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TRICARE
MANAGEMENT ACTIVITY

MB&RB

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(TMA VERSION)**

FINAL RULE

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

CHANGE TITLE: TRICARE: OFF-LABEL USES OF DEVICES; PARTIAL LIST OF EXAMPLES OF UNPROVEN DRUGS, DEVICES, MEDICAL TREATMENTS, OR PROCEDURES

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

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an opportunity to test his or her ability to function outside the inpatient setting before the actual discharge.

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

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

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

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

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

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

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

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

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

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

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

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

looks to the beneficiary or sponsor for payment of his or her charge, not CHAMPUS. In such cases, CHAMPUS pays the beneficiary or sponsor, not the provider.

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

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

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

Off-label use of a drug or device. A use other than an intended use for which the prescription drug, biologic or device is legally marketed under the Federal Food, Drug, and Cosmetic Act or the Public Health Services Act. This includes any use that is not included in the approved labeling for an approved drug, licensed biologic, approved device or combination product; any use that is not included in the cleared statement of intended use for a device that has been determined by the Food and Drug Administration (FDA) to be substantially equivalent to a legally marketed predicate device and cleared for marketing; and any use of a device for which a manufacturer or distributor would be required to seek pre-market review by the FDA in order to legally include that use in the device's labeling.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Provider exclusion and suspension. The terms “exclusion” and “suspension”, when referring to a provider under CHAMPUS, both mean the denial of status as an authorized provider, resulting in items, services, or supplies furnished by the provider not being reimbursed, directly or indirectly, under CHAMPUS. The terms may be used interchangeably to refer to a provider who has been denied status as an authorized CHAMPUS provider based on (1) a criminal conviction or civil judgment involving fraud, (2) an administrative finding of fraud or abuse under CHAMPUS, (3) an administrative finding that the provider has been excluded or suspended by another agency of the Federal Government, a state, or a local licensing authority, (4) an administrative finding that the provider has knowingly participated in a conflict of interest situation, or (5) an administrative finding that it is in the best interests of the CHAMPUS or CHAMPUS beneficiaries to exclude or suspend the provider.

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

Psychiatric emergency. A psychiatric inpatient admission is an emergency when, based on a psychiatric evaluation performed by a physician (or other qualified mental health care professional with hospital admission authority), the patient is at immediate risk of serious

harm to self or others as a result of a mental disorder and requires immediate continuous skilled observation at the acute level of care.

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

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

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

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

- (1) Develops process standards and outcome standards for health care delivery programs, or knowledge standards and skill standards for health care professional certification testing, using experts both from within and outside of the health care program area or individual specialty to which the standards are to be applied;
- (2) Creates measurable criteria that demonstrate compliance with each standard;
- (3) Publishes the organization's standards, criteria and evaluation processes so that they are available to the general public;
- (4) Performs on-site evaluations of health care delivery programs, or provides testing of individuals, to measure the extent of compliance with each standard;
- (5) Provides on-site evaluation or individual testing on a national or international basis;
- (6) Provides to evaluated programs and tested individuals time-limited written certification of compliance with the organization's standards;
- (7) Excludes certification of any program operated by an organization which has an economic interest, as defined in this section, in the accreditation organization or in which the accreditation organization has an economic interest;
- (8) Publishes promptly the certification outcomes of each program evaluation or individual test so that it is available to the general public; and
- (9) Has been found by the Director, OCHAMPUS, or designee, to apply standards, criteria, and certification processes which reinforce CHAMPUS provider authorization requirements

and promote efficient delivery of CHAMPUS benefits.

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

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

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

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

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

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

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

- (i) Well controlled studies of clinically meaningful endpoints, published in refereed medical literature.
- (ii) Published formal technology assessments.
- (iii) The published reports of national professional medical associations.
- (iv) Published national medical policy organization positions; and
- (v) The published reports of national expert opinion organizations.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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.

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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.

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

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

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

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

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

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

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

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

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

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

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

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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(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 unproven and cannot be cost-shared by CHAMPUS except as authorized under paragraph 199.4(e)(26) of this part.

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

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

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

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

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

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

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

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

for the procedures used in determining if a medical treatment or procedure is unproven.)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(26) Electrolysis.

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

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

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

(30) Therapy or counseling for sexual dysfunctions or sexual inadequacies. Sex therapy, sexual advice, sexual counseling, sex behavior modification, psychotherapy for mental disorders involving sexual deviations (i.e., transvestic fetishism), or other similar

services, and any supplies provided in connection with therapy for sexual dysfunctions or inadequacies.

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

(32) Dyslexia.

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

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

(35) Nonprescription contraceptives.

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

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

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

(39) Counseling. 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.

(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

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(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; 76 FR 57642, Sep 16, 2011; 76 FR 80743, Dec 27, 2011; 76 FR 81370, Dec 28, 2011; 77 FR 38175, Jun 27, 2012; 77 FR 38178, Jun 27, 2012]

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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