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MANAGEMENT ACTIVITY

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The Department of Defense, Office of the Secretary, has authorized the following addition(s)/revision(s) to 32 CFR Part 199, reissued April 2005.

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WHEN PRESCRIBED ACTION HAS BEEN TAKEN, FILE THIS TRANSMITTAL WITH BASIC DOCUMENT.

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TITLE 32 NATIONAL DEFENSE
CIVILIAN HEALTH AND MEDICAL PROGRAM OF THE UNIFORMED SERVICES (CHAMPUS)

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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.

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

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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 or durable medical equipment, as defined in this section that serves the same purpose that is served by an item of durable equipment or durable medical equipment 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 an 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 or durable medical equipment that are essential to provide a fail-safe in-home life support system or that replaces 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. A device or apparatus which does not qualify as durable medical equipment and which is essential to the efficient arrest or reduction of functional loss resulting from, or the disabling effects of a qualifying condition as provided in Sec. 199.5

Durable medical equipment. Equipment that--

- (1) Can withstand repeated use;
- (2) Is primarily and customarily used to serve a medical purpose; and
- (3) Generally is not useful to an individual in the absence of an illness or injury.

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.

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

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 of 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.

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.

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.

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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.

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.

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 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 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.

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.

Unlabeled or Off-Label Drugs. Food and Drug Administration (FDA) approved drugs that are used for indications or treatments not included in the approved labeling. The drug must be medically necessary for the treatment of the condition for which it is administered, according to accepted standards of medical practice.

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]

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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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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. 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.

(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/episodes of care. The terminally ill beneficiary may elect to receive hospice benefits for an initial period of 90 days, a subsequent period of 90 days, a second subsequent period of 30 days, and a final period of unlimited duration.

(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.

(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 superior non-investigational treatment alternative; and,

(ii) The available clinical or preclinical data provide a reasonable expectation that the

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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.

(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.

(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

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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

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(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.

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(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.

(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.

(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.

(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.

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(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 can also consider coverage of *unlabeled* or *off-label* uses of drugs that are Food and Drug Administration (FDA) approved drugs that are used for indications or treatments not included in the approved labeling. Approval for reimbursement of *unlabeled* or *off-label* uses requires review for medical necessity, and also requires demonstrations from medical literature, national organizations, or technology assessment bodies that the *unlabeled* or *off-label* use of the drug 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).

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(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.

(iv) Examples of unproven drugs, devices or medical treatments or procedures. This paragraph (g)(15)(iv) consists of a partial list of unproven drugs, devices or medical treatment or procedures. These are excluded from CHAMPUS program benefits. This list is not all inclusive. Other unproven drugs, devices or medical treatments or procedures, are similarly excluded, although they do not appear on this partial list. This partial list will be reviewed and updated periodically as new information becomes available. With respect to any procedure included on this partial list, if and when the Director, OCHAMPUS determines that based on reliable evidence (as defined in section 199.2) such procedure has proven medical effectiveness, the Director will initiate action to remove the procedure from this partial list of unproven drugs, devices or medical treatment or procedures. From the date established by the Director as the date the procedure has established proven medical effectiveness until the date the regulatory change is made to remove the procedures from the partial list of unproven drugs, devices or medical treatment or procedures the Director, OCHAMPUS will suspend treatment of the procedure as unproven drugs, devices, or medical treatments or procedures. Following is the non-inclusive, partial list of unproven drugs, devices or medical treatment or procedures, all of which are excluded from CHAMPUS benefits:

- (A) Radial keratotomy (refractive keratoplasty).
- (B) Cellular therapy.

- (C) Histamine therapy.
- (D) Stem cell assay, a laboratory procedure which allows a determination to be made of the type and dose of cancer chemotherapy drugs to be used, based on in vitro analysis of their effects on cancer cells taken from an individual.
- (E) Topical application of oxygen.
- (F) Immunotherapy for malignant disease, except when using drugs approved by the FDA for this purpose.
- (G) Prolotherapy, joint sclerotherapy, and ligamentous injections with sclerosing agents.
- (H) Transcervical block silicone plug.
- (I) Whole body hyperthermia in the treatment of cancer.
- (J) Portable nocturnal hypoglycemia detectors.
- (K) Testosterone pellet implants in the treatment of females.
- (L) Estradiol pellet implants.
- (M) Epikeratophakia for treatment of aphakia and myopia.
- (N) Bladder stimulators.
- (O) Ligament replacement with absorbable copolymer carbon fiber scaffold.
- (P) Intraoperative radiation therapy.
- (Q) Gastric bubble or balloon.
- (R) Dorsal root entry zone (DREZ) thermocoagulation or micorcoagulation neurosurgical procedure.
- (S) Brain electrical activity mapping (BEAM).
- (T) Topographic brain mapping (TBM) procedure.
- (U) Ambulatory blood pressure monitoring.
- (V) Bilateral carotoid body resection to relieve pulmonary system.
- (W) Intracavitary administration of cisplatin for malignant disease.
- (X) Cervicography.
- (Y) In-home uterine activity monitoring for the purpose of preventing preterm labor and/or delivery.

- (Z) Sperm evaluation, hamster penetration test.
- (AA) Transfer factor (TF).
- (BB) Continuous ambulatory esophageal pH monitoring (CAEpHM) is considered unproven for patients under age 12 for all indications, and for patients over age 12 for sleep apnea.
- (CC) Adrenal-to-brain transplantation for Parkinson's disease.
- (DD) Videofluoroscopy evaluation in speech pathology.
- (EE) Applied kinesiology.
- (FF) Hair analysis to identify mineral deficiencies from the chemical composition of the hair. Hair analysis testing may be reimbursed when necessary to determine lead poisoning.
- (GG) Iridology (links flaws in eye coloration with disease elsewhere in the body).
- (HH) Small intestinal bypass (jejunioileal bypass) for treatment of morbid obesity.
- (II) Biliopancreatic bypass.
- (JJ) Gastric wrapping/gastric banding.
- (KK) Calcium EAP/calcium orotate and selenium (also known as Nieper therapy)-- Involves inpatient care and use of calcium compounds and other non-FDA approved drugs and special diets. Used for cancer, heart disease, diabetes, and multiple sclerosis.
- (LL) Percutaneous balloon valvuloplasty for mitral and tricuspid valve stenosis.
- (MM) Amniocentesis performed for ISO immunization to the ABO blood antigens.
- (NN) Balloon dilatation of the prostate.
- (OO) Helium in radiosurgery.
- (PP) Electrostimulation of salivary production in the treatment of xerostomia secondary to Sjogren's syndrome.
- (QQ) Intraoperative monitoring of sensory evoked potentials (SEP). To include visually evoked potentials, brainstem auditory evoked response, somatosensory evoked potentials during spinal and orthopedic surgery, and sensory evoked potentials monitoring of the sciatic nerve during total hip replacement. Recording SEPs in unconscious head injured patients to assess the status of the somatosensory system. The use of SEPs to define conceptional or gestational age in preterm infants.
- (RR) Autolymphocyte therapy (ALT) (immunotherapy used for treating metastatic kidney cancer patients).

- (SS) Radioimmunoguided surgery in the detection of cancer.
- (TT) Gait analysis (also known as a walk study or electrodyneogram)
- (UU) Use of cerebellar stimulators/pacemakers for the treatment of neurologic disorders.
- (VV) Signal-averaged ECG.
- (WW) Peri-urethral Teflon injections to manage urinary incontinence.
- (XX) Extraoperative electrocorticography for stimulation and recording
- (YY) Quantitative computed tomography (QCT) for the detection and monitoring of osteoporosis.
- (ZZ) [Reserved]
- (AAA) Percutaneous transluminal angioplasty in the treatment of obstructive lesions of the carotoid, vertebral and cerebral arteries.
- (BBB) Endoscopic third ventriculostomy.
- (CCC) Holding therapy--Involves holding the patient in an attempt to achieve interpersonal contact, and to improve the patient's ability to concentrate on learning tasks.
- (DDD) In utero fetal surgery.
- (EEE) Light therapy for seasonal depression (also known as seasonal affective disorder (SAD)).
- (FFF) Dorsal column and deep brain electrical stimulation of treatment of motor function disorder.
- (GGG) Chelation therapy, except with products and for indications approved by the FDA.
- (HHH) All organ transplants *except* heart, heart-lung, lung, kidney, some bone marrow, liver, liver-kidney, corneal, heart-valve, and kidney-pancreas transplants for Type I diabetics with chronic renal failure who require kidney transplants.
- (III) Implantable infusion pumps, *except* for treatment of spasticity, chronic intractable pain, and hepatic artery perfusion chemotherapy for the treatment of primary liver cancer or metastatic colorectal liver cancer.
- (JJJ) Services related to the candidiasis hypersensitivity syndrome, yeast syndrome, or gastrointestinal candidiasis (i.e., allergenic extracts of *Candida albicans* for immunotherapy and/or provocation/neutralization).
- (KKK) Treatment of chronic fatigue syndrome.
- (LLL) Extracorporeal immunoadsorption using protein A columns for conditions other

than acute idiopathic thrombocytopenia purpura.

(MMM) Dynamic posturography (both static and computerized).

(NNN) Laparoscopic myomectomy.

(OOO) Growth factor, including platelet-derived growth factors, for treating non-healing wounds. This includes Procurene®, a platelet-derived wound-healing formula.

(PPP) High dose chemotherapy with stem cell rescue (HDC/SCR) for any of the following malignancies:

(1) Breast cancer, except for metastatic breast cancer that has relapsed after responding to a first line treatment.

(2) Ovarian cancer.

(3) Testicular cancer.

(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.

(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. Preventive care, such as routine, annual, or employment-requested physical examinations; routine screening procedures; except that the following are not excluded:

- (i) Well-child care.
- (ii) Immunizations for individuals age six and older, as recommended by the CDC.
- (iii) Rabies shots.
- (iv) Tetanus shot following an accidental injury.
- (v) Rh immune globulin.
- (vi) Genetic tests as specified in paragraph (e)(3)(ii) of this section.
- (vii) Immunizations and physical examinations provided when required in the case of dependents of active duty military personnel who are traveling outside the United States as a result of an active duty member's assignment and such travel is being performed under orders issued by a Uniformed Service.
- (viii) Cervical and breast cancer screenings in accordance with standards issued by the Director, TRICARE Management Activity, based on guidelines from the U.S. Department of Health and Human Services. Such standards may establish a specific schedule, including frequency, age specifications, and gender of the beneficiary, as appropriate.
- (ix) Health promotion and disease prevention visits may include all of the services provided pursuant to Sec. 199.18(b)(2) and may be provided in connection with immunizations and cancer screening examinations authorized by paragraphs (g)(37)(ii) or (g)(37)(viii) of this section.
- (x) Physical examinations for beneficiaries ages 5-11 that are required in connection with school enrollment, and that are provided on or after October 30, 2000.
- (xi) Other cancer screenings authorized by 10 U.S.C. 1079.
- (xii) Health promotion and disease prevention visits (which may include all of the services provided pursuant to Sec. 199.18(b)(2)) may be provided in connection with immunizations and cancer screening examinations authorized by paragraphs (g)(37)(ii) of this section or (g)(37)(viii) through (x) of this section.
- (xiii) Physical examinations for beneficiaries ages 5 through 11 that are required in connection with school enrollment, and that are provided on or after October 30, 2000.

(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.

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(39) Counseling. Counseling services that are not medically necessary in the treatment of a diagnosed medical condition: For example, educational counseling, vocational counseling, nutritional counseling, and counseling for socioeconomic purposes, stress management, lifestyle modification. Services provided by a certified marriage and family therapist, pastoral, or mental health counselor in the treatment of a mental disorder are covered only as specifically provided in Section 199.6. Services provided by alcoholism rehabilitation counselors are covered 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 devices. Exercise equipment, spas, whirlpools, hot tubs, swimming pools, health club membership 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.

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- (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, unauthorized provider. All services and supplies (including inpatient institutional costs) related to a noncovered condition or treatment, or provided by an unauthorized provider.

(64) Comfort or convenience. Personal, comfort, or convenience items such as beauty and barber services, radio, television, and telephone.

(65) "Stop smoking" programs. Services and supplies related to "stop smoking" regimens.

(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)–(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.

(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**]

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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