or other sections of this part, except as otherwise may be provided specifically in this paragraph (e).

(2) Abortion. The statute under which CHAMPUS operates prohibits payment for abortions with one single exception--where the life of the mother would be endangered if the fetus were carried to term. Covered abortion services are limited to medical services and supplies only. Physician certification is required attesting that the abortion was performed because the mother's life would be endangered if the fetus were carried to term. Abortions performed for suspected or confirmed fetal abnormality (e.g., anencephalic) or for mental health reasons (e.g., threatened suicide) do not fall within the exceptions permitted within the language of the statute and are not authorized for payment under CHAMPUS.

NOTE: Covered abortion services are limited to medical services or supplies only for the single circumstance outlined above and do not include abortion counseling or referral fees. Payment is not allowed for any services involving preparation for, or normal follow up to, a noncovered abortion. The Director, OCHAMPUS, or a designee, shall issue guidelines describing the policy on abortion.

(3) Family planning. The scope of the CHAMPUS family planning benefit is as follows:

(i) Birth control (such as contraception)--(A) Benefits provided. Benefits are available for services and supplies related to preventing conception, including the following:

(1) Surgical inserting, removal, or replacement of intrauterine devices.

(2) Measurement for, and purchase of, contraceptive diaphragms (and later remeasurement and replacement).

(3) Prescription contraceptives.

(4) Surgical sterilization (either male or female).

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- (B) Exclusions. The family planning benefit does not include the following:
 - (1) Prophylactics (condoms).
 - (2) Spermicidal foams, jellies, and sprays not requiring a prescription.
 - (3) Services and supplies related to noncoital reproductive technologies, including but not limited to artificial insemination (including any costs related to donors or semen banks), in-vitro fertilization and gamete intrafallopian transfer.
 - (4) Reversal of a surgical sterilization procedure (male or female).
- (ii) Genetic testing. Genetic testing essentially is preventive rather than related to active medical treatment of an illness or injury. However, under the family planning benefit, genetic testing is covered when performed in certain high risk situations. For the purpose of CHAMPUS, genetic testing includes to detect developmental abnormalities as well as purely genetic defects.
 - (A) Benefits provided. Benefits may be extended for genetic testing performed on a pregnant beneficiary under the following prescribed circumstances. The tests must be appropriate to the specific risk situation and must meet one of the following criteria:
 - (1) The mother-to-be is 35 years old or older; or
 - (2) The mother- or father-to-be has had a previous child born with a congenital abnormality; or
 - (3) Either the mother- or father-to-be has a family history of congenital abnormalities; or
 - (4) The mother-to-be contracted rubella during the first trimester of the pregnancy; or
 - (5) Such other specific situations as may be determined by the Director, OCHAMPUS, or a designee, to fall within the intent of paragraph (e)(3)(ii) of this section.
 - (B) Exclusions. It is emphasized that routine or demand genetic testing is not covered. Further, genetic testing does not include the following:
 - (1) Tests performed to establish paternity of a child.
 - (2) Tests to determine the sex of an unborn child.
- (4) Treatment of substance use disorders. Emergency and inpatient hospital care for complications of alcohol and drug abuse or dependency and detoxification are covered as for any other medical condition. Specific coverage for the treatment of substance use disorders includes detoxification, rehabilitation, and outpatient care provided in authorized substance use disorder rehabilitation facilities.
 - (i) Emergency and inpatient hospital services. Emergency and inpatient hospital services are covered when medically necessary for the active medical treatment of the acute phases of substance abuse withdrawal (detoxification), for stabilization, and for treatment of

medical complications of substance use disorders. Emergency and inpatient hospital services are considered medically necessary only when the patient's condition is such that the personnel and facilities of a hospital are required. Stays provided for substance use disorder rehabilitation in a hospital-based rehabilitation facility are covered, subject to the provisions of paragraph (e)(4)(ii) of this section. Inpatient hospital services also are subject to the provisions regarding the limit on inpatient mental health services.

(ii) Authorized substance use disorder treatment. Only those services provided by TRICARE-authorized institutional providers are covered. Such a provider must be either an authorized hospital, or an organized substance use disorder treatment program in an authorized free-standing or hospital-based substance use disorder rehabilitation facility. Covered services consist of any or all of the services listed below, including the substitution of a therapeutic drug, with addictive potential, for a drug addiction when medically or psychologically necessary and appropriate medical care for a beneficiary undergoing medically supervised treatment for a substance use disorder. A qualified mental health provider (physicians, clinical psychologists, clinical social workers, psychiatric nurse specialists) (see paragraph (c)(3)(ix) of this section) shall prescribe the particular level of treatment. Each TRICARE beneficiary is entitled to three substance use disorder treatment benefit periods in his or her lifetime, unless this limit is waived pursuant to paragraph (e)(4)(v) of this section. (A benefit period begins with the first date of covered treatment and ends 365 days later, regardless of the total services actually used within the benefit period. Unused benefits cannot be carried over to subsequent benefit periods. Emergency and inpatient hospital services (as described in paragraph (e)(4)(i) of this section) do not constitute substance abuse treatment for purposes of establishing the beginning of a benefit period.)

(A) Rehabilitative care. Rehabilitative care in a authorized hospital or substance use disorder rehabilitative facility, whether free-standing or hospital-based, is covered on either a residential or partial care (day or night program) basis. Coverage during a single benefit period is limited to no more than inpatient stay (exclusive of stays classified in DRG 433) in hospitals subject to CHAMPUS DRG-based payment system or 21 days in a DRG-exempt facility for rehabilitation care, unless the limit is waived pursuant to paragraph (e)(4)(v) of this section. If the patient is medically in need of chemical detoxification, but does not require the personnel or facilities of a general hospital setting, detoxification services are covered in addition to the rehabilitative care, but in a DRG-exempt facility detoxification services are limited to 7 days unless the limit is waived pursuant to paragraph (e)(4)(v) of this section. The medical necessity for the detoxification must be documented. Any detoxification services provided by the substance use disorder rehabilitation facility must be under general medical supervision.

(B) Outpatient care. Outpatient treatment provided by an approved substance use disorder rehabilitation facility, whether free-standing or hospital-based, is covered for up to 60 visits in a benefit period, unless the limit is waived pursuant to paragraph (e)(4)(v) of this section.

(C) Family therapy. Family therapy provided by an approved substance use disorder rehabilitation facility, whether free-standing or hospital-based, is covered for up to 15 visits in a benefit period, unless the limit is waived pursuant to paragraph (e)(4)(v) of this section.

(iii) Exclusions--(A) Aversion therapy. The programmed use of physical measures, such as electric shock, alcohol, or other drugs as negative reinforcement (aversion therapy) is not covered, even if recommended by a physician.

(B) Domiciliary settings. Domiciliary facilities, generally referred to as halfway or quarterway houses, are not authorized providers and charges for services provided by these facilities are not covered.

(iv) Confidentiality. Release of any patient identifying information, including that required to adjudicate a claim, must comply with the provisions of section 544 of the Public Health Service Act, as amended, (42 U.S.C. 290dd-3), which governs the release of medical and other information from the records of patients undergoing treatment of substance abuse. If the patient refuses to authorize the release of medical records which are, in the opinion of the Director, OCHAMPUS, or a designee, necessary to determine benefits on a claim for treatment of substance abuse the claim will be denied.

(v) Waiver of benefit limits. The specific benefit limits set forth in paragraphs (e)(4)(ii) of this section may be waived by the Director, OCHAMPUS in special cases based on a determination that all of the following criteria are met:

(A) Active treatment has taken place during the period of the benefit limit and substantial progress has been made according to the plan of treatment.

(B) Further progress has been delayed due to the complexity of the illness.

(C) Specific evidence has been presented to explain the factors that interfered with further treatment progress during the period of the benefit limit.

(D) The waiver request includes specific time frames and a specific plan of treatment which will complete the course of treatment.

(5) Transplants. (i) Organ transplants. Basic Program benefits are available for otherwise covered services or supplies in connection with an organ transplant procedure, provided such transplant procedure is in accordance with accepted professional medical standards and is not considered unproven.

(A) General. (1) Benefits may be allowed for medically necessary services and supplies related to an organ transplant for:

(i) Evaluation of potential candidate's suitability for an organ transplant, whether or not the patient is ultimately accepted as a candidate for transplant.

(ii) Pre- and post-transplant inpatient hospital and outpatient services.

(iii) Pre- and post-operative services of the transplant team.

(iv) Blood and blood products.

(v) FDA approved immunosuppression drugs to include off-label uses when determined to be medically necessary for the treatment of the condition for which it is administered,

according to accepted standards of medical practice.

(vi) Complications of the transplant procedure, including inpatient care, management of infection and rejection episodes.

(vii) Periodic evaluation and assessment of the successfully transplanted patient.

(viii) The donor acquisition team, including the costs of transportation to the location of the donor organ and transportation of the team and the donated organ to the location of the transplant center.

(ix) The maintenance of the viability of the donor organ after all existing legal requirements for excision of the donor organ have been met.

(2) TRICARE benefits are payable for recipient costs when the recipient of the transplant is a CHAMPUS beneficiary, whether or not the donor is a CHAMPUS beneficiary.

(3) Donor costs are payable when:

(i) Both the donor and recipient are CHAMPUS beneficiaries.

(ii) The donor is a CHAMPUS beneficiary but the recipient is not.

(iii) The donor is the sponsor and the recipient is a CHAMPUS beneficiary. (In such an event, donor costs are paid as a part of the beneficiary and recipient costs.)

(iv) The donor is neither a CHAMPUS beneficiary nor a sponsor, if the recipient is a CHAMPUS beneficiary. (Again, in such an event, donor costs are paid as a part of the beneficiary and recipient costs.)

(4) If the donor is not a CHAMPUS beneficiary, TRICARE benefits for donor costs are limited to those directly related to the transplant procedure itself and do not include any medical care costs related to other treatment of the donor, including complications.

(5) TRICARE benefits will not be allowed for transportation of an organ donor.

(B) (Reserved)

(ii) Stem cell transplants. TRICARE benefits are payable for beneficiaries whose conditions are considered appropriate for stem cell transplant according to guidelines adopted by the Executive Director, TMA, or a designee.

(6) Eyeglasses, spectacles, contact lenses, or other optical devices. Eyeglasses, spectacles, contact lenses, or other optical devices are excluded under the Basic Program except under very limited and specific circumstances.

(i) Exception to general exclusion. Benefits for glasses and lenses may be extended only in connection with the following specified eye conditions and circumstances:

(A) Eyeglasses or lenses that perform the function of the human lens, lost as a result of

intraocular surgery or ocular injury or congenital absence.

NOTE: Notwithstanding the general requirement for U.S. Food and Drug Administration approval of any surgical implant set forth in paragraph (d)(3)(vii) of this section, intraocular lenses are authorized under CHAMPUS if they are either approved for marketing by FDA or are subject to an investigational device exemption.

(B) "Pinhole" glasses prescribed for use after surgery for detached retina.

(C) Lenses prescribed as "treatment" instead of surgery for the following conditions:

(1) Contract lenses used for treatment of infantile glaucoma.

(2) Corneal or scleral lenses prescribed in connection with treatment of keratoconus.

(3) Scleral lenses prescribed to retain moisture when normal tearing is not present or is inadequate.

(4) Corneal or scleral lenses prescribed to reduce a corneal irregularity other than astigmatism.

(ii) Limitations. The specified benefits are limited further to one set of lenses related to one of the qualifying eye conditions set forth in paragraph (e)(6)(i) of this section. If there is a prescription change requiring a new set of lenses (but still related to the qualifying eye condition), benefits may be extended for a second set of lenses, subject to specific medical review.

(7) Transsexualism or such other conditions as gender dysphoria. All services and supplies directly or indirectly related to transsexualism or such other conditions as gender dysphoria are excluded under CHAMPUS. This exclusion includes, but is not limited to, psychotherapy, prescription drugs, and intersex surgery that may be provided in connection with transsexualism or such other conditions as gender dysphoria. There is only one very limited exception to this general exclusion, that is, notwithstanding the definition of congenital anomaly, CHAMPUS benefits may be extended for surgery and related medically necessary services performed to correct sex gender confusion (that is, ambiguous genitalia) which has been documented to be present at birth.

(8) Cosmetic, reconstructive, or plastic surgery. For the purposes of CHAMPUS, cosmetic, reconstructive, or plastic surgery is surgery that can be expected primarily to improve physical appearance or that is performed primarily for psychological purposes or that restores form, but does not correct or improve materially a bodily function.

NOTE: If a surgical procedure primarily restores function, whether or not there is also a concomitant improvement in physical appearance, the surgical procedure does not fall within the provisions set forth in this paragraph (e)(8).

(i) Limited benefits under CHAMPUS. Benefits under the Basic Program generally are not available for cosmetic, reconstructive, or plastic surgery. However, under certain limited circumstances, benefits for otherwise covered services and supplies may be provided in connection with cosmetic, reconstructive, or plastic surgery as follows:

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- (A) Correction of a congenital anomaly; or
- (B) Restoration of body form following an accidental injury; or
- (C) Revision of disfiguring and extensive scars resulting from neoplastic surgery.
- (D) Reconstructive breast surgery following a medically necessary mastectomy performed for the treatment of carcinoma, severe fibrocystic disease, other nonmalignant tumors or traumatic injuries.
- (E) Penile implants and testicular prostheses for conditions resulting from organic origins (i.e., trauma, radical surgery, disease process, for correction of congenital anomaly, etc.). Also, penile implants for organic impotency.

NOTE: Organic impotence is defined as that which can be reasonably expected to occur following certain diseases, surgical procedures, trauma, injury, or congenital malformation. Impotence does not become organic because of psychological or psychiatric reasons.

(F) Generally, benefits are limited to those cosmetic, reconstructive, or plastic surgery procedures performed no later than December 31 of the year following the year in which the related accidental injury or surgical trauma occurred, except for authorized postmastectomy breast reconstruction for which there is no time limitation between mastectomy and reconstruction. Also, special consideration for exception will be given to cases involving children who may require a growth period.

(ii) General exclusions.(A) For the purposes of CHAMPUS, dental congenital anomalies such as absent tooth buds or malocclusion specifically are excluded. Also excluded are any procedures related to transsexualism or such other conditions as gender dysphoria, except as provided in paragraph (e)(7) of this section.

(B) Cosmetic, reconstructive, or plastic surgery procedures performed primarily for psychological reasons or as a result of the aging process also are excluded.

(C) Procedures performed for elective correction of minor dermatological blemishes and marks or minor anatomical anomalies also are excluded.

(iii) Noncovered surgery, all related services and supplies excluded. When it is determined that a cosmetic, reconstructive, or plastic surgery procedure does not qualify for CHAMPUS benefits, all related services and supplies are excluded, including any institutional costs.

(iv) Example of noncovered cosmetic, reconstructive, or plastic surgery procedures. The following is a partial list of cosmetic, reconstructive, or plastic surgery procedures that do not qualify for benefits under CHAMPUS. This list is for example purposes only and is not to be construed as being all-inclusive.

(A) Any procedure performed for personal reasons to improve the appearance of an obvious feature or part of the body that would be considered by an average observer to be normal and acceptable for the patient's age or ethnic or racial background.

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- (B) Cosmetic, reconstructive, or plastic surgical procedures that are justified primarily on the basis of a psychological or psychiatric need.
- (C) Augmentation mammoplasties. Augmentation mammoplasties, except for breast reconstruction following a covered mastectomy and those specifically authorized in paragraph (e)(8)(i) of this section.
- (D) Face lifts and other procedures related to the aging process.
- (E) Reduction mammoplasties. Reduction mammoplasties (unless there is medical documentation of intractable pain, not amenable to other forms of treatment, resulting from large, pendulous breasts or unless performed as an integral part of an authorized breast reconstruction procedure under paragraph (e)(8)(i) of this section, including reduction of the collateral breast for purposes of ensuring breast symmetry)
- (F) Panniculectomy; body sculpture procedures.
- (G) Repair of sagging eyelids (without demonstrated and medically documented significant impairment of vision).
- (H) Rhinoplasties (without evidence of accidental injury occurring within the previous 6 months that resulted in significant obstruction of breathing).
- (I) Chemical peeling for facial wrinkles.
- (J) Dermabrasion of the face.
- (K) Elective correction of minor dermatological blemishes and marks or minor anatomical anomalies.
- (L) Revision of scars resulting from surgery or a disease process, except disfiguring and extensive scars resulting from neoplastic surgery.
- (M) Removal of tattoos.
- (N) Hair transplants.
- (O) Electrolysis.
- (P) Any procedures related to transsexualism or such other conditions as gender dysphoria except as provided in paragraph (e)(7) of this section.
- (Q) Penile implant procedure for psychological impotency, transsexualism, or such other conditions as gender dysphoria.
- (R) Insertion of prosthetic testicles for transsexualism, or such other conditions as gender dysphoria.
- (9) Care related to non-covered initial surgery or treatment. (i) Benefits are available for otherwise covered services and supplies required in the treatment of complications

resulting from a non-covered incident of treatment (such as nonadjunctive dental care or cosmetic surgery) but only if the later complication represents a separate medical condition such as a systemic infection, cardiac arrest, and acute drug reaction. Benefits may not be extended for any later care or a procedure related to the complication that essentially is similar to the initial non-covered care. Examples of complications similar to the initial episode of care (and thus not covered) would be repair of facial scarring resulting from dermabrasion for acne.

(ii) Benefits are available for otherwise covered services and supplies required in the treatment of complications (unfortunate sequelae) and any necessary follow-on care resulting from a non-covered incident of treatment provided in an MTF, when the initial non-covered service has been authorized by the MTF Commander and the MTF is unable to provide the necessary treatment of the complications or required follow-on care, according to the guidelines adopted by the Director, DHA, or a designee.

(iii) Benefits are available for otherwise covered services and supplies required in the treatment of complications (unfortunate sequelae) and any necessary follow-on care resulting from a non-covered incident of treatment provided in the private sector pursuant to a properly granted waiver under Sec. 199.16(f). The Director, DHA, or designee, shall issue guidelines for implementing this provision.

(10) Dental. TRICARE/CHAMPUS does not include a dental benefit. However, in connection with dental treatment for patients with developmental, mental, or physical disabilities or for pediatric patients age 5 or under, only institutional and anesthesia services may be provided as a benefit.

(i) Adjunctive dental care: Limited. Adjunctive dental care is limited to those services and supplies provided under the following conditions:

(A) Dental care which is medically necessary in the treatment of an otherwise covered medical (not dental) condition, is an integral part of the treatment of such medical condition and is essential to the control of the primary medical condition. The following is a list of conditions for which CHAMPUS benefits are payable under this provision:

- (1) Intraoral abscesses which extend beyond the dental alveolus.
- (2) Extraoral abscesses.
- (3) Cellulitis and osteitis which is clearly exacerbating and directly affecting a medical condition currently under treatment.
- (4) Removal of teeth and tooth fragments in order to treat and repair facial trauma resulting from an accidental injury.
- (5) Myofacial Pain Dysfunction Syndrome.
- (6) Total or complete ankyloglossia.
- (7) Adjunctive dental and orthodontic support for cleft palate.

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(8) The prosthetic replacement of either the maxilla or the mandible due to the reduction of body tissues associated with traumatic injury (e.g., impact, gun shot wound), in addition to services related to treating neoplasms or iatrogenic dental trauma.

NOTE: The test of whether dental trauma is covered is whether the trauma is solely dental trauma. Dental trauma, in order to be covered, must be related to, and an integral part of medical trauma; or a result of medically necessary treatment of an injury or disease.

(B) Dental care required in preparation for medical treatment of a disease or disorder or required as the result of dental trauma caused by the medically necessary treatment of an injury or disease (iatrogenic).

(1) Necessary dental care including prophylaxis and extractions when performed in preparation for or as a result of in-line radiation therapy for oral or facial cancer.

(2) Treatment of gingival hyperplasia, with or without periodontal disease, as a direct result of prolonged therapy with Dilantin (diphenylhydantoin) or related compounds.

(C) Dental care is limited to the above and similar conditions specifically prescribed by the Director, OCHAMPUS, as meeting the requirements for coverage under the provisions of this section.

(ii) General exclusions.(A) Dental care which is routine, preventative, restorative, prosthodontic, periodontic or emergency does not qualify as adjunctive dental care for the purposes of CHAMPUS except when performed in preparation for or as a result of dental trauma caused by medically necessary treatment of an injury or disease.

(B) The adding or modifying of bridgework and dentures.

(C) Orthodontia, except when directly related to and an integral part of the medical or surgical correction of a cleft palate or when required in preparation for, or as a result of, trauma to the teeth and supporting structures caused by medically necessary treatment of an injury or disease.

(iii) Preauthorization required. In order to be covered, adjunctive dental care requires preauthorization from the Director, TRICARE Management Activity, or a designee, in accordance with paragraph (a)(12) of this section. When adjunctive dental care involves a medical (not dental) emergency (such as facial injuries resulting from an accident), the requirement for preauthorization is waived. Such waiver, however, is limited to the essential adjunctive dental care related to the medical condition requiring the immediate emergency treatment. A complete explanation, with supporting medical documentation, must be submitted with claims for emergency adjunctive dental care.

(iv) Covered oral surgery. Notwithstanding the above limitations on dental care, there are certain oral surgical procedures that are performed by both physicians and dentists, and that are essentially medical rather than dental care. For the purposes of CHAMPUS, the following procedures, whether performed by a physician or dentist, are considered to be in this

category and benefits may be extended for otherwise covered services and supplies without preauthorization:

- (A) Excision of tumors and cysts of the jaws, cheeks, lips, tongue, and roof and floor of the mouth, when such conditions require a pathological (histological) examination.
- (B) Surgical procedures required to correct accidental injuries of the jaws, cheeks, lips, tongue, and roof and floor of the mouth.
- (C) Treatment of oral or facial cancer.
- (D) Treatment of fractures of facial bones.
- (E) External (extra-oral) incision and drainage of cellulitis.
- (F) Surgery of accessory sinuses, salivary glands, or ducts.
- (G) Reduction of dislocations and the excision of the temporomandibular joints, when surgery is a necessary part of the reduction.
- (H) Any oral surgical procedure that falls within the cosmetic, reconstructive, or plastic surgery definition is subject to the limitations and requirements set forth in paragraph (e)(8) of this section.

NOTE: Extraction of unerupted or partially erupted, malposed or impacted teeth, with or without the attached follicular or development tissues, is not a covered oral surgery procedure except when the care is indicated in preparation for medical treatment of a disease or disorder or required as a result of dental trauma caused by the necessary medical treatment of an injury or illness. Surgical preparation of the mouth for dentures is not covered by CHAMPUS.

(v) Inpatient hospital stay in connection with non-adjunctive, noncovered dental care. Institutional benefits specified in paragraph (b) of this section may be extended for inpatient hospital stays related to noncovered, nonadjunctive dental care when such inpatient stay is medically necessary to safeguard the life of the patient from the effects of dentistry because of the existence of a specific and serious nondental organic impairment currently under active treatment. (Hemophilia is an example of a condition that could be considered a serious nondental impairment.) Preauthorization by the Director, OCHAMPUS, or a designee, is required for such inpatient stays to be covered in the same manner as required for adjunctive dental care described in paragraph (e)(10)(iii) of this section. Regardless of whether or not the preauthorization request for the hospital admission is approved and thus qualifies for institutional benefits, the professional service related to the nonadjunctive dental care is not covered.

(vi) Anesthesia and institutional costs for dental care for children and certain other patients. Institutional benefits specified in paragraph (b) of this section may be extended for hospital and in-out surgery settings related to noncovered, nonadjunctive dental care when such outpatient care or inpatient stay is in conjunction with dental treatment for patients with developmental, mental, or physical disabilities or for pediatric patients age 5 or under. For these patients, anesthesia services will be limited to the administration of general

anesthesia only. Patients with developmental, mental, or physical disabilities are those patients with conditions that prohibit dental treatment in a safe and effective manner. Therefore, it is medically or psychologically necessary for these patients to require general anesthesia for dental treatment. Patients with physical disabilities include those patients having disabilities as defined in Sec. 199.2 as a serious physical disability. Preauthorization by the Director, TRICARE Management Activity, or a designee, is required for such outpatient care or inpatient stays to be covered in the same manner as required for adjunctive dental care described in paragraph (e)(10)(iii) of this section. Regardless of whether or not the preauthorization request for outpatient care or hospital admission is approved and thus qualifies for institutional benefits, the professional service related to the nonadjunctive dental care is not covered, with the exception of coverage for anesthesia services.

(11) Drug abuse. Under the Basic Program, benefits may be extended for medically necessary prescription drugs required in the treatment of an illness or injury or in connection with maternity care (refer to paragraph (d) of this section). However, TRICARE benefits cannot be authorized to support or maintain an existing or potential drug abuse situation whether or not the drugs (under other circumstances) are eligible for benefit consideration and whether or not obtained by legal means. Drugs, including the substitution of a therapeutic drug with addictive potential for a drug of addiction, prescribed to beneficiaries undergoing medically supervised treatment for a substance use disorder as authorized under paragraph (e)(4)(ii) of this section are not considered to be in support of, or to maintain, an existing or potential drug abuse situation and are allowed. The Director, TRICARE Management Activity, may prescribe appropriate policies to implement this prescription drug benefit for those undergoing medically supervised treatment for a substance use disorder.

(i) Limitations on who can prescribe drugs. CHAMPUS benefits are not available for any drugs prescribed by a member of the beneficiary's family or by a nonfamily member residing in the same household with the beneficiary or sponsor.

(ii) (Reserved).

(iii) Kinds of prescription drugs that are monitored carefully by CHAMPUS for possible abuse situations--(A) Narcotics. Examples are Morphine and Demerol.

(B) Nonnarcotic analgesics. Examples are Talwin and Darvon.

(C) Tranquilizers. Examples are Valium, Librium, and Meproamate.

(D) Barbiturates. Examples are Seconal and Nembuttal.

(E) Nonbarbituate hypnotics. Examples are Doriden and Chloral Hydrate.

(F) Stimulants. Examples are amphetamines.

(iv) CHAMPUS fiscal intermediary responsibilities. CHAMPUS fiscal intermediaries are responsible for implementing utilization control and quality assurance procedures designed to identify possible drug abuse situations. The CHAMPUS fiscal intermediary is directed to screen all drug claims for potential overutilization and irrational prescribing of drugs, and to

subject any such cases to extensive review to establish the necessity for the drugs and their appropriateness on the basis of diagnosis or definitive symptoms.

(A) When a possible drug abuse situation is identified, all claims for drugs for that specific beneficiary or provider will be suspended pending the results of a review.

(B) If the review determines that a drug abuse situation does in fact exist, all drug claims held in suspense will be denied.

(C) If the record indicates previously paid drug benefits, the prior claims for that beneficiary or provider will be reopened and the circumstances involved reviewed to determine whether or not drug abuse also existed at the time the earlier claims were adjudicated. If drug abuse is later ascertained, benefit payments made previously will be considered to have been extended in error and the amounts so paid recouped.

(D) Inpatient stays primarily for the purpose of obtaining drugs and any other services and supplies related to drug abuse also are excluded.

(v) Unethical or illegal provider practices related to drugs. Any such investigation into a possible drug abuse that uncovers unethical or illegal drug dispensing practices on the part of an institution, a pharmacy, or physician will be referred to the professional or investigative agency having jurisdiction. CHAMPUS fiscal intermediaries are directed to withhold payment of all CHAMPUS claims for services and supplies rendered by a provider under active investigation for possible unethical or illegal drug dispensing activities.

(vi) Detoxification. The above monitoring and control of drug abuse situations shall in no way be construed to deny otherwise covered medical services and supplies related to drug detoxification (including newborn, addicted infants) when medical supervision is required.

(12) (Reserved)

(13) Domiciliary care. The statute under which CHAMPUS operates also specifically excludes domiciliary care (refer to Sec. 199.2 of this part for the definition of "Domiciliary Care").

(i) Examples of domiciliary care situations. The following are examples of domiciliary care for which CHAMPUS benefits are not payable.

(A) Home care is not available. Institutionalization primarily because parents work, or extension of a hospital stay beyond what is medically necessary because the patient lives alone, are examples of domiciliary care provided because there is no other family member or other person available in the home.

(B) Home care is not suitable. Institutionalization of a child because a parent (or parents) is an alcoholic who is not responsible enough to care for the child, or because someone in the home has a contagious disease, are examples of domiciliary care being provided because the home setting is unsuitable.

(C) Family unwilling to care for a person in the home. A child who is difficult to manage may be placed in an institution, not because institutional care is medically necessary,

but because the family does not want to handle him or her in the home. Such institutionalization would represent domiciliary care, that is, the family being unwilling to assume responsibility for the child.

(ii) Benefits available in connection with a domiciliary care case. Should the beneficiary receive otherwise covered medical services or supplies while also being in a domiciliary care situation, CHAMPUS benefits are payable for those medical services or supplies, or both, in the same manner as though the beneficiary resided in his or her own home. Such benefits would be cost-shared as though rendered to an outpatient.

(iii) General exclusion. Domiciliary care is institutionalization essentially to provide a substitute home--not because it is medically necessary for the beneficiary to be in the institution (although there may be conditions present that have contributed to the fact that domiciliary care is being rendered). CHAMPUS benefits are not payable for any costs or charges related to the provision of domiciliary care. While a substitute home or assistance may be necessary for the beneficiary, domiciliary care does not represent the kind of care for which CHAMPUS benefits can be provided.

(14) CT scanning--(i) Approved CT scan services. Benefits may be extended for medically necessary CT scans of the head or other anatomical regions of the body when all of the following conditions are met:

(A) The patient is referred for the diagnostic procedure by a physician.

(B) The CT scan procedure is consistent with the preliminary diagnosis or symptoms.

(C) Other noninvasive and less costly means of diagnosis have been attempted or are not appropriate.

(D) The CT scan equipment is licensed or registered by the appropriate state agency responsible for licensing or registering medical equipment that emits ionizing radiation.

(E) The CT scan equipment is operated under the general supervision and direction of a physician.

(F) The results of the CT scan diagnostic procedure are interpreted by a physician.

(ii) Review guidelines and criteria. The Director, OCHAMPUS, or a designee, will issue specific guidelines and criteria for CHAMPUS coverage of medically necessary head and body part CT scans.

(15) Morbid obesity. The TRICARE morbid obesity benefit is limited to those bariatric surgical procedures for which the safety and efficacy has been proven comparable or superior to conventional therapies and is consistent with the generally accepted norms for medical practice in the United States medical community. (See the definition of reliable evidence in Sec. 199.2 of this part for the procedures used in determining if a medical treatment or procedure is unproven.)

(i) Conditions for coverage.

(A) Payment for bariatric surgical procedures is determined by the requirements specified in paragraph (g)(15) of this section, and as defined in Sec. 199.2(b) of this part.

(B) Covered bariatric surgical procedures are payable only when the patient has completed growth (18 years of age or documentation of completion of bone growth) and has met one of the following selection criteria:

(1) The patient has a BMI that is equal to or exceeds 40 kg/m² and has previously been unsuccessful with medical treatment for obesity.

(2) The patient has a BMI of 35 to 39.9 kg/m², has at least one high-risk co-morbid condition associated with morbid obesity, and has previously been unsuccessful with medical treatment for obesity.

NOTE: The Director, TMA, shall issue guidelines for review of the specific high-risk co-morbid conditions, exacerbated or caused by obesity based on the Reliable Evidence Standard as defined in Sec. 199.2 of this part.

(ii) Treatment of complications.

(A) Payment may be extended for repeat bariatric surgery when medically necessary to correct or treat complications from the initial covered bariatric surgery (a takedown). For instance, the surgeon in many cases will do a gastric bypass or gastroplasty to help the patient avoid regaining the weight that was lost. In this situation, payment is authorized even though the patient's condition technically may not meet the definition of morbid obesity because of the weight that was already lost following the initial surgery.

(B) Payment is authorized for otherwise covered medical services and supplies directly related to complications of obesity when such services and supplies are an integral and necessary part of the course of treatment that was aggravated by the obesity.

(iii) Exclusions. CHAMPUS payment may not be extended for weight control services, weight control/loss programs, dietary regimens and supplements, appetite suppressants and other medications; food or food supplements, exercise and exercise programs, or other programs and equipment that are primarily intended to control weight or for the purpose of weight reduction, regardless of the existence of co-morbid conditions.

(16) Maternity care.(i) Benefit. The CHAMPUS Basic Program may share the cost of medically necessary services and supplies associated with maternity care which are not otherwise excluded by this part.

(ii) Cost-share. Maternity care cost-share shall be determined as follows:

(A) Inpatient cost-share formula applies to maternity care ending in childbirth in, or on the way to, a hospital inpatient childbirth unit, and for maternity care ending in a non-birth outcome not otherwise excluded by this part.

(B) Ambulatory surgery cost-share formula applies to maternity care ending in childbirth

in, or on the way to, a birthing center to which the beneficiary is admitted and from which the beneficiary has received prenatal care, or a hospital-based outpatient birthing room.

(C) Outpatient cost-share formula applies to maternity care which terminates in a planned childbirth at home.

(D) Otherwise covered medical services and supplies directly related to "Complications of pregnancy," as defined in Sec. 199.2 of this part, will be cost-shared on the same basis as the related maternity care for a period not to exceed 42 days following termination of the pregnancy and thereafter cost-shared on the basis of the inpatient or outpatient status of the beneficiary when medically necessary services and supplies are received.

(17) Biofeedback Therapy. Biofeedback therapy is a technique by which a person is taught to exercise control over a physiologic process occurring within the body. By using modern biomedical instruments the patient learns how a specific physiologic system within his body operates and how to modify the performance of this particular system.

(i) Benefits Provided. CHAMPUS benefits are payable for services and supplies in connection with electrothermal, electromyograph and electrodermal biofeedback therapy when there is documentation that the patient has undergone an appropriate medical evaluation, that their present condition is not responding to or no longer responds to other forms of conventional treatment, and only when provided as treatment for the following conditions:

(A) Adjunctive treatment for Raynaud's Syndrome.

(B) Adjunctive treatment for muscle re-education of specific muscle groups or for treating pathological muscle abnormalities of spasticity, or incapacitating muscle spasm or weakness.

(ii) Limitations. Payable benefits include initial intake evaluation. Treatment following the initial intake evaluation is limited to a maximum of 20 inpatient and outpatient biofeedback treatments per calendar year.

(iii) Exclusions. Benefits are excluded for biofeedback therapy for the treatment of ordinary muscle tension states or for psychosomatic conditions. Benefits are also excluded for the rental or purchase of biofeedback equipment.

(iv) Provider Requirements. A provider of biofeedback therapy must be a CHAMPUS-authorized provider. (Refer to Sec. 199.6, "Authorized Providers). If biofeedback treatment is provided by other than a physician, the patient must be referred by a physician.

(v) Implementation Guidelines. The Director of OCHAMPUS shall issue guidelines as are necessary to implement the provision of this paragraph.

(18) Cardiac rehabilitation. Cardiac rehabilitation is the process by which individuals are restored to their optimal physical, medical, and psychological status, after a cardiac event. Cardiac rehabilitation is often divided into three phases. Phase I begins during inpatient hospitalization and is managed by the patient's personal physician. Phase II is a medically supervised outpatient program which begins following discharge. Phase III is a lifetime maintenance program emphasizing continuation of physical fitness with periodic follow up.

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Each phase includes an exercise component, patient education, and risk factor modification. There may be considerable variation in program components, intensity, and duration.

(i) Benefits Provided. CHAMPUS benefits are available on an inpatient or outpatient basis for services and supplies provided in connection with a cardiac rehabilitation program when ordered by a physician and provided as treatment for patients who have experienced the following cardiac events within the preceding twelve (12) months:

- (A) Myocardial Infarction.
- (B) Coronary Artery Bypass Graft.
- (C) Coronary Angioplasty.
- (D) Percutaneous Transluminal Coronary Angioplasty
- (E) Chronic Stable Angina (see limitations below).
- (F) Heart valve surgery.
- (G) Heart or Heart-lung Transplantation.

(ii) Limitations. Payable benefits include separate allowance for the initial evaluation and testing. Outpatient treatment following the initial intake evaluation and testing is limited to a maximum of thirty-six (36) sessions per cardiac event, usually provided 3 sessions per week for twelve (12) weeks. Patients diagnosed with chronic stable angina are limited to one treatment episode (36 sessions) in a calendar year.

(iii) Exclusions. Phase III cardiac rehabilitation lifetime maintenance programs performed at home or in medically unsupervised settings are not covered.

(iv) Providers. A provider of cardiac rehabilitation services must be a TRICARE authorized hospital (see Sec. 199.6 (b)(4)(i)) or a freestanding cardiac rehabilitation facility that meets the requirements of Sec. 199.6 (f). All cardiac rehabilitation services must be ordered by a physician.

(v) Payment. Payment for outpatient treatment will be based on an all inclusive allowable charge per session. Inpatient treatment will be paid based upon the reimbursement system in place for the hospital where the services are rendered.

(vi) Implementation Guidelines. The Director of OCHAMPUS shall issue guidelines as are necessary to implement the provisions of this paragraph.

(19) Hospice care. Hospice care is a program which provides an integrated set of services and supplies designed to care for the terminally ill. This type of care emphasizes palliative care and supportive services, such as pain control and home care, rather than cure-oriented services provided in institutions that are otherwise the primary focus under CHAMPUS. The benefit provides coverage for a humane and sensible approach to care during the last days of life for some terminally ill patients.

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(i) Benefit coverage. CHAMPUS beneficiaries who are terminally ill (that is, a life expectancy of six months or less if the disease runs its normal course) will be eligible for the following services and supplies in lieu of most other CHAMPUS benefits:

(A) Physician services.

(B) Nursing care provided by or under the supervision of a registered professional nurse.

(C) Medical social services provided by a social worker who has at least a bachelor's degree from a school accredited or approved by the Council on Social Work Education, and who is working under the direction of a physician. Medical social services include, but are not limited to the following:

(1) Assessment of social and emotional factors related to the beneficiary's illness, need for care, response to treatment, and adjustment to care.

(2) Assessment of the relationship of the beneficiary's medical and nursing requirements to the individual's home situation, financial resources, and availability of community resources.

(3) Appropriate action to obtain available community resources to assist in resolving the beneficiary's problem.

(4) Counseling services that are required by the beneficiary.

(D) Counseling services provided to the terminally ill individual and the family member or other persons caring for the individual at home. Counseling, including dietary counseling, may be provided both for the purpose of training the individual's family or other care-giver to provide care, and for the purpose of helping the individual and those caring for him or her to adjust to the individual's approaching death. Bereavement counseling, which consists of counseling services provided to the individual's family after the individual's death, is a required hospice service but it is not reimbursable.

(E) Home health aide services furnished by qualified aides and homemaker services. Home health aides may provide personal care services. Aides also may perform household services to maintain a safe and sanitary environment in areas of the home used by the patient. Examples of such services are changing the bed or light cleaning and laundering essential to the comfort and cleanliness of the patient. Aide services must be provided under the general supervision of a registered nurse. Homemaker services may include assistance in personal care, maintenance of a safe and healthy environment, and services to enable the individual to carry out the plan of care. Qualifications for home health aides can be found in 42 CFR 484.36.

(F) Medical appliances and supplies, including drugs and biologicals. Only drugs that are used primarily for the relief of pain and symptom control related to the individual's terminal illness are covered. Appliances may include covered durable medical equipment, as well as other self-help and personal comfort items related to the palliation or management of the patient's condition while he or she is under hospice care. Equipment is provided by the hospice for use in the beneficiary's home while he or she is under hospice care. Medical supplies include those that are part of the written plan of care. Medical appliances and supplies are included within the hospice all-inclusive rates.

(G) Physical therapy, occupational therapy and speech-language pathology services provided for purposes of symptom control or to enable the individual to maintain activities of daily living and basic functional skills.

(H) Short-term inpatient care provided in a Medicare participating hospice inpatient unit, or a Medicare participating hospital, skilled nursing facility (SNF) or, in the case of respite care, a Medicaid-certified nursing facility that additionally meets the special hospice standards regarding staffing and patient areas. Services provided in an inpatient setting must conform to the written plan of care. Inpatient care may be required for procedures necessary for pain control or acute or chronic symptom management. Inpatient care may also be furnished to provide respite for the individual's family or other persons caring for the individual at home. Respite care is the only type of inpatient care that may be provided in a Medicaid-certified nursing facility. The limitations on custodial care and personal comfort items applicable to other CHAMPUS services are not applicable to hospice care.

(ii) Core services. The hospice must ensure that substantially all core services are routinely provided directly by hospice employees; i.e., physician services, nursing care, medical social services, and counseling for individuals and care givers. Refer to paragraphs (e)(19)(i)(A), (e)(19)(i)(B), (e)(19)(i)(C), and (e)(19)(i)(D) of this section.

(iii) Non-core services. While non-core services (i.e., home health aide services, medical appliances and supplies, drugs and biologicals, physical therapy, occupational therapy, speech-language pathology and short-term inpatient care) may be provided under arrangements with other agencies or organizations, the hospice must maintain professional management of the patient at all times and in all settings. Refer to paragraphs (e)(19)(i)(E), (e)(19)(i)(F), (e)(19)(i)(G), and (e)(19)(i)(H) of this section.

(iv) Availability of services. The hospice must make nursing services, physician services, and drugs and biologicals routinely available on a 24-hour basis. All other covered services must be made available on a 24-hour basis to the extent necessary to meet the needs of individuals for care that is reasonable and necessary for the palliation and management of the terminal illness and related condition. These services must be provided in a manner consistent with accepted standards of practice.

(v) Periods of care. Hospice care is divided into distinct periods of care. The periods of care that may be elected by the terminally ill CHAMPUS beneficiary shall be as the Director, TRICARE determines to be appropriate, but shall not be less than those offered under Medicare's Hospice Program.

(vi) Conditions for coverage. The CHAMPUS beneficiary must meet the following conditions/criteria in order to be eligible for the hospice benefits and services referenced in paragraph (e)(19)(i) of this section.

(A) There must be written certification in the medical record that the CHAMPUS beneficiary is terminally ill with a life expectancy of six months or less if the terminal illness runs its normal course.

(1) Timing of certification. The hospice must obtain written certification of terminal illness for each of the election periods described in paragraph (e)(19)(vi)(B) of this section, even if a single election continues in effect for two, three or four periods.

(i) Basic requirement. Except as provided in paragraph (e)(19)(vi)(A)(1)(ii) of this section the hospice must obtain the written certification no later than two calendar days after the period begins.

(ii) Exception. For the initial 90-day period, if the hospice cannot obtain the written certifications within two calendar days, it must obtain oral certifications within two calendar days, and written certifications no later than eight calendar days after the period begins.

(2) Sources of certification. Physician certification is required for both initial and subsequent election periods.

(i) For the initial 90-day period, the hospice must obtain written certification statements (and oral certification statements if required under paragraph (e)(19)(vi)(A)(1)(ii) of this section) from:

(A) The individual's attending physician if the individual has an attending physician; and

(B) The medical director of the hospice or the physician member of the hospice interdisciplinary group.

(ii) For subsequent periods, the only requirement is certification by one of the physicians listed in paragraph (e)(19)(vi)(A)(2)(i)(B) of this section.

(B) The terminally ill beneficiary must elect to receive hospice care for each specified period of time; i.e., the two 90-day periods, a subsequent 30-day period, and a final period of unlimited duration. If the individual is found to be mentally incompetent, his or her representative may file the election statement. Representative means an individual who has been authorized under State law to terminate medical care or to elect or revoke the election of hospice care on behalf of a terminally ill individual who is found to be mentally incompetent.

(1) The episodes of care must be used consecutively; i.e., the two 90-day periods first, then the 30-day period, followed by the final period. The periods of care may be elected separately at different times.

(2) The initial election will continue through subsequent election periods without a break in care as long as the individual remains in the care of the hospice and does not revoke the election.

(3) The effective date of the election may begin on the first day of hospice care or any subsequent day of care, but the effective date cannot be made prior to the date that the election was made.

(4) The beneficiary or representative may revoke a hospice election at any time, but in doing so, the remaining days of that particular election period are forfeited and standard CHAMPUS coverage resumes. To revoke the hospice benefit, the beneficiary or representative must file a signed statement of revocation with the hospice. The statement must provide the date that the revocation is to be effective. An individual or representative may not designate an effective date earlier than the date that the revocation is made.

(5) If an election of hospice benefits has been revoked, the individual, or his or her

representative may at any time file a hospice election for any period of time still available to the individual, in accordance with Sec. 199.4(e)(19)(vi)(B).

(6) A CHAMPUS beneficiary may change, once in each election period, the designation of the particular hospice from which he or she elects to receive hospice care. To change the designation of hospice programs the individual or representative must file, with the hospice from which care has been received and with the newly designated hospice, a statement that includes the following information:

(i) The name of the hospice from which the individual has received care and the name of the hospice from which he or she plans to receive care.

(ii) The date the change is to be effective.

(7) Each hospice will design and print its own election statement to include the following information:

(i) Identification of the particular hospice that will provide care to the individual.

(ii) The individual's or representative's acknowledgment that he or she has been given a full understanding of the palliative rather than curative nature of hospice care, as it relates to the individual's terminal illness.

(iii) The individual's or representative's acknowledgment that he or she understands that certain other CHAMPUS services are waived by the election.

(iv) The effective date of the election.

(v) The signature of the individual or representative, and the date signed.

(8) The hospice must notify the CHAMPUS contractor of the initiation, change or revocation of any election.

(C) The beneficiary must waive all rights to other CHAMPUS payments for the duration of the election period for:

(1) Care provided by any hospice program other than the elected hospice unless provided under arrangements made by the elected hospice; and

(2) Other CHAMPUS basic program services/benefits related to the treatment of the terminal illness for which hospice care was elected, or to a related condition, or that are equivalent to hospice care, except for services provided by:

(i) The designated hospice;

(ii) Another hospice under arrangement made by the designated hospice; or

(iii) An attending physician who is not employed by or under contract with the hospice program.

- (3) Basic CHAMPUS coverage will be reinstated upon revocation of the hospice election.
- (D) A written plan of care must be established by a member of the basic interdisciplinary group assessing the patient's needs. This group must have at least one physician, one registered professional nurse, one social worker, and one pastoral or other counselor.
- (1) In establishing the initial plan of care the member of the basic interdisciplinary group who assesses the patient's needs must meet or call at least one other group member before writing the initial plan of care.
- (2) At least one of the persons involved in developing the initial plan must be a nurse or physician.
- (3) The plan must be established on the same day as the assessment if the day of assessment is to be a covered day of hospice care.
- (4) The other two members of the basic interdisciplinary group--the attending physician and the medical director or physician designee--must review the initial plan of care and provide their input to the process of establishing the plan of care within two calendar days following the day of assessment. A meeting of group members is not required within this 2-day period. Input may be provided by telephone.
- (5) Hospice services must be consistent with the plan of care for coverage to be extended.
- (6) The plan must be reviewed and updated, at intervals specified in the plan, by the attending physician, medical director or physician designee and interdisciplinary group. These reviews must be documented in the medical records.
- (7) The hospice must designate a registered nurse to coordinate the implementation of the plan of care for each patient.
- (8) The plan must include an assessment of the individual's needs and identification of the services, including the management of discomfort and symptom relief. It must state in detail the scope and frequency of services needed to meet the patient's and family's needs.
- (E) Complete medical records and all supporting documentation must be submitted to the CHAMPUS contractor within 30 days of the date of its request. If records are not received within the designated time frame, authorization of the hospice benefit will be denied and any prior payments made will be recouped. A denial issued for this reason is not an initial determination under Sec. 199.10, and is not appealable.
- (vii) Appeal rights under hospice benefit. A beneficiary or provider is entitled to appeal rights for cases involving a denial of benefits in accordance with the provisions of this part and Sec. 199.10.
- (20) (Reserved)
- (21) Home health services. Home health services are covered when furnished by, or under arrangement with, a home health agency (HHA) that participates in the TRICARE program, and provides care on a visiting basis in the beneficiary's home. Covered HHA

services are the same as those provided under Medicare under section 1861(m) of the Social Security Act (42 U.S.C. 1395x(m)) and 42 CFR part 409, subpart E.

(i) **Benefit coverage.** Coverage will be extended for the following home health services subject to the conditions of coverage prescribed in paragraph (e)(21)(ii) of this section:

(A) Part-time or intermittent skilled nursing care furnished by a registered nurse or a licensed practical (vocational) nurse under the supervision of a registered nurse;

(B) Physical therapy, speech-language pathology, and occupational therapy;

(C) Medical social services under the direction of a physician;

(D) Part-time or intermittent services of a home health aide who has successfully completed a state-established or other training program that meets the requirements of 42 CFR Part 484;

(E) Medical supplies, a covered osteoporosis drug (as defined in the Social Security Act 1861(kk), but excluding other drugs and biologicals) and durable medical equipment;

(F) Medical services provided by an interim or resident-in-training of a hospital, under an approved teaching program of the hospital in the case of an HHA that is affiliated or under common control of a hospital; and

(G) Services at hospitals, SNFs or rehabilitation centers when they involve equipment too cumbersome to bring to the home but not including transportation of the individual in connection with any such item or service.

(ii) **Conditions for Coverage.** The following conditions/criteria must be met in order to be eligible for the HHA benefits and services referenced in paragraph (e)(21)(i) of this section:

(A) The person for whom the services are provided is an eligible TRICARE beneficiary.

(B) The HHA that is providing the services to the beneficiary has in effect a valid agreement to participate in the TRICARE program.

(C) Physician certifies the need for home health services because the beneficiary is homebound.

(D) The services are provided under a plan of care established and approved by a physician.

(1) The plan of care must contain all pertinent diagnoses, including the patient's mental status, the types of services, supplies, and equipment required, the frequency of visits to be made, prognosis, rehabilitation potential, functional limitations, activities permitted, nutritional requirements, all medications and treatments, safety measures to protect against injury, instructions for timely discharge or referral, and any additional items the HHA or physician chooses to include.

(2) The orders on the plan of care must specify the type of services to be provided to the

beneficiary, both with respect to the professional who will provide them and the nature of the individual services, as well as the frequency of the services.

(E) The beneficiary must need skilled nursing care on an intermittent basis or physical therapy or speech-language pathology services, or have continued need for occupational therapy after the need for skilled nursing care, physical therapy, or speech-language pathology services has ceased.

(F) The beneficiary must receive, and an HHA must provide, a patient-specific, comprehensive assessment that:

(1) Accurately reflects the patient's current health status and includes information that may be used to demonstrate the patient's progress toward achievement of desired outcomes;

(2) Identifies the beneficiary's continuing need for home care and meets the beneficiary's medical, nursing, rehabilitative, social, and discharge planning needs.

(3) Incorporates the use of the current version of the Outcome and Assessment Information Set (OASIS) items, using the language and groupings of the OASIS items, as specified by the Director, TRICARE Management Activity.

(G) TRICARE is the appropriate payer.

(H) The services for which payment is claimed are not otherwise excluded from payment.

(I) Any other conditions of coverage/participation that may be required under Medicare's HHA benefit; i.e., coverage guidelines as prescribed under Sections 1861(o) and 1891 of the Social Security Act (42 U.S.C. 1395x(o) and 1395bbb), 42 CFR Part 409, Subpart E and 42 CFR Part 484.

(22) Pulmonary rehabilitation. TRICARE benefits are payable for beneficiaries whose conditions are considered appropriate for pulmonary rehabilitation according to guidelines adopted by the Executive Director, TMA, or a designee.

(23) A speech generating device (SGD) as defined in Sec. 199.2 of this part is covered as a voice prosthesis. The prosthesis provisions found in paragraph (d)(3)(vii) of this section apply.

(24) A hearing aid, but only for a dependent of a member of the uniformed services on active duty and only if the dependent has a profound hearing loss as defined in Sec. 199.2 of this part. Medically necessary and appropriate services and supplies, including hearing examinations, required in connection with this hearing aid benefit are covered.

(25) Rehabilitation therapy as defined in Sec. 199.2 of this part to improve, restore, or maintain function, or to minimize or prevent deterioration of function, of a patient when prescribed by a physician. The rehabilitation therapy must be medically necessary and appropriate medical care, rendered by an authorized provider, necessary to the establishment of a safe and effective maintenance program in connection with a specific medical condition, and must not be custodial care or otherwise excluded from coverage.

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(26) National Institutes of Health clinical trials. By law, the general prohibition against CHAMPUS cost-sharing of unproven drugs, devices, and medical treatments or procedures may be waived in connection with clinical trials sponsored or approved by the National Institutes of Health National Cancer Institute if it is determined that such a waiver will promote access by covered beneficiaries to promising new treatments and contribute to the development of such treatments. A waiver shall only be exercised as authorized under this paragraph.

(i) Demonstration waiver. A waiver may be granted through a demonstration project established in accordance with Sec. 199.1(o) of this part.

(ii) Continuous waiver.(A) General. As a result of a demonstration project under which a waiver has been granted in connection with a National Institutes of Health National Cancer Institute clinical trial, a determination may be made that it is in the best interest of the government and CHAMPUS beneficiaries to end the demonstration and continue to provide a waiver for CHAMPUS cost-sharing of the specific clinical trial. Only those specified clinical trials identified under paragraph (e)(26)(ii) of this section have been authorized a continuous waiver under CHAMPUS.

(B) National Cancer Institute (NCI) sponsored cancer prevention, screening, and early detection clinical trials. A continuous waiver under paragraph (e)(26) of this regulation has been granted for CHAMPUS cost-sharing for those CHAMPUS-eligible patients selected to participate in NCI sponsored Phase II and Phase III studies for the prevention and treatment of cancer. Additionally, Phase I studies may be approved on a case by case basis when the requirements below are met.

(1) TRICARE will cost-share all medical care and testing required to determine eligibility for an NCI-sponsored trial, including the evaluation for eligibility at the institution conducting the NCI-sponsored study. TRICARE will cost-share all medical care required as a result of participation in NCI-sponsored studies. This includes purchasing and administering all approved chemotherapy agents (except for NCI-funded investigational drugs), all inpatient and outpatient care, including diagnostic and laboratory services not otherwise reimbursed under an NCI grant program if the following conditions are met:

(i) The provider seeking treatment for a CHAMPUS-eligible patient in an NCI approved protocol has obtained pre-authorization for the proposed treatment before initial evaluation; and,

(ii) Such treatments are NCI sponsored Phase I, Phase II or Phase III protocols; and

(iii) The patient continues to meet entry criteria for said protocol; and,

(iv) The institutional and individual providers are CHAMPUS authorized providers; and,

(v) The requirements for Phase I protocols in paragraph (e)(26)(ii)(B)(2) of this section are met:

(2) Requirements for Phase I protocols are:

(i) Standard treatment has been or would be ineffective, does not exist, or there is no

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superior non-investigational treatment alternative; and,

(ii) The available clinical or preclinical data provide a reasonable expectation that the treatment will be at least as effective as the non-investigational alternative; and,

(iii) The facility and personnel providing the treatment are capable of doing so by virtue of their experience, training, and volume of patients treated to maintain expertise; and,

(iv) The referring physician has concluded that the enrollee's participation in such a trial would be appropriate based upon the satisfaction of paragraphs (e)(26)(ii)(B)(2)(i) through (iii) of this section.

(3) TRICARE will not provide reimbursement for care rendered in the National Institutes of Health Clinical Center or costs associated with non-treatment research activities associated with the clinical trials.

(4) Cost-shares and deductibles applicable to CHAMPUS will also apply under the NCI-sponsored clinical trials.

(5) The Director, TRICARE (or designee), shall issue procedures and guidelines establishing NCI-sponsorship of clinical trials and the administrative process by which individual patients apply for and receive cost-sharing under NCI-sponsored cancer clinical trials.

(27) TRICARE will cost share forensic examinations following a sexual assault or domestic violence. The forensic examination includes a history of the event and a complete physical and collection of forensic evidence, and medical and psychological follow-up care. The examination for sexual assault also includes, but is not limited to, a test kit to retrieve forensic evidence, testing for pregnancy, testing for sexually transmitted disease and HIV, and medical services and supplies for prevention of sexually transmitted diseases, HIV, pregnancy, and counseling services.

(28) Preventive care. The following preventive services are covered:

(i) Cervical, breast, colon and prostate cancer screenings according to standards issued by the Director, TRICARE Management Activity, based on guidelines from the U.S. Department of Health and Human Services. The standards may establish a specific schedule that includes frequency, age specifications, and gender of the beneficiary, as appropriate.

(ii) Immunizations as recommended by the Centers for Disease Control and Prevention (CDC).

(iii) Well-child visits for children under 6 years of age as described in paragraph (c)(3)(xi) of this section.

(iv) Health promotion and disease prevention visits (which may include all of the services provided pursuant to Sec. 199.18(b)(2)) for beneficiaries 6 years of age or older may be provided in connection with immunizations and cancer screening examinations authorized by paragraphs (e)(28)(i) and (ii) of this section.

(29) Physical examinations. In addition to the health promotion and disease prevention visits authorized in paragraph (e)(28)(iv) of this section, the following physical examinations are specifically authorized:

(i) Physical examinations for dependents of Active Duty military personnel who are traveling outside the United States. The examination must be required because of an Active Duty member's assignment and the travel is being performed under orders issued by a Uniformed Service. Any immunizations required for a dependent of an Active Duty member to travel outside of the United States is covered as a preventive service under paragraph (e)(28) of this section.

(ii) Physical examinations for beneficiaries ages 5-11 that are required for school enrollment and that are provided on or after October 30, 2000.

(iii) Other types of physical examinations not listed above are excluded including routine, annual, or employment-requested physical examinations and routine screening procedures that are not part of medically necessary care or treatment or otherwise specifically authorized by statute.

(30) Smoking cessation program. The TRICARE smoking cessation program is a behavioral modification program to assist eligible beneficiaries who desire to quit smoking. The program consists of a pharmaceutical benefit; smoking cessation counseling; access to a toll-free quit line for non-medical assistance; and, access to print and internet web-based tobacco cessation materials.

(i) Availability. The TRICARE smoking cessation program is available to all TRICARE beneficiaries who reside in one of the 50 United States or the District of Columbia who are not eligible for Medicare benefits authorized under Title XVIII of the Social Security Act. In addition, pursuant to Sec. 199.17, if authorized by the Assistant Secretary of Defense (Health Affairs), the TRICARE smoking cessation program may be implemented in whole or in part in areas outside the 50 states and the District of Columbia for active duty members and their dependents who are enrolled in TRICARE Prime (overseas Prime beneficiaries). In such cases, the Assistant Secretary of Defense (Health Affairs) may also authorize modifications to the TRICARE smoking cessation program rules and procedures as may be appropriate to the overseas area involved. Notice of the use of this authority, not otherwise mentioned in this paragraph (e)(30), shall be published in the **Federal Register**.

(ii) Benefits. There is no requirement for an eligible beneficiary to be diagnosed with a smoking related illness to access benefits under this program. The specific benefits available under the TRICARE smoking cessation program are:

(A) Pharmaceutical agents. Products available under this program are identified through the DoD Pharmacy and Therapeutics Committee, consistent with the DoD Uniform Formulary in Sec. 199.21. Smoking cessation pharmaceutical agents, including FDA-approved over-the-counter (OTC) pharmaceutical agents, are available through the TRICARE Mail Order Pharmacy (TMOP) or the MTF at no cost to the beneficiary. Smoking cessation pharmaceuticals through the TRICARE program will not be available at any retail pharmacies. A prescription from a TRICARE-authorized provider is required to obtain any pharmaceutical agent used for smoking cessation, including OTC agents. For overseas Prime

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beneficiaries, pharmaceutical agents may be provided either in the MTF or through the TMOP where such facility or service is available.

(B) Face-to-face smoking cessation counseling. Both individual and group smoking cessation counseling are covered. The number and mix of face-to-face counseling sessions covered under this program shall be determined by the Director, TMA; however, shall not exceed the limits established in paragraph (e)(30)(iii) of this section. A TRICARE-authorized provider listed in Sec. 199.6 must render all counseling sessions.

(C) Toll-free quit line. Access to a non-medical toll-free quit line 7 days a week, 24 hours a day will be available. The quit line will be staffed with smoking cessation counselors trained to assess a beneficiary's readiness to quit, identify barriers to quitting, and provide specific suggested actions and motivational counseling to enhance the chances of a successful quit attempt. When appropriate, quit line counselors will refer beneficiaries to a TRICARE-authorized provider for medical intervention. The quit line may, at the discretion of the Director, TMA, include the opportunity for the beneficiary to request individual follow-up contact initiated by quit line personnel; however, the beneficiary is not required to participate in the quit line initiated follow-up. Printed educational materials on the effects of tobacco use will be provided to the beneficiary upon request. This benefit may be made available to overseas Prime beneficiaries should the ASD(HA) exercise his authority to do so and provide appropriate notice in the **Federal Register**.

(D) Web-based resources. Downloadable educational materials on the effects of tobacco use will be available through the internet or other electronic media. This service may be made available to overseas Prime beneficiaries in all locations where web based resources are available. There shall be no requirement to create web based resources in any geographic area in order to make this service available.

(iii) Limitations of smoking cessation program. Eligible beneficiaries are entitled to two quit attempts per year (consecutive 12 month period). A third quit attempt may be covered per year with physician justification and pre-authorization. A quit attempt is defined as up to eighteen face-to-face counseling sessions over a 120 consecutive day period and/or 120 days of pharmacologic intervention for the purpose of smoking cessation. Counseling and pharmacological treatment periods that overlap by at least 60-days are considered a single quit attempt.

(f) Beneficiary or sponsor liability--(1) General. As stated in the introductory paragraph to this section, the Basic Program is essentially a supplemental program to the Uniformed Services direct medical care system. To encourage use of the Uniformed Services direct medical care system wherever its facilities are available and appropriate, the Basic Program benefits are designed so that it is to the financial advantage of a CHAMPUS beneficiary or sponsor to use the direct medical care system. When medical care is received from civilian sources, a CHAMPUS beneficiary is responsible for payment of certain deductible and cost-sharing amounts in connection with otherwise covered services and supplies. By statute, this joint financial responsibility between the beneficiary or sponsor and CHAMPUS is more favorable for dependents of members than for other classes of beneficiaries.

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(2) Dependents of members of the Uniformed Services. CHAMPUS beneficiary or sponsor liability set forth for dependents of members is as follows:

(i) Annual fiscal year deductible for outpatient services and supplies.

(A) For care rendered all eligible beneficiaries prior to April 1, 1991, or when the active duty sponsor's pay grade is E-4 or below, regardless of the date of care:

(1) Individual Deductible: Each beneficiary is liable for the first fifty dollars (\$50.00) of the CHAMPUS-determined allowable amount on claims for care provided in the same fiscal year.

(2) Family Deductible: The total deductible amount for all members of a family with the same sponsor during one fiscal year shall not exceed one hundred dollars (\$100.00).

(B) For care rendered on or after April 1, 1991, for all CHAMPUS beneficiaries except dependents of active duty sponsors in pay grades E-4 or below.

(1) Individual Deductible: Each beneficiary is liable for the first one hundred and fifty dollars (\$150.00) of the CHAMPUS-determined allowable amount on claims for care provided in the same fiscal year.

(2) Family Deductible: The total deductible amount for all members of a family with the same sponsor during one fiscal year shall not exceed three hundred dollars (\$300.00).

(C) CHAMPUS-approved Ambulatory Surgical Centers or Birthing Centers. No deductible shall be applied to allowable amounts for services or items rendered to active duty for authorized NATO dependents.

(D) Allowable Amount does not exceed Deductible Amount. If fiscal year allowable amounts for two or more beneficiary members of a family total less than \$100.00 (\$300.00 if paragraph (f) (2)(i)(B)(2) of this section applies), but more of the beneficiary members submit a claim for over \$50.00 (\$150.00 if paragraph (f)(2)(i)(B)(1) of this section applies), neither the family nor the individual deductible will have been met and no CHAMPUS benefits are payable.

(E) For any family the outpatient deductible amounts will be applied sequentially as the CHAMPUS claims are processed.

(F) If the fiscal year outpatient deductible under either paragraphs (f)(2)(i)(A) or (f)(2)(i)(B) of this section has been met by a beneficiary or a family through the submission of a claim or claims to a CHAMPUS fiscal intermediary in another geographic location from the location where a current claim is being submitted, the beneficiary or sponsor must obtain a deductible certificate from the CHAMPUS fiscal intermediary where the applicable beneficiary or family fiscal year deductible was met. Such deductible certificate must be attached to the current claim being submitted for benefits. Failure to obtain a deductible certificate under such circumstances will result in a second beneficiary or family fiscal year deductible being applied. However, this second deductible may be reimbursed once appropriate documentation, as described in paragraph (f)(2)(i)(F) of this section, is supplied to the CHAMPUS fiscal intermediary applying the second deductible.

(G) Notwithstanding the dates specified in paragraphs (f)(2)(i)(A) and (f)(2)(i)(B) of this section in the case of dependents of active duty members of rank E-5 or above with Persian Gulf Conflict service, dependents of service members who were killed in the Gulf, or who died subsequent to Gulf service, and of members who retired prior to October 1, 1991, after having served in the Gulf War, the deductible shall be the amount specified in paragraph (f)(2)(i)(A) of this section for care rendered prior to October 1, 1991, and the amount specified in paragraph (f)(2)(i)(B) of this section for care rendered on or after October 1, 1991.

(H) The Director, TRICARE Management Activity, may waive the annual individual or family fiscal year deductible for dependents of a Reserve Component member who is called or ordered to active duty for a period of more than 30 days or a National Guard member who is called or ordered to fulltime federal National Guard duty for a period of more than 30 days in support of a contingency operation (as defined in 10 U.S.C. 101(a)(13)). For purposes of this paragraph, a dependent is a lawful husband or wife of the member and a child is defined in paragraphs (b)(2)(ii)(A) through (F) and (b)(2)(ii)(H)(1), (2), and (4) of Sec 199.3.

(ii) Inpatient cost-sharing. Dependents of members of the Uniformed Services are responsible for the payment of the first \$25 of the allowable institutional costs incurred with each covered inpatient admission to a hospital or other authorized institutional provider (refer to Sec. 199.6 of the part), or the amount the beneficiary or sponsor would have been charged had the inpatient care been provided in a Uniformed Service hospital, whichever is greater.

NOTE: The Secretary of Defense (after consulting with the Secretary of Health and Human Services and the Secretary of Transportation) prescribes the fair charges for inpatient hospital care provided through Uniformed Services medical facilities. This determination is made each fiscal year.

(A) Inpatient cost-sharing payable with each separate inpatient admission. A separate cost-sharing amount (as described in paragraph (f)(2) of this section) is payable for each inpatient admission to a hospital or other authorized institution, regardless of the purpose of the admission (such as medical or surgical), regardless of the number of times the beneficiary is admitted, and regardless of whether or not the inpatient admissions are for the same or related conditions; except that successive inpatient admissions shall be deemed one inpatient confinement for the purpose of computing the inpatient cost-share payable, provided not more than 60 days have elapsed between the successive admissions. However, notwithstanding this provision, all admissions related to a single maternity episode shall be considered one confinement, regardless of the number of days between admissions (refer to paragraph (b) of this section).

(B) Multiple family inpatient admissions. A separate cost-sharing amount is payable for each inpatient admission, regardless of whether or not two or more beneficiary members of a family are admitted at the same time or from the same cause (such as an accident). A separate beneficiary inpatient cost-sharing amount must be applied for each separate admission on each beneficiary member of the family.

(C) Newborn patient in his or her own right. When a newborn infant remains as an inpatient in his or her own right (usually after the mother is discharged), the newborn child becomes the beneficiary and patient and the extended inpatient stay becomes a separate inpatient admission. In such a situation, a new, separate inpatient cost-sharing amount is

applied. If a multiple birth is involved (such as twins or triplets) and two or more newborn infants become patients in their own right, a separate inpatient cost-sharing amount must be applied to the inpatient stay for each newborn child who has remained as an inpatient in his or her own right.

(D) Inpatient cost-sharing for mental health services. For care provided on or after October 1, 1995, the inpatient cost-sharing for mental health services is \$20 per day for each day of the inpatient admission. This \$20 per day cost sharing amount applies to admissions to any hospital for mental health services, any residential treatment facility, any substance abuse rehabilitation facility, and any partial hospitalization program providing mental health or substance use disorder rehabilitation services.

(iii) Outpatient cost-sharing. Dependents of members of the Uniformed Services are responsible for payment of 20 percent of the CHAMPUS-determined allowable cost or charge beyond the annual fiscal year deductible amount (as described in paragraph (f)(2)(i) of this section) for otherwise covered services or supplies provided on an outpatient basis by authorized providers.

(iv) Ambulatory surgery. Notwithstanding the above provisions pertaining to outpatient cost-sharing, dependents of members of the Uniformed Services are responsible for payment of \$25 for surgical care that is authorized and received while in an outpatient status and that has been designated in guidelines issued by the Director, OCHAMPUS, or a designee.

(v) Psychiatric partial hospitalization services. Institutional and professional services provided under the psychiatric partial hospitalization program authorized by paragraph (b)(10) of this section shall be cost shared as inpatient services.

(vi) Transitional Assistance Management Program (TAMP). Members of the Armed Forces (and their family members) who are eligible for TAMP under paragraph 199.3(e) of this Part are subject to the same beneficiary or sponsor liability as family members of members of the uniformed services described in this paragraph (f)(2).

(3) Former members and dependents of former members. CHAMPUS beneficiary liability set forth for former members and dependents of former members is as follows:

(i) Annual fiscal year deductible for outpatient services or supplies. The annual fiscal year deductible for otherwise covered outpatient services or supplies provided former members and dependents of former members is the same as the annual fiscal year outpatient deductible applicable to dependents of active duty members of rank E-5 or above (refer to paragraph (f)(2)(i)(A) or (B) of this section).

(ii) Inpatient cost-sharing. Cost-sharing amounts for inpatient services shall be as follows:

(A) Services subject to the CHAMPUS DRG-based payment system. The cost-share shall be the lesser of: an amount calculated by multiplying a per diem amount by the total number of days in the hospital stay except the day of discharge; or 25 percent of the hospital's billed charges. The per diem amount shall be calculated so that, in the aggregate, the total cost-sharing amounts for these beneficiaries is equivalent to 25 percent of the CHAMPUS-determined allowable costs for covered services or supplies provided on an

inpatient basis by authorized providers. The per diem amount shall be published annually by OCHAMPUS.

(B) Services subject to the CHAMPUS mental health per diem payment system. The cost-share is dependent upon whether the hospital is paid a hospital-specific per diem or a regional per diem under the provisions of Sec. 199.14(a)(2). With respect to care paid for on the basis of a hospital specific per diem, the cost-share shall be 25% of the hospital-specific per diem amount. For care paid for on the basis of a regional per diem, the cost share shall be the lower of a fixed daily amount or 25% of the hospital's billed charges. The fixed daily amount shall be 25 percent of the per diem adjusted so that total beneficiary cost shares will equal 25 percent of total payments under the mental health per diem payment system. These fixed daily amount shall be updated annually and published in the Federal Register along with the per diems published pursuant to Sec. 199.14(a)(2)(iv)(B).

(C) Other services. For services exempt from the CHAMPUS DRG-based payment system and the CHAMPUS mental health per diem payment system and services provided by institutions other than hospitals, the cost-share shall be 25% of the CHAMPUS-determined allowable charges.

(iii) Outpatient cost-sharing. Former members and dependents of former members are responsible for payment of 25 percent of the CHAMPUS-determined allowable costs or charges beyond the annual fiscal year deductible amount (as described in paragraph (f)(2)(i) of this section) for otherwise covered services or supplies provided on an outpatient basis by authorized providers.

(iv) Psychiatric partial hospitalization services. Institutional and professional services provided under the psychiatric partial hospitalization program authorized by paragraph (b)(10) of this section shall be cost shared as inpatient services.

(4) Former spouses. CHAMPUS beneficiary liability for former spouses eligible under the provisions set forth in Sec. 199.3 of this part is as follows:

(i) Annual fiscal year deductible for outpatient services or supplies. An eligible former spouse is responsible for the payment of the first \$150.00 of the CHAMPUS-determined reasonable costs or charges for otherwise covered outpatient services or supplies provided in any one fiscal year. (Except for services received prior to April 1, 1991, the deductible amount is \$50.00). The former spouse cannot contribute to, nor benefit from, any family deductible of the member or former member to whom the former spouse was married or of any CHAMPUS-eligible children.

(ii) Inpatient cost-sharing. Eligible former spouses are responsible for payment of cost-sharing amounts the same as those required for former members and dependents of former members.

(iii) Outpatient cost-sharing. Eligible former spouses are responsible for payment of 25 percent of the CHAMPUS-determined reasonable costs or charges beyond the annual fiscal year deductible amount for otherwise covered services or supplies provided on an outpatient basis by authorized providers.

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(5) Cost-Sharing under the Military-Civilian Health Services Partnership Program. Cost-sharing is dependent upon the type of partnership program entered into, whether external or internal. (See paragraph (p) of Sec. 199.1, for general requirements of the Military-Civilian Health Services Partnership Program.)

(i) External Partnership Agreement. Authorized costs associated with the use of the civilian facility will be financed through CHAMPUS under the normal cost-sharing and reimbursement procedures applicable under CHAMPUS.

(ii) Internal Partnership Agreement. Beneficiary cost-sharing under internal agreements will be the same as charges prescribed for care in military treatment facilities.

(6)–(7) [Reserved]

(8) Cost-sharing for services provided under special discount arrangements--

(i) General rule. With respect to services determined by the Director, OCHAMPUS (or designee) to be covered by Sec. 199.14(e), the Director, OCHAMPUS (or designee) has authority to establish, as an exception to the cost-sharing amount normally required pursuant to this section, a different cost-share amount that appropriately reflects the application of the statutory cost-share to the discount arrangement.

(ii) Specific applications. The following are examples of applications of the general rule; they are not all inclusive.

(A) In the case of services provided by individual health care professionals and other noninstitutional providers, the cost-share shall be the usual percentage of the CHAMPUS allowable charge determined under Sec. 199.14(e).

(B) In the case of services provided by institutional providers normally paid on the basis of a pre-set amount (such as DRG-based amount under Sec. 199.14(a)(1) or per-diem amount under Sec. 199.14(a)(2)), if the discount rate is lower than the pre-set rate, the cost-share amount that would apply for a beneficiary other than an active duty dependent pursuant to the normal pre-set rate would be reduced by the same percentage by which the pre-set rate was reduced in setting the discount rate.

(9) Waiver of deductible amounts or cost-sharing not allowed--(i) General rule. Because deductible amounts and cost sharing are statutorily mandated, except when specifically authorized by law (as determined by the Director, OCHAMPUS), a provider may not waive or forgive beneficiary liability for annual deductible amounts or inpatient or outpatient cost sharing, as set forth in this section.

(ii) Exception for bad debts. This general rule is not violated in cases in which a provider has made all reasonable attempts to effect collection, without success, and determines in accordance with generally accepted fiscal management standards that the beneficiary liability in a particular case is an uncollectible bad debt.

(iii) Remedies for noncompliance. Potential remedies for noncompliance with this requirement include:

(A) A claim for services regarding which the provider has waived the beneficiary's liability

may be disallowed in full, or, alternatively, the amount payable for such a claim may be reduced by the amount of the beneficiary liability waived.

(B) Repeated noncompliance with this requirement is a basis for exclusion of a provider.

(10) Catastrophic loss protection for basic program benefits. Fiscal year limits, or catastrophic caps, on the amounts beneficiaries are required to pay are established as follows:

(i) Dependents of active duty members. The maximum family liability is \$1,000 for deductibles and cost-shares based on allowable charges for Basic Program services and supplies received in a fiscal year.

(ii) All other beneficiaries. For all other categories of beneficiary families (including those eligible under CHAMPVA) the fiscal year cap is \$3,000.

(iii) Payment after cap is met. After a family has paid the maximum cost-share and deductible amounts (dependents of active duty members \$1,000 and all others \$3,000), for a fiscal year, CHAMPUS will pay allowable amounts for remaining covered services through the end of that fiscal year.

Note to paragraph (f)(10): Under the Defense Authorization Act for Fiscal Year 2001, the cap for beneficiaries other than dependents of active duty members was reduced from \$7,500 to \$3,000 effective October 30, 2000. Prior to this, the Defense Authorization Act for Fiscal Year 1993 reduced this cap from \$10,000 to \$7,500 on October 1, 1992. The cap remains at \$1,000 for dependents of active duty members.

(11) Beneficiary or sponsor liability under the Pharmacy Benefits Program. Beneficiary or sponsor liability under the Pharmacy Benefits Program is addressed in Sec. 199.21.

(12) Elimination of cost-sharing for certain preventive services.(i) (i) Effective for dates of service on or after October 14, 2008, beneficiaries, subject to the limitation in paragraph (f)(12)(iii) of this section, shall not pay any cost-share for preventive services listed in paragraph (e)(28)(i) through (iv) of this section. The beneficiary shall not be required to pay any portion of the cost of these preventive services even if the beneficiary has not satisfied the deductible for that year.

(ii) Beneficiaries who paid a cost-share for preventive services listed in paragraph (e)(28)(i) through (iv) of this section on or after October 14, 2008, may request reimbursement until January 28, 2013 according to procedures established by the Director, TRICARE Management Activity.

(iii) This elimination of cost-sharing for preventive services does not apply to any beneficiary who is a Medicare-eligible beneficiary. For purposes of this section, the term "Medicare-eligible" beneficiary is defined in 10 U.S.C. 1111(b) and refers to a person eligible for Medicare Part A.

(iv) Appropriate copayments and deductibles will apply for all services not listed in paragraph (e)(28) of this section, whether considered preventive in nature or not.

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(g) Exclusions and limitations. In addition to any definitions, requirements, conditions, or limitations enumerated and described in other sections of this part, the following specifically are excluded from the Basic Program:

(1) Not medically or psychologically necessary. Services and supplies that are not medically or psychologically necessary for the diagnosis or treatment of a covered illness (including mental disorder) or injury, for the diagnosis and treatment of pregnancy or well-baby care except as provided in the following paragraph.

(2) Unnecessary diagnostic tests. X-ray, laboratory, and pathological services and machine diagnostic tests not related to a specific illness or injury or a definitive set of symptoms except for cancer screening mammography and cancer screening papanicolaou (PAP) tests provided under the terms and conditions contained in the guidelines adopted by the Director, OCHAMPUS.

(3) Institutional level of care. Services and supplies related to inpatient stays in hospitals or other authorized institutions above the appropriate level required to provide necessary medical care.

(4) Diagnostic admission. Services and supplies related to an inpatient admission primarily to perform diagnostic tests, examinations, and procedures that could have been and are performed routinely on an outpatient basis.

NOTE: If it is determined that the diagnostic x-ray, laboratory, and pathological services and machine tests performed during such admission were medically necessary and would have been covered if performed on an outpatient basis, CHAMPUS benefits may be extended for such diagnostic procedures only, but cost-sharing will be computed as if performed on an outpatient basis.

(5) Unnecessary postpartum inpatient stay, mother or newborn. Postpartum inpatient stay of a mother for purposes of staying with the newborn infant (usually primarily for the purpose of breast feeding the infant) when the infant (but not the mother) requires the extended stay; or continued inpatient stay of a newborn infant primarily for purposes of remaining with the mother when the mother (but not the newborn infant) requires extended postpartum inpatient stay.

(6) Therapeutic absences. Therapeutic absences from an inpatient facility, except when such absences are specifically included in a treatment plan approved by the Director, OCHAMPUS, or a designee. For cost-sharing provisions refer to Sec. 199.14, paragraph (f)(3).

(7) Custodial care. Custodial care as defined in Sec. 199.2.

(8) Domiciliary care. Domiciliary care as defined in Sec. 199.2.

(9) Rest or rest cures. Inpatient stays primarily for rest or rest cures.

(10) Amounts above allowable costs or charges. Costs of services and supplies to the extent amounts billed are over the CHAMPUS determined allowable cost or charge, as provided for in Sec. 199.14.

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(11) No legal obligation to pay, no charge would be made. Services or supplies for which the beneficiary or sponsor has no legal obligation to pay; or for which no charge would be made if the beneficiary or sponsor was not eligible under CHAMPUS; or whenever CHAMPUS is a secondary payer for claims subject to the CHAMPUS DRG-based payment system, amounts, when combined with the primary payment, which would be in excess of charges (or the amount the provider is obligated to accept as payment in full, if it is less than the charges).

(12) Furnished without charge. Services or supplies furnished without charge.

(13) Furnished by local, state, or Federal Government. Services and supplies paid for, or eligible for payment, directly or indirectly by a local, state, or Federal Government, except as provided under CHAMPUS, or by government hospitals serving the general public, or medical care provided by a Uniformed Service medical care facility, or benefits provided under title XIX of the Social Security Act (Medicaid) (refer to Sec. 199.8 of this part).

(14) Study, grant, or research programs. Services and supplies provided as a part of or under a scientific or medical study, grant, or research program.

(15) Unproven drugs, devices, and medical treatments or procedures. By law, CHAMPUS can only cost-share medically necessary supplies and services. Any drug, device, or medical treatment or procedure, the safety and efficacy of which have not been established, as described in this paragraph (g)(15), is unproved and cannot be cost-shared by CHAMPUS except as authorized under paragraph 199.4(e)(26) of this part.

(i) A drug, device, or medical treatment or procedure is unproven:

(A) If the drug or device cannot be lawfully marketed without the approval or clearance of the United States Food and Drug Administration (FDA) and approval or clearance for marketing has not been given at the time the drug or device is furnished to the patient.

NOTE: Although the use of drugs and medicines not approved by the FDA for commercial marketing, that is for use by humans, (even though permitted for testing on humans) is excluded from coverage as unproven, drugs grandfathered by the Federal Food, Drug and Cosmetic Act of 1938 may be covered by CHAMPUS as if FDA approved.

Certain cancer drugs, designated as Group C drugs (approved and distributed by the National Cancer Institute) and Treatment Investigational New Drugs (INDs), are not covered under CHAMPUS because they are not approved for commercial marketing by the FDA. However, medical care related to the use of Group C drugs and Treatment INDs can be cost-shared under CHAMPUS when the patient's medical condition warrants their administration and the care is provided in accordance with generally accepted standards of medical practice.

CHAMPUS will consider coverage of off-label uses of drugs and devices that meet the definition of Off-Label Use of a Drug or Device in Sec. 199.2(b). Approval for reimbursement of off-label uses requires review for medical necessity and also requires demonstrations from medical literature, national organizations, or technology assessment bodies that the off-label use of the drug or device is safe, effective, and in accordance with nationally accepted standards of practice in the medical community.

(B) If a medical device (as defined by 21 U.S.C. 321(h)) with an Investigational Device Exemption (IDE) approved by the Food and Drug Administration is categorized by the FDA as experimental/investigational (FDA Category A).

NOTE: CHAMPUS will consider for coverage a device with an FDA-approved IDE categorized by the FDA as non-experimental/investigational (FDA Category B) for CHAMPUS beneficiaries participating in FDA approved clinical trials. Coverage of any such Category B device is dependent on its meeting all other requirements of the laws and rules governing CHAMPUS and upon the beneficiary involved meeting the FDA-approved IDE study protocols.

(C) Unless reliable evidence shows that any medical treatment or procedure has been the subject of well-controlled studies of clinically meaningful endpoints, which have determined its maximum tolerated dose, its toxicity, its safety, and its efficacy as compared with standard means of treatment or diagnosis. (See the definition of *reliable evidence* in Sec. 199.2 of this part for the procedures used in determining if a medical treatment or procedure is unproven.)

(D) If reliable evidence shows that the consensus among experts regarding the medical treatment or procedure is that further studies or clinical trials are necessary to determine its maximum tolerated doses, its toxicity, its safety, or its effectiveness as compared with the standard means of treatment or diagnosis (see the definition of reliable evidence in Sec. 199.2 for the procedures used in determining if a medical treatment or procedure is unproven).

(ii) CHAMPUS benefits for rare diseases are reviewed on a case-by-case basis by the Director, Office of CHAMPUS, or a designee. In reviewing the case, the Director, or a designee, may consult with any or all of the following sources to determine if the proposed therapy is considered safe and effective:

- (A) Trials published in refereed medical literature.
- (B) Formal technology assessments.
- (C) National medical policy organization positions.
- (D) National professional associations.
- (E) National expert opinion organizations.

(iii) Care excluded. This exclusion from benefits includes all services directly related to the unproven drug, device, or medical treatment or procedure. However, CHAMPUS may cover services or supplies when there is no logical or causal relationship between the unproven drug, device or medical treatment or procedure and the treatment at issue or where such a logical or causal relationship cannot be established with a sufficient degree of certainty. This CHAMPUS coverage is authorized in the following circumstances:

- (A) Treatment that is not related to the unproven drug, device or medical treatment or procedure; e.g., medically necessary in the absence of the unproven treatment.
- (B) Treatment which is necessary follow-up to the unproven drug, device or medical treatment or procedure but which might have been necessary in the absence of the unproven

treatment.

(16) Immediate family, household. Services or supplies provided or prescribed by a member of the beneficiary's immediate family, or a person living in the beneficiary's or sponsor's household.

(17) Double coverage. Services and supplies that are (or are eligible to be) payable under another medical insurance or program, either private or governmental, such as coverage through employment or Medicare (refer to Sec. 199.8 of this part).

(18) Nonavailability Statement required. Services and supplies provided under circumstances or in geographic locations requiring a Nonavailability Statement (DD Form 1251), when such a statement was not obtained.

(19) Preauthorization required. Services or supplies which require preauthorization if preauthorization was not obtained. Services and supplies which were not provided according to the terms of the preauthorization. The Director, OCHAMPUS, or a designee, may grant an exception to the requirement for preauthorization if the services otherwise would be payable except for the failure to obtain preauthorization.

(20) Psychoanalysis or psychotherapy, part of education. Psychoanalysis or psychotherapy provided to a beneficiary or any member of the immediate family that is credited towards earning a degree or furtherance of the education or training of a beneficiary or sponsor, regardless of diagnosis or symptoms that may be present.

(21) Runaways. Inpatient stays primarily to control or detain a runaway child, whether or not admission is to an authorized institution.

(22) Services or supplies ordered by a court or other government agency. Services or supplies, including inpatient stays, directed or agreed to by a court or other governmental agency. However, those services and supplies (including inpatient stays) that otherwise are medically or psychologically necessary for the diagnosis or treatment of a covered condition and that otherwise meet all CHAMPUS requirements for coverage are not excluded.

(23) Work-related (occupational) disease or injury. Services and supplies required as a result of occupational disease or injury for which any benefits are payable under a worker's compensation or similar law, whether or not such benefits have been applied for or paid; except if benefits provided under such laws are exhausted.

(24) Cosmetic, reconstructive, or plastic surgery. Services and supplies in connection with cosmetic, reconstructive, or plastic surgery except as specifically provided in paragraph (e)(8) of this section.

(25) Surgery, psychological reasons. Surgery performed primarily for psychological reasons (such as psychogenic).

(26) Electrolysis.

(27) Dental care. Dental care or oral surgery, except as specifically provided in paragraph (e)(10) of this section.

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(28) Obesity, weight reduction. Service and supplies related "solely" to obesity or weight reduction or weight control whether surgical or nonsurgical; wiring of the jaw or any procedure of similar purpose, regardless of the circumstances under which performed (except as provided in paragraph (e)(15) of this section).

(29) Transsexualism or such other conditions as gender dysphoria. Services and supplies related to transsexualism or such other conditions as gender dysphoria (including, but not limited, to intersex surgery, psychotherapy, and prescription drugs), except as specifically provided in paragraph (e)(7) of this section.

(30) Therapy or counseling for sexual dysfunctions or sexual inadequacies. Sex therapy, sexual advice, sexual counseling, sex behavior modification, psychotherapy for mental disorders involving sexual deviations (i.e., transvestic fetishism), or other similar services, and any supplies provided in connection with therapy for sexual dysfunctions or inadequacies.

(31) Corns, calluses, and toenails. Removal of corns or calluses or trimming of toenails and other routine podiatry services, except those required as a result of a diagnosed systemic medical disease affecting the lower limbs, such as severe diabetes.

(32) Dyslexia.

(33) Surgical sterilization, reversal. Surgery to reverse surgical sterilization procedures.

(34) Noncoital reproductive procedures including artificial insemination, in-vitro fertilization, gamete intrafallopian transfer and all other such reproductive technologies. Services and supplies related to artificial insemination (including semen donors and semen banks), in-vitro fertilization, gamete intrafallopian transfer and all other noncoital reproductive technologies.

(35) Nonprescription contraceptives.

(36) Tests to determine paternity or sex of a child. Diagnostic tests to establish paternity of a child; or tests to determine sex of an unborn child.

(37) Preventive care. Except as stated in paragraph (e)(28) of this section, preventive care, such as routine, annual, or employment-requested physical examinations and routine screening procedures.

(38) Chiropractors and naturopaths. Services of chiropractors and naturopaths whether or not such services would be eligible for benefits if rendered by an authorized provider.

(39) Counseling. Educational, vocational, and nutritional counseling and counseling for socioeconomic purposes, stress management, and/or lifestyle modification purposes, except that the following are not excluded:

(i) Services provided by a certified marriage and family therapist, pastoral or mental health counselor in the treatment of a mental disorder as specifically provided in paragraph (c)(3)(ix) of this section and in Sec. 199.6.

(ii) Diabetes self-management training (DSMT) as specifically provided in paragraph (d)(3)(ix) of this section.

(iii) Smoking cessation counseling and education as specifically provided in paragraph (e)(30) of this section.

(iv) Services provided by alcoholism rehabilitation counselors only when rendered in a CHAMPUS-authorized treatment setting and only when the cost of those services is included in the facility's CHAMPUS-determined allowable cost rate.

(40) Acupuncture. Acupuncture, whether used as a therapeutic agent or as an anesthetic.

(41) Hair transplants, wigs/hair pieces/cranial prosthesis.

NOTE: In accordance with section 744 of the DoD Appropriation Act for 1981 (Pub. L. 96-527), CHAMPUS coverage for wigs or hairpieces is permitted effective December 15, 1980, under the conditions listed below. Continued availability of benefits will depend on the language of the annual DoD Appropriation Acts.

(i) Benefits provided. Benefits may be extended, in accordance with the CHAMPUS-determined allowable charge, for one wig or hairpiece per beneficiary (lifetime maximum) when the attending physician certifies that alopecia has resulted from treatment of a malignant disease and the beneficiary certifies that a wig or hairpiece has not been obtained previously through the U.S. Government (including the Veterans Administration).

(ii) Exclusions. The wig or hairpiece benefit does not include coverage for the following:

(A) Alopecia resulting from conditions other than treatment of malignant disease.

(B) Maintenance, wig or hairpiece supplies, or replacement of the wig or hairpiece.

(C) Hair transplants or any other surgical procedure involving the attachment of hair or a wig or hairpiece to the scalp.

(D) Any diagnostic or therapeutic method or supply intended to encourage hair regrowth.

(42) Education or training. Self-help, academic education or vocational training services and supplies, unless the provisions of Sec. 199.4, paragraph (b)(1)(v) relating to general or special education, apply.

(43) Exercise/relaxation/comfort/sporting items or sporting devices. Exercise equipment, to include items primarily and customarily designed for use in sports or recreational activities, spas, whirlpools, hot tubs, swimming pools health club memberships or other such charges or items.

(44) Exercise. General exercise programs, even if recommended by a physician and regardless of whether or not rendered by an authorized provider. In addition, passive exercises and range of motion exercises also are excluded, except when prescribed by a physician and rendered by a physical therapist concurrent to, and as an integral part of, a comprehensive program of physical therapy.

(45) (Reserved).

(46) Vision care. Eye exercises or visual training (orthoptics).

(47) Eye and hearing examinations. Eye and hearing examinations except as specifically provided in paragraphs (c)(2)(xvi), (c)(3)(xi), and (e)(24) of this section, or except when rendered in connection with medical or surgical treatment of a covered illness or injury.

(48) Prosthetic devices. Prostheses other than those determined by the Director, OCHAMPUS to be necessary because of significant conditions resulting from trauma, congenital anomalies, or disease. All dental prostheses are excluded, except for those specifically required in connection with otherwise covered orthodontia directly related to the surgical correction of a cleft palate anomaly.

(49) Orthopedic shoes. Orthopedic shoes, arch supports, shoe inserts, and other supportive devices for the feet, including special-ordered, custom-made built-up shoes, or regular shoes later built up.

(50) Eyeglasses. Eyeglasses, spectacles, contact lenses, or other optical devices, except as specifically provided under paragraph (e)(6) of this section.

(51) Hearing aids. Hearing aids or other auditory sensory enhancing devices, except those allowed in paragraph (e)(24) of this section.

(52) Telephone services. Services or advice rendered by telephone are excluded, except that a diagnostic or monitoring procedure which incorporates electronic transmission of data or remote detection and measurement of a condition, activity, or function (biotelemetry) is not excluded when:

(i) The procedure without electronic transmission of data or biotelemetry is otherwise an explicit or derived benefit of this section; and

(ii) The addition of electronic transmission of data or biotelemetry to the procedure is found by the Director, CHAMPUS, or designee, to be medically necessary and appropriate medical care which usually improves the efficiency of the management of a clinical condition in defined circumstances; and

(iii) That each data transmission or biotelemetry device incorporated into a procedure that is otherwise an explicit or derived benefit of this section, has been classified by the U.S. Food and Drug Administration, either separately or as a part of a system, for use consistent with the defined circumstances in paragraph (g)(52)(ii) of this section.

(53) Air conditioners, humidifiers, dehumidifiers, and purifiers.

(54) Elevators or chair lifts.

(55) Alterations. Alterations to living spaces or permanent features attached thereto, even when necessary to accommodate installation of covered durable medical equipment or to facilitate entrance or exit.

- (56) Clothing. Items of clothing or shoes, even if required by virtue of an allergy (such as cotton fabric as against synthetic fabric and vegetable-dyed shoes).
- (57) Food, food substitutes. Food, food substitutes, vitamins, or other nutritional supplements, including those related to prenatal care.
- (58) Enuretic. Enuretic conditioning programs, but enuretic alarms may be cost-shared when determined to be medically necessary in the treatment of enuresis.
- (59) Duplicate equipment. As defined in Sec. 199.2, duplicate equipment is excluded.
- (60) Autopsy and postmortem.
- (61) Camping. All camping even though organized for a specific therapeutic purpose (such as diabetic camp or a camp for emotionally disturbed children), and even though offered as a part of an otherwise covered treatment plan or offered through a CHAMPUS-approved facility.
- (62) Housekeeper, companion. Housekeeping, homemaker, or attendant services; sitter or companion.
- (63) Noncovered condition/treatment, unauthorized provider. All services and supplies (including inpatient institutional costs) related to a non-covered condition or treatment, including any necessary follow-on care or the treatment of complications, are excluded from coverage except as provided under paragraph (e)(9) of this section. In addition, all services and supplies provided by an unauthorized provider are excluded.
- (64) Comfort or convenience. Personal, comfort, or convenience items such as beauty and barber services, radio, television, and telephone.
- (65) (Reserved)
- (66) Megavitamin psychiatric therapy, orthomolecular psychiatric therapy.
- (67) Transportation. All transportation except by ambulance, as specifically provided under paragraph (d), and except as authorized in paragraph (e)(5) of this section.
- (68) Travel. All travel even though prescribed by a physician and even if its purpose is to obtain medical care, except as specified in paragraph (a)(6) of this section in connection with a CHAMPUS-required physical examination and as specified in Sec. 199.17(n)(2)(vi).
- (69) Institutions. Services and supplies provided by other than a hospital, unless the institution has been approved specifically by OCHAMPUS. Nursing homes, intermediate care facilities, halfway houses, homes for the aged, or institutions of similar purpose are excluded from consideration as approved facilities under the Basic Program.

NOTE: In order to be approved under CHAMPUS, an institution must, in addition to meeting CHAMPUS standards, provide a level of care for which CHAMPUS benefits are payable.

(70) (Reserved)

(71) (Reserved)

(72) Inpatient mental health services. Effective for care received on or after October 1, 1991, services in excess of 30 days in any fiscal year (or in an admission), in the case of a patient nineteen years of age or older, 45 days in any fiscal year (or in an admission) in the case of a patient under 19 years of age, or 150 days in any fiscal year (or in an admission) in the case of inpatient mental health services provided as residential treatment care, unless coverage for such services is granted by a waiver by the Director, OCHAMPUS, or a designee. In cases involving the day limitations, waivers shall be handled in accordance with paragraphs (b)(8) or (b)(9) of this section. For services prior to October 1, 1991, services in excess of 60 days in any calendar year unless additional coverage is granted by the Director, OCHAMPUS, or a designee.

(73) Economic interest in connection with mental health admissions. Inpatient mental health services (including both acute care and RTC services) are excluded for care received when a patient is referred to a provider of such services by a physician (or other health care professional with authority to admit) who has an economic interest in the facility to which the patient is referred, unless a waiver is granted. Requests for waiver shall be considered under the same procedure and based on the same criteria as used for obtaining preadmission authorization (or continued stay authorization for emergency admissions), with the only additional requirement being that the economic interest be disclosed as part of the request. The same reconsideration and appeals procedures that apply to day limit waivers shall also apply to decisions regarding requested waivers of the economic interest exclusion. However, a provider may appeal a reconsidered determination that an economic relationship constitutes an economic interest within the scope of the exclusion to the same extent that a provider may appeal determination under Sec. 199.15(i)(3). This exclusion does not apply to services under the Extended Care Health Option (ECHO) in Sec. 199.5 or provided as partial hospital care. If a situation arises where a decision is made to exclude CHAMPUS payment solely on the basis of the provider's economic interest, the normal CHAMPUS appeals process will be available.

(74) Not specifically listed. Services and supplies not specifically listed as a benefit in this part. This exclusion is not intended to preclude extending benefits for those services or supplies specifically determined to be covered within the intent of this part by the Director, OCHAMPUS, or a designee, even though not otherwise listed.

NOTE: The fact that a physician may prescribe, order, recommend, or approve a service or supply does not, of itself, make it medically necessary or make the charge an allowable expense, even though it is not listed specifically as an exclusion.

(h) Payment and liability for certain potentially excludable services under the Peer Review Organization program--(1) Applicability. This subsection provides special rules that apply only to services retrospectively determined under the Peer Review organization (PRO) program (operated pursuant to Sec. 199.15) to be potentially excludable (in whole or in part) from the basic program under paragraph (g) of this section. Services may be excluded by reason of being not medically necessary (paragraph (g)(1) of this section), at an inappropriate level (paragraph (g)(3) of this section), custodial care (paragraph (g)(7) of this section) or other reason relative to reasonableness, necessity or appropriateness (which

services shall throughout the remainder of this subsection, be referred to as “not medically necessary”). (Also throughout the remainder of the subsection, “services” includes items and “provider” includes supplier). This paragraph does not apply to coverage determinations made by OCHAMPUS or the fiscal intermediaries which are not based on medical necessity determinations made under the PRO program.

(2) Payment for certain potentially excludable expenses. Services determined under the PRO program to be potentially excludable by reason of the exclusions in paragraph (g) of this section for not medically necessary services will not be determined to be excludable if neither the beneficiary to whom the services were provided nor the provider (institutional or individual) who furnished the services knew, or could reasonably have been expected to know, that the services were subject to those exclusions. Payment may be made for such services as if the exclusions did not apply.

(3) Liability for certain excludable services. In any case in which items or services are determined excludable by the PRO program by reason of being not medically necessary and payment may not be made under paragraph (h)(2) of this section because the requirements of paragraph (h)(2) of this section are not met, the beneficiary may not be held liable (and shall be entitled to a full refund from the provider of the amount excluded and any cost share amount already paid) if:

(i) The beneficiary did not know and could not reasonably have been expected to know that the services were excludable by reason of being not medically necessary; and

(ii) The provider knew or could reasonably have been expected to know that the items or services were excludable by reason of being not medically necessary.

(4) Criteria for determining that beneficiary knew or could reasonably have been expected to have known that services were excludable. A beneficiary who receives services excludable by reason of being not medically necessary will be found to have known that the services were excludable if the beneficiary has been given written notice that the services were excludable or that similar or comparable services provided on a previous occasion were excludable and that notice was given by the OCHAMPUS, CHAMPUS PRO or fiscal intermediary, a group or committee responsible for utilization review for the provider, or the provider who provided the services.

(5) Criteria for determining that provider knew or could reasonably have been expected to have known that services were excludable. An institutional or individual provider will be found to have known or been reasonably expected to have known that services were excludable under this subsection under any one of the following circumstances:

(i) The PRO or fiscal intermediary had informed the provider that the services provided were excludable or that similar or reasonably comparable services were excludable.

(ii) The utilization review group or committee for an institutional provider or the beneficiary’s attending physician had informed the provider that the services provided were excludable.

(iii) The provider had informed the beneficiary that the services were excludable.

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(iv) The provider had received written materials, including notices, manual issuances, bulletins, guides, directives or other materials, providing notification of PRO screening criteria specific to the condition of the beneficiary. Attending physicians who are members of the medical staff of an institutional provider will be found to have also received written materials provided to the institutional provider.

(v) The services that are at issue are the subject of what are generally considered acceptable standards of practice by the local medical community.

(vi) Preadmission authorization was available but not requested, or concurrent review requirements were not followed.

[51 FR 24008, Jul 1, 1986; 67 FR 15725, Apr 3, 2002; 67 FR 18826, Apr 17, 2002; 67 FR 40602, Jun 13, 2002; 67 FR 42720, Jun 25, 2002; 67 FR 45311, Jul 9, 2002; 68 FR 44880, Jul 31, 2003; 68 FR 44883, Jul 31, 2003; 68 FR 65173, Nov 19, 2003; 69 FR 29229, May 21, 2004; 69 FR 44947, Jul 28, 2004; 69 FR 51564, Aug 20, 2004; 69 FR 55359, Sep 14, 2004; 69 FR 60554, Oct 12, 2004; 70 FR 12802, Mar 16, 2005; 70 FR 61377, Oct 24, 2005; 71 FR 31944, Jun 2, 2006; 71 FR 35390, Jun 20, 2006; 72 FR 54353, Sep 25, 2007; 73 FR 46809, Aug 12, 2008; 73 FR 74965, Dec 10, 2008; 74 FR 34696, Jul 17, 2009; 75 FR 47459, Aug 6, 2010; 75 FR 47461, Aug 6, 2010; 75 FR 50882, Aug 18, 2010; 75 FR 2253, Jan 13, 2011; 76 FR 8297, Feb 14, 2011; 76 FR 57642, Sep 16, 2011; 76 FR 80743, Dec 27, 2011; 76 FR 81370, Dec 28, 2011; 77 FR 38175, Jun 27, 2012; 77 FR 38178, Jun 27, 2012; 78 FR 12952, Feb 26, 2013; 78 FR 13240, Feb 27, 2013; 78 FR 62430, Oct 22, 2013; 79 FR 41641, Jul 17, 2014; 79 FR 78707, Dec 31, 2014; **79 FR 78712, Dec 31, 2014**]

EDITORIAL NOTE: For Federal Register citations affecting Sec. 199.4, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

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PART 199.5 - TRICARE EXTENDED CARE HEALTH OPTION (ECHO)

(a) General. (1) The TRICARE ECHO is essentially a supplemental program to the TRICARE Basic Program. It does not provide acute care nor benefits available through the TRICARE Basic Program.

(2) The purpose of the ECHO is to provide an additional financial resource for an integrated set of services and supplies designed to assist in the reduction of the disabling effects of the ECHO-eligible dependent's qualifying condition. Services include those necessary to maintain, minimize or prevent deterioration of function of an ECHO-eligible dependent.

(b) Eligibility. (1) The following categories of TRICARE/CHAMPUS beneficiaries with a qualifying condition are ECHO-eligible dependents:

(i) A spouse, child, or unmarried person (as described in Sec. 199.3(b)(2)(i), (b)(2)(ii), or (b)(2)(iv)) of a member of the Uniformed Services on active duty for a period of more than 30 days.

(ii) An abused dependent as described in Sec. 199.3(b)(2)(iii).

(iii) A spouse, child, or unmarried person (as described in Sec. 199.3(b)(2)(i), (b)(2)(ii), or (b)(2)(iv)), of a member of the Uniformed Services who dies while on active duty for a period of more than 30 days and whose death occurs on or after October 7, 2001. In such case, an eligible surviving spouse remains eligible for benefits under the ECHO for a period of 3 years from the date the active duty sponsor dies. Any other eligible surviving dependent remains eligible for benefits under the ECHO for a period of three years from the date the active duty sponsor dies or until the surviving eligible dependent:

(A) Attains 21 years of age, or

(B) Attains 23 years of age or ceases to pursue a full-time course of study prior to attaining 23 years of age, if, at 21 years of age, the eligible surviving dependent is enrolled in a full-time course of study in a secondary school or in a full-time course of study in an institution of higher education approved by Secretary of Defense and was, at the time of the sponsor's death, in fact dependent on the member for over one-half of such dependent's support.

(iv) A spouse, child, or unmarried person (as defined in paragraphs Sec. 199.3(b)(2)(i), (b)(2)(ii), or (b)(2)(iv)) of a deceased member of the Uniformed Services who, at the time of the member's death was receiving benefits under ECHO, and the member at the time of death was eligible for receipt of hostile-fire pay, or died as a result of a disease or injury incurred while eligible for such pay. In such a case, the surviving dependent remains eligible for benefits under ECHO through midnight of the dependent's twenty-first birthday.

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- (2) Qualifying condition. The following are qualifying conditions:
 - (i) Mental retardation. A diagnosis of moderate or severe mental retardation made in accordance with the criteria of the current edition of the "Diagnostic and Statistical Manual of Mental Disorders" published by the American Psychiatric Association.
 - (ii) Serious physical disability. A serious physical disability as defined in Sec. 199.2.
 - (iii) Extraordinary physical or psychological condition. An extraordinary physical or psychological condition as defined in Sec. 199.2.
 - (iv) Infant/toddler. Beneficiaries under the age of 3 years who are diagnosed with a neuromuscular developmental condition or other condition that is expected to precede a diagnosis of moderate or severe mental retardation or a serious physical disability, shall be deemed to have a qualifying condition for the ECHO. The Director, TRICARE Management Activity or designee shall establish criteria for ECHO eligibility in lieu of the requirements of paragraphs (b)(2)(i), (ii) or (iii) of this section.
 - (v) Multiple disabilities. The cumulative effect of multiple disabilities, as determined by the Director, TRICARE Management Activity or designee shall be used in lieu of the requirements of paragraphs (b)(2)(i), (ii) or (iii) of this section to determine a qualifying condition when the beneficiary has two or more disabilities involving separate body systems.
- (3) Loss of ECHO eligibility. Eligibility for ECHO benefits ceases as of 12:01 a.m. of the day following the day that:
 - (i) The sponsor ceases to be an active duty member for any reason other than death; or
 - (ii) Eligibility based upon the abused dependent provisions of paragraph (b)(1)(ii) of this section expires; or
 - (iii) Eligibility based upon the deceased sponsor provisions of paragraphs (b)(1)(iii) or (iv) of this section expires; or
 - (iv) Eligibility based upon a beneficiary's participation in the Transitional Assistance Management Program ends; or
 - (v) The Director, TRICARE Management Activity or designee determines that the beneficiary no longer has a qualifying condition.
- (c) **ECHO benefit.** Items and services that the Director, TRICARE Management Activity or designee has determined are capable of confirming, arresting, or reducing the severity of the disabling effects of a qualifying condition, includes, but are not limited to:
 - (1) Diagnostic procedures to establish a qualifying condition or to measure the extent of functional loss resulting from a qualifying condition.
 - (2) Medical, habilitative, rehabilitative services and supplies, durable equipment and assistive technology (AT) devices that assist in the reduction of the disabling effects of a qualifying condition. Benefits shall be provided in the beneficiary's home or another

environment, as appropriate. An AT device may be covered only if it is recommended in a beneficiary's Individual Educational Program (IEP) or, if the beneficiary is not eligible for an IEP, the AT device is an item or educational learning device normally included in an IEP and is preauthorized under ECHO as an integral component of the beneficiary's individual comprehensive health care services plan (including rehabilitation) as prescribed by a TRICARE authorized provider.

(i) An AT device may be covered under ECHO only if it is not otherwise covered by TRICARE as durable equipment, a prosthetic, augmentation communication device, or other benefits under Sec. 199.4.

(ii) An AT device may include an educational learning device directly related to the beneficiary's qualifying condition when recommended by an IEP and not otherwise provided by State or local government programs. If an individual is not eligible for an IEP, an educational learning device normally included in the IEP may be authorized as if directly related to the beneficiary's qualifying condition and prescribed by a TRICARE authorized provider as part of the beneficiary's individual comprehensive health care services plan.

(iii) Electronic learning devices may include the hardware and software as appropriate. The Director, DHA, shall determine the types and (or) platforms of electronic devices and the replacement lifecycle of the hardware and its supporting software. All upgrades or replacements shall require a recommendation from the individual's IEP or the individual's comprehensive health care services plan.

(iv) Duplicative or redundant hardware platforms are not authorized.

Note to paragraph (c)(2)(iv): When one or more electronic platforms such as a desktop computer, laptop, notebook or tablet can perform the same functions in relation to the teaching or educational objective directly related to the qualifying condition, it is the intent of this provision to allow only one electronic platform that may be chosen by the beneficiary. Duplicative or redundant platforms are not allowed; however, a second platform may be obtained, if the individual's IEP recommends one platform such as a computer for the majority of the learning objectives, but there exists another objective, which cannot be performed on that platform. In these limited circumstances, the beneficiary may submit a request with the above justification to the Director, TMA, who may authorize a second device.

(v) AT devices damaged through improper use of the device as well as lost or stolen devices may not be replaced until the device would next be eligible for a lifecycle replacement.

(vi) AT devices do not include equipment or devices whose primary purpose is to assist the individual to engage in sports or recreational activities.

(3) Training that teaches the use of assistive technology devices or to acquire skills that are necessary for the management of the qualifying condition. Such training is also authorized for the beneficiary's immediate family. Vocational training, in the beneficiary's home or a facility providing such, is also allowed.

(4) Special education as provided by the Individuals with Disabilities Education Act and

defined at 34 CFR 300.26 and that is specifically designed to accommodate the disabling effects of the qualifying condition.

(5) Institutional care within a state, as defined in Sec. 199.2, in private nonprofit, public, and state institutions and facilities, when the severity of the qualifying condition requires protective custody or training in a residential environment. For the purpose of this section protective custody means residential care that is necessary when the severity of the qualifying condition is such that the safety and well-being of the beneficiary or those who come into contact with the beneficiary may be in jeopardy without such care.

(6) Transportation of an ECHO beneficiary receiving benefits under paragraph (c)(5), and a medical attendant when necessary to assure the beneficiary's safety, to or from a facility or institution to receive authorized ECHO services or items.

(7) Respite care. ECHO beneficiaries are eligible for 16 hours of respite care per month in any month during which the beneficiary otherwise receives an ECHO benefit(s). Respite care is defined in Sec. 199.2. Respite care services will be provided by a TRICARE-authorized home health agency and will be designed to provide health care services for the covered beneficiary, and not baby-sitting or child-care services for other members of the family. The benefit will not be cumulative, that is, any respite care hours not used in one month will not be carried over or banked for use on another occasion.

(i) TRICARE-authorized home health agencies must provide and bill for all authorized ECHO respite care services through established TRICARE claims' mechanisms. No special billing arrangements will be authorized in conjunction with coverage that may be provided by Medicaid or other federal, state, community or private programs.

(ii) For authorized ECHO respite care, TRICARE will reimburse the allowable charges or negotiated rates.

(iii) The Government's cost-share incurred for these services accrues to the fiscal year benefit limit of \$36,000.

(8) Other services. (i) Assistive services. Services of qualified personal assistants, such as an interpreter or translator for ECHO beneficiaries who are deaf or mute and readers for ECHO beneficiaries who are blind, when such services are necessary in order for the ECHO beneficiary to receive authorized ECHO benefits.

(ii) Equipment adaptation. The allowable equipment and an AT device purchase shall include such services and modifications to the equipment as necessary to make the equipment usable for a particular ECHO beneficiary.

(iii) Equipment maintenance. Reasonable repairs and maintenance of the beneficiary owned or rented DE or AT devices provided by this section shall be allowed while a beneficiary is registered in the ECHO Program. Repairs of DE and/or AT devices damaged while using the item in a manner inconsistent with its common use, and replacement of lost or stolen DE and/or AT devices are not authorized coverage as an ECHO benefit. In addition, repairs and maintenance of deluxe, luxury, or immaterial features of DE or AT devices are not authorized coverage as an ECHO benefit.

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(d) **ECHO Exclusions--**(1) Basic Program. Benefits allowed under the TRICARE Basic Program will not be provided through the ECHO.

(2) Inpatient care. Inpatient acute care for medical or surgical treatment of an acute illness, or of an acute exacerbation of the qualifying condition, is excluded.

(3) **Structural alterations. Alterations to living space and permanent fixtures attached thereto, including alterations necessary to accommodate installation of equipment or AT devices to facilitate entrance or exit, are excluded.**

(4) Homemaker services. Services that predominantly provide assistance with household chores are excluded.

(5) Dental care or orthodontic treatment. Both are excluded.

(6) Deluxe travel or accommodations. The difference between the price for travel or accommodations that provide services or features that exceed the requirements of the beneficiary's condition and the price for travel or accommodations without those services or features is excluded.

(7) **Equipment. Purchase or rental of DE and AT devices otherwise allowed by this section is excluded when:**

(i) **The beneficiary is a patient in an institution or facility that ordinarily provides the same type of equipment or AT devices to its patients at no additional charge in the usual course of providing services; or**

(ii) The item is available to the beneficiary from a Uniformed Services Medical Treatment Facility; or

(iii) The item has deluxe, luxury, immaterial or nonessential features that increase the cost to the Department relative to a similar item without those features; or

(iv) **The item is a duplicate DE or an AT device, as defined in Sec. 199.2.**

(v) **The item (or charge for access to such items through health club membership or other activities) is exercise equipment including an item primarily and customarily designed for use in sports or recreational activities, spa, whirlpool, hot tub, swimming pool, an electronic device used to locate or monitor the location of the beneficiary, or other similar items or charges.**

(8) **Maintenance agreements. Maintenance agreements for beneficiary owned or rented equipment or AT device are excluded.**

(9) No obligation to pay. Services or items for which the beneficiary or sponsor has no legal obligation to pay are excluded.

(10) Public facility or Federal government. Services or items paid for, or eligible for payment, directly or indirectly by a public facility, as defined in Sec. 199.2, or by the Federal government, other than the Department of Defense, are excluded for training, rehabilitation,

special education, assistive technology devices, institutional care in private nonprofit, public, and state institutions and facilities, and if appropriate, transportation to and from such institutions and facilities, except when such services or items are eligible for payment under a state plan for medical assistance under Title XIX of the Social Security Act (Medicaid). Rehabilitation and assistive technology services or supplies may be available under the TRICARE Basic Program.

(11) Study, grant, or research programs. Services and items provided as a part of a scientific clinical study, grant, or research program are excluded.

(12) Unproven status. Drugs, devices, medical treatments, diagnostic, and therapeutic procedures for which the safety and efficacy have not been established in accordance with Sec. 199.4 are excluded.

(13) Immediate family or household. Services or items provided or prescribed by a member of the beneficiary's immediate family, or a person living in the beneficiary's or sponsor's household, are excluded.

(14) Court or agency ordered care. Services or items ordered by a court or other government agency, which are not otherwise an allowable ECHO benefit, are excluded.

(15) Excursions. Excursions are excluded regardless of whether or not they are part of a program offered by a TRICARE-authorized provider. The transportation benefit available under ECHO is specified elsewhere in this section.

(16) Drugs and medicines. Drugs and medicines that do not meet the requirements of Sec. 199.4 or Sec. 199.21 are excluded.

(17) Therapeutic absences. Therapeutic absences from an inpatient facility or from home for a homebound beneficiary are excluded.

(18) Custodial care. Custodial care, as defined in Sec. 199.2, is not a stand-alone benefit. Services generally rendered as custodial care may be provided only as specifically set out in this section.

(19) Domiciliary care. Domiciliary care, as defined in Sec. 199.2, is excluded.

(20) Respite care. Respite care for the purpose of covering primary caregiver (as defined in Sec. 199.2) absences due to deployment, employment, seeking of employment or to pursue education is excluded. Authorized respite care covers only the ECHO beneficiary, not siblings or others who may reside in or be visiting in the beneficiary's residence.

(e) ECHO Home Health Care (EHHC). The EHHC benefit provides coverage of home health care services and respite care services specified in this section.

(1) Home health care. Covered ECHO home health care services are the same as, and provided under the same conditions as those services described in Sec. 199.4(e)(21)(i), except that they are not limited to part-time or intermittent services. Custodial care services, as defined in Sec. 199.2, may be provided to the extent such services are provided in conjunction with authorized ECHO home health care services, including the EHHC respite care benefit

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specified in this section. Beneficiaries who are authorized EHHC will receive all home health care services under EHHC and no portion will be provided under the Basic Program. TRICARE-authorized home health agencies are not required to use the Outcome and Assessment Information Set (OASIS) to assess beneficiaries who are authorized EHHC.

(2) Respite care. EHHC beneficiaries whose plan of care includes frequent interventions by the primary caregiver(s) are eligible for respite care services in lieu of the ECHO general respite care benefit. For the purpose of this section, the term "frequent" means "more than two interventions during the eight-hour period per day that the primary caregiver would normally be sleeping." The services performed by the primary caregiver are those that can be performed safely and effectively by the average non-medical person without direct supervision of a health care provider after the primary caregiver has been trained by appropriate medical personnel. EHHC beneficiaries in this situation are eligible for a maximum of eight hours per day, 5 days per week, of respite care by a TRICARE-authorized home health agency. The home health agency will provide the health care interventions or services for the covered beneficiary so that the primary caregiver is relieved of the responsibility to provide such interventions or services for the duration of that period of respite care. The home health agency will not provide baby-sitting or child care services for other members of the family. The benefit is not cumulative, that is, any respite care hours not used in a given day may not be carried over or banked for use on another occasion. Additionally, the eight-hour respite care periods will not be provided consecutively, that is, a respite care period on one calendar day will not be immediately followed by a respite care period the next calendar day. The Government's cost-share incurred for these services accrue to the maximum yearly ECHO Home Health Care benefit.

(3) EHHC eligibility. The EHHC is authorized for beneficiaries who meet all applicable ECHO eligibility requirements and who:

- (i) Physically reside within the 50 United States, the District of Columbia, Puerto Rico, the Virgin Islands, or Guam; and
- (ii) Are homebound, as defined in Sec. 199.2; and
- (iii) Require medically necessary skilled services that exceed the level of coverage provided under the Basic Program's home health care benefit; and/or
- (iv) Require frequent interventions by the primary caregiver(s) such that respite care services are necessary to allow primary caregiver(s) the opportunity to rest; and
- (v) Are case managed to include a reassessment at least every 90 days, and receive services as outlined in a written plan of care; and
- (vi) Receive all home health care services from a TRICARE-authorized home health agency, as described in Sec. 199.6(b)(4)(xv), in the beneficiary's primary residence.

(4) EHHC plan of care. A written plan of care is required prior to authorizing ECHO home health care. The plan must include the type, frequency, scope and duration of the care to be provided and support the professional level of provider. Reimbursement will not be authorized for a level of provider not identified in the plan of care.

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(5) EHHC exclusions--(i) General. ECHO Home Health Care services and supplies are excluded from those who are being provided continuing coverage of home health care as participants of the former Individual Case Management Program for Persons with Extraordinary Conditions (ICMP-PEC) or previous case management demonstrations.

(ii) Respite care. Respite care for the purpose of covering primary caregiver absences due to deployment, employment, seeking of employment or to pursue education is excluded. Authorized respite care covers only the ECHO beneficiary, not siblings or others who may reside in or be visiting in the beneficiary's residence.

(f) Cost-share liability--(1) No deductible. ECHO benefits are not subject to a deductible amount.

(2) Sponsor cost-share liability. (i) Regardless of the number of family members receiving ECHO benefits or ECHO Home Health Care in a given month, the sponsor's cost-share is according to the following table:

E-1 through E-5.....	\$25
E-6.....	30
E-7 and O-1.....	35
E-8 and O-2.....	40
E-9, W-1, W-2 and O-3.....	45
W-3, W-4 and O-4.....	50
W-5 and O-5.....	65
O-6.....	75
O-7.....	100
O-8.....	150
O-9.....	200
O-10.....	250

(ii) The sponsor's cost-share shown in Table 1 in paragraph (f)(2)(i) of this section will be applied to the first allowed ECHO charges in any given month. The Government's share will be paid, up to the maximum amount specified in paragraph (f)(3) of this section, for allowed charges after the sponsor's cost-share has been applied.

(iii) The provisions of Sec. 199.18(d)(1) and (e)(1) regarding elimination of copayments for active duty family members enrolled in TRICARE Prime do not eliminate, reduce, or otherwise affect the sponsor's cost-share shown in Table 1 in paragraph (f)(2)(i) of this section.

(iv) The sponsor's cost-share shown in Table 1 in paragraph (f)(2)(i) of this section does not accrue to the Basic Program's Catastrophic Loss Protection under 10 U.S.C. 1079(b)(5) as shown at Sec. 199.4(f)(10) and 199.18(f).

(3) Government cost-share liability--(i) ECHO. The total Government share of the cost of all ECHO benefits, except ECHO Home Health Care (EHHC) and EHHC respite care, provided in a given fiscal year to a beneficiary, may not exceed \$36,000 after application of the allowable payment methodology.

(ii) ECHO home health care. (A) The maximum annual fiscal year Government cost-share per EHC-eligible beneficiary for ECHO home health care, including EHC respite care may not exceed the local wage-adjusted highest Medicare Resource Utilization Group (RUG-III) category cost for care in a TRICARE-authorized skilled nursing facility.

(B) When a beneficiary moves to a different locality within the 50 United States, the District of Columbia, Puerto Rico, the Virgin Islands, or Guam, the annual fiscal year cap will be recalculated to reflect the maximum established under paragraph (f)(3)(ii)(A) of this section for the beneficiary's new location and will apply to the EHC benefit for the remaining portion of that fiscal year.

(g) Benefit payment--(1) Transportation. The allowable amount for transportation of an ECHO beneficiary is limited to the actual cost of the standard published fare plus any standard surcharge made to accommodate any person with a similar disability or to the actual cost of specialized medical transportation when non-specialized transport cannot accommodate the beneficiary's qualifying condition related needs, or when specialized transport is more economical than non-specialized transport. When transport is by private vehicle, the allowable amount is limited to the Federal government employee mileage reimbursement rate in effect on the date the transportation is provided.

(2) Equipment. (i) The TRICARE allowable amount for DE or AT devices shall be calculated in the same manner as DME allowable through section 199.4 of this title, and accrues to the fiscal year benefit limit specified in paragraph (f)(3) of this section.

(ii) Cost-share. A cost-share, as provided by paragraph (f)(2) of this section, is required for each month in which equipment or an AT device is purchased under this section. However, in no month shall a sponsor be required to pay more than one cost-share regardless of the number of benefits the sponsor's dependents received under this section.

(3) For-profit institutional care provider. Institutional care provided by a for-profit entry may be allowed only when the care for a specific ECHO beneficiary:

(i) Is contracted for by a public facility as a part of a publicly funded long-term inpatient care program; and

(ii) Is provided based upon the ECHO beneficiary's being eligible for the publicly funded program which has contracted for the care; and

(iii) Is authorized by the public facility as a part of a publicly funded program; and

(iv) Would cause a cost-share liability in the absence of TRICARE eligibility; and

(v) Produces an ECHO beneficiary cost-share liability that does not exceed the maximum charge by the provider to the public facility for the contracted level of care.

(4) ECHO home health care and EHC respite care. (i) TRICARE-authorized home health agencies must provide and bill for all authorized home health care services through established TRICARE claims' mechanisms. No special billing arrangements will be authorized in conjunction with coverage that may be provided by Medicaid or other federal, state, community or private programs.

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(ii) For authorized ECHO home health care and respite care, TRICARE will reimburse the allowable charges or negotiated rates.

(iii) The maximum monthly Government reimbursement for EHHC, including EHHC respite care, will be based on the actual number of hours of EHHC services rendered in the month, but in no case will it exceed one-twelfth of the annual maximum Government cost-share as determined in this section and adjusted according to the actual number of days in the month the services were provided.

(h) Other Requirements--(1) Applicable part. All provisions of this part, except the provisions of Sec. 199.4 unless otherwise provided by this section or as directed by the Director, TRICARE Management Activity or designee, apply to the ECHO.

(2) Registration. Active duty sponsors must register potential ECHO-eligible beneficiaries through the Director, TRICARE Management Activity, or designee prior to receiving ECHO benefits. The Director, TRICARE Management Activity, or designee will determine ECHO eligibility and update the Defense Enrollment Eligibility Reporting System accordingly. Unless waived by the Director, TRICARE Management Activity or designee, sponsors must provide evidence of enrollment in the Exceptional Family Member Program provided by their branch of Service at the time they register their family member(s) for the ECHO.

(3) Benefit authorization. All ECHO benefits require authorization by the Director, TRICARE Management Activity or designee prior to receipt of such benefits.

(i) Documentation. The sponsor shall provide such documentation as the Director, TRICARE Management Activity or designee requires as a prerequisite to authorizing ECHO benefits. Such documentation shall describe how the requested benefit will contribute to confirming, arresting, or reducing the disabling effects of the qualifying condition, including maintenance of function or prevention of further deterioration of function, of the beneficiary.

(ii) Format. An authorization issued by the Director, TRICARE Management Activity or designee shall specify such description, dates, amounts, requirements, limitations or information as necessary for exact identification of approved benefits and efficient adjudication of resulting claims.

(iii) Valid period. An authorization for ECHO benefits shall be valid until such time as the Director, TRICARE Management Activity or designee determines that the authorized services are no longer appropriate or required or the beneficiary is no longer eligible under paragraph (b) of this section.

(iv) Authorization waiver. The Director, TRICARE Management Activity or designee may waive the requirement for a written authorization for rendered ECHO benefits that, except for the absence of the written authorization, would be allowable as an ECHO benefit.

(v) Public facility use. (A) An ECHO beneficiary residing within a state must demonstrate that a public facility is not available and adequate to meet the needs of their qualifying condition. Such requirements shall apply to beneficiaries who request authorization for training, rehabilitation, special education, assistive technology, and institutional care in private nonprofit, public, and state institutions and facilities, and if appropriate for beneficiaries receiving institutional care, transportation to and from such institutions and

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facilities. The maximum Government cost-share for services that require demonstration of public facility non-availability or inadequacy is limited to \$36,000 per fiscal year per beneficiary. State-administered plans for medical assistance under Title XIX of the Social Security Act (Medicaid) are not considered available and adequate facilities for the purpose of this section.

(B) The domicile of the beneficiary shall be the basis for the determination of public facility availability when the sponsor and beneficiary are separately domiciled due to the sponsor's move to a new permanent duty station or due to legal custody requirements.

(C) Written certification, in accordance with information requirements, formats, and procedures established by the Director, TRICARE Management Activity or designee that requested ECHO services or items cannot be obtained from public facilities because the services or items are not available and adequate, is a prerequisite for ECHO benefit payment for training, rehabilitation, special education, assistive technology, and institutional care in private nonprofit, public, and state institutions and facilities, and if appropriate, transportation to and from such institutions and facilities.

(1) An administrator or designee of a public facility may make such certification for a beneficiary residing within the service area of that public facility.

(2) The Director, TRICARE Management Activity or designee may determine, on a case-by-case basis, that apparent public facility availability or adequacy for a requested type of service or item cannot be substantiated for a specific beneficiary's request for ECHO benefits and therefore is not available.

(i) A case-specific determination shall be based upon a written statement by the beneficiary (or sponsor or guardian acting on behalf of the beneficiary) which details the circumstances wherein a specific individual representing a specific public facility refused to provide a public facility use certification, and such other information as the Director, TRICARE Management Activity or designee determines to be material to the determination.

(ii) A case-specific determination of public facility availability by the Director, TRICARE Management Activity or designee is conclusive and is not appealable under Sec. 199.10.

(4) Repair or maintenance of DE owned by the beneficiary or an AT device is exempt from the public facility-use certification requirements.

(5) The requirements of this paragraph (h)(3)(v)(A) notwithstanding, no public facility use certification is required for services and items that are provided under Part C of the Individuals with Disabilities Education Act in accordance with the Individualized Family Services Plan and that are otherwise allowable under the ECHO.

(i) Implementing instructions. The Director, TRICARE Management Activity or designee shall issue TRICARE policies, instructions, procedures, guidelines, standards, and criteria as may be necessary to implement the intent of this section.

(j) Effective date. All changes to this section are effective as of October 14, 2008, and claims for ECHO benefits provided on or after that date will be reprocessed retroactively to that date as necessary.

CIVILIAN HEALTH AND MEDICAL PROGRAM OF THE UNIFORMED SERVICES (CHAMPUS)
PART 199.5 TRICARE EXTENDED CARE HEALTH OPTION (ECHO)

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