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

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## PART 199.2 - DEFINITIONS

**(a) General.** In an effort to be as specific as possible as to the word and intent of CHAMPUS, the following definitions have been developed. While many of the definitions are general and some assign meaning to relatively common terms within the health insurance environment, others are applicable only to CHAMPUS; however, they all appear in this part solely for the purpose of the Program. Except when otherwise specified, the definitions in this section apply generally throughout this part.

**(b) Specific definitions.**

**Abortion.** Abortion means the intentional termination of a pregnancy by artificial means done for a purpose other than that of producing a live birth. A spontaneous, missed or threatened abortion or termination of an ectopic (tubal) pregnancy are not included within the term "abortion" as used herein.

**Absent treatment.** Services performed by Christian Science practitioners for a person when the person is physically present.

NOTE: Technically, "Absent Treatment" is an obsolete term. The current Christian Science terminology is "treatment through prayer and spiritual means," which is employed by an authorized Christian Science practitioner either with the beneficiary being present or absent. However, to be considered for coverage under CHAMPUS, the beneficiary must be present physically when a Christian Science service is rendered, regardless of the terminology used.

**Abuse.** For the purposes of this part, abuse is defined as any practice that is inconsistent with accepted sound fiscal, business, or professional practice which results in a CHAMPUS claim, unnecessary cost, or CHAMPUS payment for services or supplies that are: (1) Not within the concepts of medically necessary and appropriate care, as defined in this part, or (2) that fail to meet professionally recognized standards for health care providers. The term "abuse" includes deception or misrepresentation by a provider, or any person or entity acting on behalf of a provider in relation to a CHAMPUS claim.

NOTE: Unless a specific action is deemed gross and flagrant, a pattern of inappropriate practice will normally be required to find that abuse has occurred. Also, any practice or action that constitutes fraud, as defined by this part, would also be abuse.

**Abused dependent.** An eligible spouse or child, who meets the criteria in Sec. 199.3 of this part, of 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, or of a member or former member who has had their entitlement to receive retired pay terminated because of misconduct involving physical or emotional abuse.

**Accidental injury.** Physical bodily injury resulting from an external force, blow or fall, or the ingestion of a foreign body or harmful substance, requiring immediate medical treatment.

Accidental injury also includes animal and insect bites and sunstrokes. For the purpose of CHAMPUS, the breaking of a tooth or teeth does not constitute a physical bodily injury.

Active duty. Full-time duty in the Uniformed Services of the United States. It includes duty on the active list, full-time training duty, annual training duty, and attendance while in the active Military Service, at a school designated as a Service school by law or by the Secretary of the Military Department concerned.

Active duty 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.

Activities of daily living. Care that consists of providing food (including special diets), clothing, and shelter; personal hygiene services; observation and general monitoring; bowel training or management (unless abnormalities in bowel function are of a severity to result in a need for medical or surgical intervention in the absence of skilled services); safety precautions; general preventive procedures (such as turning to prevent bedsores); passive exercise; companionship; recreation; transportation; and such other elements of personal care that reasonably can be performed by an untrained adult with minimal instruction or supervision. Activities of daily living may also be referred to as "essentials of daily living".

Acupuncture. The practice of inserting needles into various body parts to pierce specific peripheral nerves for the production of counter-irritation to relieve the discomfort of pain, induce surgical anesthesia, or for other treatment purposes.

NOTE: Acupuncture is not covered by CHAMPUS.

Adequate Medical Documentation, Medical Treatment Records. Adequate medical documentation contains sufficient information to justify the diagnosis, the treatment plan, and the services and supplies furnished. Under CHAMPUS, it is required that adequate and sufficient clinical records be kept by the health care provider(s) to substantiate that specific care was actually and appropriately furnished, was medically necessary and appropriate (as defined by this part), and to identify the individual(s) who provided the care. All procedures billed must be documented in the records. In determining whether medical records are adequate, the records will be reviewed under the generally acceptable standards such as the applicable Joint Commission on Accreditation of Healthcare Organizations (JCAHO) standards, the Peer Review Organization (PRO) standards (and the provider's state or local licensing requirements) and other requirements specified by this part. In general, the documentation requirements for a professional provider are not less in the outpatient setting than the inpatient setting.

Adequate medical documentation, mental health records. Adequate medical documentation provides the means for measuring the type, frequency, and duration of active treatment mechanisms employed and progress under the treatment plan. Under CHAMPUS, it is required that adequate and sufficient clinical records be kept by the provider to substantiate that specific care was actually and appropriately furnished, was medically or psychologically necessary (as defined by this part), and to identify the individual(s) who provided the care. Each service provided or billed must be documented in the records. In determining whether medical records are adequate, the records will be reviewed under the generally acceptable standards (e.g., the standards of an accrediting organization approved by the Director, and the provider's state or local licensing requirements) and other

requirements specified by this part. The psychiatric and psychological evaluations, physician orders, the treatment plan, integrated progress notes (and physician progress notes if separate from the integrated progress notes), and the discharge summary are the more critical elements of the mental health record. However, nursing and staff notes, no matter how complete, are not a substitute for the documentation of services by the individual professional provider who furnished treatment to the beneficiary. In general, the documentation requirements of a professional provider are not less in the outpatient setting than the inpatient setting. Furthermore, even though a hospital that provides psychiatric care may be accredited under The Joint Commission (TJC) manual for hospitals rather than the behavioral health standards manual, the critical elements of the mental health record listed above are required for CHAMPUS claims.

Adjunctive dental care. Dental care which is medically necessary in the treatment of an otherwise covered medical (not dental) condition, is an integral part of the treatment of such medical condition and is essential to the control of the primary medical condition; or, is required in preparation for or as the result of dental trauma which may be or is caused by medically necessary treatment of an injury or disease (iatrogenic).

Admission. The formal acceptance by a CHAMPUS authorized institutional provider of a CHAMPUS beneficiary for the purpose of diagnosis and treatment of illness, injury, pregnancy, or mental disorder.

Adopted Child. A child taken into one's own family by legal process and treated as one's own child. In case of adoption, CHAMPUS eligibility begins as of 12:01 a.m. of the day of the final adoption decree.

NOTE: There is no CHAMPUS benefit entitlement during any interim waiting period.

All-Inclusive Per Diem Rate. The OCHAMPUS determined rate that encompasses the daily charge for inpatient care and, unless specifically excepted, all other treatment determined necessary and rendered as part of the treatment plan established for a patient, and accepted by OCHAMPUS.

Allowable charge. The CHAMPUS-determined level of payment to physicians, other individual professional providers and other providers, based on one of the approved reimbursement methods set forth in Sec. 199.14 of this part. Allowable charge also may be referred to as the CHAMPUS-determined reasonable charge.

Allowable cost. The CHAMPUS-determined level of payment to hospitals or other institutions, based on one of the approved reimbursement methods set fourth in Sec. 199.14 of this part. Allowable cost may also be referred to as the CHAMPUS-determined reasonable cost.

Ambulance. A specially designed vehicle for transporting the sick or injured that contains a stretcher, linens, first aid supplies, oxygen equipment, and such lifesaving equipment required by state and local law, and that is staffed by personnel trained to provide first aid treatment.

Ambulatory Payment Classifications (APCs). Payment of services under the TRICARE OPSS is based on grouping outpatient procedures and services into ambulatory payment

classification groups based on clinical and resource homogeneity, provider concentration, frequency of service and minimal opportunities for upcoding and code fragmentation. Nationally established rates for each APC are calculated by multiplying the APC's relative weight derived from median costs for procedures assigned to the APC group, scaled to the median cost of the APC group representing the most frequently provided services, by the conversion factor.

Amount in dispute. The amount of money, determined under this part, that CHAMPUS would pay for medical services and supplies involved in an adverse determination being appealed if the appeal were resolved in favor of the appealing party. See Sec. 199.10 for additional information concerning the determination of "amount in dispute" under this part.

Anesthesia services. The administration of an anesthetic agent by injection or inhalation, the purpose and effect of which is to produce surgical anesthesia characterized by muscular relaxation, loss of sensation, or loss of consciousness when administered by or under the direction of a physician or dentist in connection with otherwise covered surgery or obstetrical care, or shock therapy. Anesthesia services do not include hypnosis or acupuncture.

Appealable issue. Disputed questions of fact which, if resolved in favor of the appealing party, would result in the authorization of CHAMPUS benefits, or approval as an authorized provider in accordance with this part. An appealable issue does not exist if no facts are in dispute, if no CHAMPUS benefits would be payable, or if there is no authorized provider, regardless of the resolution of any disputed facts. See Sec. 199.10 for additional information concerning the determination of "appealable issue" under this part.

Appealing party. Any party to the initial determination who files an appeal of an adverse determination or requests a hearing under the provisions of this part.

Appropriate medical care. (i) Services performed in connection with the diagnosis or treatment of disease or injury, pregnancy, mental disorder, or well-baby care which are in keeping with the generally accepted norms for medical practice in the United States;

(ii) The authorized individual professional provider rendering the medical care is qualified to perform such medical services by reason of his or her training and education and is licensed or certified by the state where the service is rendered or appropriate national organization or otherwise meets CHAMPUS standards; and

(iii) The services are furnished economically. For purposes of this part, "economically" means that the services are furnished in the least expensive level of care or medical environment adequate to provide the required medical care regardless of whether or not that level of care is covered by CHAMPUS.

Approved teaching programs. For purposes of CHAMPUS, an approved teaching program is a program of graduate medical education which has been duly approved in its respective specialty or subspecialty by the Accreditation Council for Graduate Medical Education of the American Medical Association, by the Committee on Hospitals of the Bureau of Professional Education of the American Osteopathic Association, by the Council on Dental Education of the American Dental Association, or by the Council on Podiatry Education of the American Podiatry Association.

**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, including mental health and substance use disorder needs, using communication and available resources to promote quality, cost effective outcomes.

**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.

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**Consultation.** A deliberation with a specialist physician, dentist, or qualified mental health provider 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 or qualified mental health provider may perform a limited examination of a given system or one requiring a complete diagnostic history and examination. To qualify as a consultation, a written report to the attending physician of the findings of the consultant is required.

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

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

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

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

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

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

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

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

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

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

Days. Calendar days.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Director. The Director of the Defense Health Agency, Director, TRICARE Management Activity, or Director, Office of CHAMPUS. Any references to the Director, Office of CHAMPUS, or OCHAMPUS, or TRICARE Management Activity, shall mean the Director, Defense Health Agency (DHA). 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.

Intensive outpatient program (IOP). A treatment setting capable of providing an organized day or evening program that includes assessment, treatment, case management and rehabilitation for individuals not requiring 24-hour care for mental health disorders, to include substance use disorders, as appropriate for the individual patient. The program structure is regularly scheduled, individualized and shares monitoring and support with the patient's family and support system.

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.

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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.

Medication assisted treatment (MAT). MAT for diagnosed opioid use disorder is a holistic modality for recovery and treatment that employs evidence-based therapy, including psychosocial treatments and psychopharmacology, and FDA-approved medications as indicated for the management of withdrawal symptoms and maintenance.

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, to include substance use 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. A substance use disorder is a mental condition that involves a maladaptive pattern of substance use leading to clinically significant impairment or distress; impaired control over substance use; social impairment; and risky use of a substance(s). Additionally, the mental disorder must be one of those conditions listed in the current edition of the Diagnostic and Statistical Manual of Mental Disorders. "Conditions Not Attributable to a Mental Disorder," or V codes, are not considered diagnosable mental disorders. Co-occurring mental and substance use disorders are common and assessment should proceed as soon as it is possible to distinguish the substance related symptoms from other independent conditions.

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/m<sup>2</sup>), or a BMI equal to or greater than 35 kg/m<sup>2</sup> 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.

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.

Office-based opioid treatment. TRICARE authorized providers acting within the scope of their licensure or certification to prescribe outpatient supplies of the medication to assist in withdrawal management (detoxification) and/or maintenance of opioid use disorder, as regulated by 42 CFR part 8, addressing office-based opioid treatment (OBOT).

Opioid Treatment Program. Opioid Treatment Programs (OTPs) are service settings for opioid treatment, either free standing or hospital based, that adhere to the Department of Health and Human Services' regulations at 42 CFR part 8 and use medications indicated and approved by the Food and Drug Administration. Treatment in OTPs provides a comprehensive, individually tailored program of medication therapy integrated with psychosocial and medical treatment and support services that address factors affecting each patient, as certified by the Center for Substance Abuse Treatment (CSAT) of the Department of Health and Human Services' Substance Abuse and Mental Health Services Administration. Treatment in OTPs can include management of withdrawal symptoms (detoxification) from opioids and medically supervised withdrawal from maintenance medications. Patients receiving care for substance use and co-occurring disorders care can be referred to, or otherwise concurrently enrolled in, OTPs.

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 part; 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 or other accrediting organization approved by the Director 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 medically monitored therapeutic services, to include management of withdrawal symptoms, as medically indicated. Services may include 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 disorders, to include substance disorders, and a transition from an inpatient program when medically necessary.

**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 psychiatry 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.

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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.

**Qualified mental health provider.** Psychiatrists or other physicians; clinical psychologists, certified psychiatric nurse specialists, certified clinical social workers, certified marriage and family therapists, TRICARE certified mental health counselors, pastoral counselors under a physician's supervision, and supervised mental health counselors under a physician's supervision.

**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)(vii).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**Substance use disorder rehabilitation facility (SUDRF). A facility or a distinct part of a facility that meets the criteria in Sec. 199.6(b)(4)(xiv).**

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

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

indemnity plans, and those offered through a direct service health maintenance organization (HMO).

(1) An indemnity supplemental insurance plan must meet all of the following criteria:

(i) It provides insurance coverage, regulated by state insurance agencies, which is available only to beneficiaries of CHAMPUS.

(ii) It is premium based and all premiums relate only to the CHAMPUS supplemental coverage.

(iii) Its benefits for all covered CHAMPUS beneficiaries are predominantly limited to non-covered services, to the deductible and cost-shared portions of the pre-determined allowable charges, and/or to amounts exceeding the allowable charges for covered services.

(iv) It provides insurance reimbursement by making payment directly to the CHAMPUS beneficiary or to the participating provider.

(v) It does not operate in a manner which results in lower deductibles or cost-shares than those imposed by law, or that waives the legally imposed deductibles or cost-shares.

(2) A supplemental insurance plan offered by a Health Maintenance Organization (HMO) must meet all of the following criteria:

(i) The HMO must be authorized and must operate under relevant provisions of state law.

(ii) The HMO supplemental plan must be premium based and all premiums must relate only to CHAMPUS supplemental coverage.

(iii) The HMO's benefits, above those which are directly reimbursed by CHAMPUS, must be limited predominantly to services not covered by CHAMPUS and CHAMPUS deductible and cost-share amounts.

(iv) The HMO must provide services directly to CHAMPUS beneficiaries through its affiliated providers who, in turn, are reimbursed by CHAMPUS.

(v) The HMO's premium structure must be designed so that no overall reduction in the amount of the beneficiary deductibles or cost-shares will result.

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

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

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

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

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

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

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

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

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

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

**Treatment plan.** A detailed description of the medical care being rendered or expected to be rendered a CHAMPUS beneficiary seeking approval for inpatient and other benefits for which preauthorization is required as set forth in Sec. 199.4(b). Medical care described in the plan must meet the requirements of medical and psychological necessity. A treatment plan

must include, at a minimum, a diagnosis (either current International Statistical Classification of Diseases and Related Health Problems (ICD) or current Diagnostic and Statistical Manual of Mental Disorders (DSM)); detailed reports of prior treatment, medical history, family history, social history, and physical examination; diagnostic test results; consultant's reports (if any); proposed treatment by type (such as surgical, medical, and psychiatric); a description of who is or will be providing treatment (by discipline or specialty); anticipated frequency, medications, and specific goals of treatment; type of inpatient facility required and why (including length of time the related inpatient stay will be required); and prognosis. If the treatment plan involves the transfer of a CHAMPUS patient from a hospital or another inpatient facility, medical records related to that inpatient stay also are required as a part of the treatment plan documentation.

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

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

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

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

TRICARE program. The program establish under Sec. 199.17.

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

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

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

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

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

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

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

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

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

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

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

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

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

[51 FR 24008, Jul 1, 1986, as amended at 64 FR 46134, Aug 24, 1999; 66 FR 40606, Aug 3, 2001; 66 FR 45172, Aug 28, 2001; 67 FR 18826, Apr 17, 2002; 67 FR 40602, Jun 13, 2002; 68 FR 6618, Feb 10, 2003; 68 FR 23032, Apr 30, 2003; 68 FR 32361, May 30, 2003; 68 FR 44880, Jul 31, 2003; 69 FR 17048, Apr 1, 2004; 69 FR 44946, Jul 28, 2004; 69 FR 51563, Aug 20, 2004; 69 FR 60554, Oct 12, 2004; 70 FR 12802, Mar 16, 2005; 70 FR 61377, Oct 24, 2005; 71 FR 31944, Jun 2, 2006; 71 FR 35532, Jun 21, 2006; 71 FR 47092, Aug 16, 2006; 72 FR 46383, Aug 20, 2007; 73 FR 74964, Dec 10, 2008; 74 FR 44755, Aug 31, 2009; 75 FR 47455, Aug 6, 2010; 75 FR 47458, Aug 6, 2010; 76 FR 8297, Feb 14, 2011; 76 FR 23483, Apr 27, 2011; 77 FR 38178, Jun 27, 2012; 78 FR 12954, Feb 26, 2013; 78 FR 48309, Aug 8, 2013; 79 FR 41641, Jul 17, 2014; 78 FR 78711, Dec 31, 2014; **81 FR 61085, Sep 2, 2016**]

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

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



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## PART 199.4 - BASIC PROGRAM BENEFITS

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

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

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

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

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

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

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

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

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

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

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

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

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(8) Double coverage and third party recoveries. CHAMPUS claims involving double coverage or the possibility that the United States can recover all or a part of its expenses from a third party, are specifically subject to the provisions of Sec. 199.8 or Sec. 199.12 of this part as appropriate.

(9) Nonavailability Statements within a 40-mile catchment area. Unless required by action of the Assistant Secretary of Defense for Health Affairs (ASD(HA)) under this paragraph (a)(9), nonavailability statements are not required. If they are required by ASD(HA) action, in some geographic locations, CHAMPUS beneficiaries not enrolled in TRICARE Prime may be required to obtain a nonavailability statement from a military medical treatment facility in order to receive specifically identified health care services from a civilian provider. If the required care cannot be provided through the Uniformed Service facility, the hospital commander, or a designee, will issue a Nonavailability Statement (NAS) (DD Form 1251). Failure to secure such a statement may waive the beneficiary's rights to benefits under CHAMPUS/TRICARE.

(i) With the exception of maternity services, the ASD(HA) may require an NAS prior to TRICARE cost-sharing for additional services from civilian sources if such services are to be provided to a beneficiary who lives within a 40-mile catchment area of an MTF where such services are available and the ASD(HA):

(A) Demonstrates that significant costs would be avoided by performing specific procedures at the affected MTF or MTFs; or

(B) Determines that a specific procedure must be provided at the affected MTF or MTFs to ensure the proficiency levels of the practitioners at the MTF or MTFs; or

(C) Determines that the lack of NAS data would significantly interfere with TRICARE contract administration; and

(D) Provides notification of the ASD(HA)'s intent to require an NAS under this authority to covered beneficiaries who receive care at the MTF or MTFs that will be affected by the decision to require an NAS under this authority; and

(E) Provides at least 60-day notification to the Committees on Armed Services of the House of Representatives and the Senate of the ASD(HA)'s intent to require an NAS under this authority, the reason for the NAS requirement, and the date that an NAS will be required.

(ii) Rules in effect at the time civilian medical care is provided apply. The applicable rules and regulations regarding Nonavailability Statements in effect at the time the civilian care is rendered apply in determining whether a NAS is required.

(iii) The Director, TMA is responsible for issuing the procedural rules and regulations regarding Nonavailability Statements. Such rules and regulations should address:

(A) When and for what services a NAS is required. However, a NAS may not be required for services otherwise available at an MTF located within a 40-mile radius of the beneficiary's residence when another insurance plan or program provides the beneficiary's primary coverage for the services. This requirement for an NAS does not apply to beneficiaries enrolled in TRICARE Prime, even when those beneficiaries use the point-of-service option

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under Sec. 199.17(n)(3) of this part; and

(B) When and how notifications will be made to a beneficiary who is not enrolled in TRICARE Prime as to whether or not he or she resides in a geographic area that requires obtaining a NAS; and

(C) What information relating to claims submissions, including the documentation, if any, that is required to document that a valid NAS was issued. However, when documentation of a NAS is required, then that documentation shall be valid for the adjudication of CHAMPUS claims for all related care otherwise authorized by this part which is received from a civilian source while the beneficiary resided within the Uniformed Service facility catchment area which issued the NAS.

(iv) In the case of any service subject to a NAS requirement under this paragraph (a)(9) and also subject to a preadmission (or other pre-service) authorization requirement under Sec. 199.4 or Sec. 199.15 of this part, the administrative processes for the NAS and pre-service authorization may be combined.

(10) (Reserved)

(11) Quality and Utilization Review Peer Review Organization program. All benefits under the CHAMPUS program are subject to review under the CHAMPUS Quality and Utilization Review Peer Review Organization program pursuant to Sec 199.15.

(12) (Reserved)

(13) Implementing instructions. The Director, OCHAMPUS shall issue policies, procedures, instructions, guidelines, standards and/or criteria to implement this section.

(14) Confidentiality of substance use disorder treatment. Release of any patient identifying information, including that required to adjudicate a claim, must comply with the provisions of section 543 of the Public Health Service Act, as amended, (42 U.S.C. 290dd-2), and implementing regulations at 42 CFR part 2, which governs the release of medical and other information from the records of patients undergoing treatment of substance use disorder. If the patient refuses to authorize the release of medical records which are, in the opinion of the Director, Defense Health Agency, or a designee, necessary to determine benefits on a claim for treatment of substance use disorder, the claim will be denied.

**(b) Institutional benefits.** (1) General. Services and supplies provided by an institutional provider authorized as set forth in Sec. 199.6 may be cost-shared only when such services or supplies: are otherwise authorized by this part; are medically necessary; are ordered, directed, prescribed, or delivered by an OCHAMPUS-authorized individual professional provider as set forth in Sec. 199.6 or by an employee of the authorized institutional provider who is otherwise eligible to be a CHAMPUS authorized individual professional provider; are delivered in accordance with generally accepted norms for clinical practice in the United States; meet established quality standards; and comply with applicable definitions, conditions, limitations, exceptions, or exclusions as otherwise set forth in this part.

(i) Billing practices. To be considered for benefits under Sec. 199.4(b), covered services and supplies must be provided and billed for by a hospital or other authorized institutional

provider. Such billings must be fully itemized and sufficiently descriptive to permit CHAMPUS to determine whether benefits are authorized by this part. Depending on the individual circumstances, teaching physician services may be considered an institutional benefit in accordance with Sec. 199.4(b) or a professional benefit under Sec. 199.4(c). See paragraph (c)(3)(xiii) of this section for the CHAMPUS requirements regarding teaching physicians. In the case of continuous care, claims shall be submitted to the appropriate CHAMPUS fiscal intermediary at least every 30 days either by the beneficiary or sponsor or, on a participating basis, directly by the facility on behalf of the beneficiary (refer to Sec. 199.7).

(ii) Successive inpatient admissions. Successive inpatient admissions shall be deemed one inpatient confinement for the purpose of computing the active duty dependent's share of the inpatient institutional charges, provided not more than 60 days have elapsed between the successive admissions, except that successive inpatient admissions related to a single maternity episode shall be considered one confinement, regardless of the number of days between admissions. For the purpose of applying benefits, successive admissions will be determined separately for maternity admissions and admissions related to an accidental injury (refer to Sec. 199.4(f)).

(iii) Related services and supplies. Covered services and supplies must be rendered in connection with and related directly to a covered diagnosis or definitive set of symptoms requiring otherwise authorized medically necessary treatment.

(iv) Inpatient, appropriate level required. For purposes of inpatient care, the level of institutional care for which Basic Program benefits may be extended must be at the appropriate level required to provide the medically necessary treatment except for patients requiring skilled nursing facility care. For patients for whom skilled nursing facility care is adequate, but is not available in the general locality, benefits may be continued in the higher level care facility. General locality means an area that includes all the skilled nursing facilities within 50 miles of the higher level facility, unless the higher level facility can demonstrate that the skilled nursing facilities are inaccessible to its patients. The decision as to whether a skilled nursing facility is within the higher level facility's general locality, or the skilled nursing facility is inaccessible to the higher level facility's patients shall be a CHAMPUS contractor initial determination for the purposes of appeal under Sec. 199.10 of this part. CHAMPUS institutional benefit payments shall be limited to the allowable cost that would have been incurred in the skilled nursing facility, as determined by the Director, OCHAMPUS, or a designee. If it is determined that the institutional care can be provided reasonably in the home setting, no CHAMPUS institutional benefits are payable.

(v) General or special education not covered. Services and supplies related to the provision of either regular or special education generally are not covered. Such exclusion applies whether a separate charge is made for education or whether it is included as a part of an overall combined daily charge of an institution. In the latter instance, that portion of the overall combined daily charge related to education must be determined, based on the allowable costs of the educational component, and deleted from the institution's charges before CHAMPUS benefits can be extended. The only exception is when appropriate education is not available from or not payable by the cognizant public entity. Each case must be referred to the Director, OCHAMPUS, or a designee, for review and a determination of the applicability of CHAMPUS benefits.

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(vi) Substance use disorder treatment exclusions. (A) The programmed use of physical measures, such as electric shock, alcohol, or other drugs as negative reinforcement (aversion therapy) is not covered, even if recommended by a physician.

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

(2) Covered hospital services and supplies--(i) Room and board. Includes special diets, laundry services, and other general housekeeping support services (inpatient only).

(ii) General staff nursing services.

(iii) ICU. Includes specialized units, such as for respiratory conditions, cardiac surgery, coronary care, burn care, or neurosurgery (inpatient only).

(iv) Operating room, recovery room. Operating room and recovery room, including other special treatment rooms and equipment, and hyperbaric chamber.

(v) Drugs and medicines. Includes sera, biologicals, and pharmaceutical preparations (including insulin) that are listed in the official formularies of the institution or facility at the time of use. (To be considered as an inpatient supply, drugs and medicines must be consumed during the specific period the beneficiary is a registered inpatient. Drugs and medicines prescribed for use outside the hospital, even though prescribed and obtained while still a registered inpatient, will be considered outpatient supplies and the provisions of paragraph (d) of this section will apply.)

(vi) Durable medical equipment, medical supplies, and dressings. Includes durable medical equipment, medical supplies essential to a surgical procedure (such as artificial heart valve and artificial ball and socket joint), sterile trays, casts, and orthopedic hardware. Use of durable medical equipment is restricted to an inpatient basis.

NOTE: If durable medical equipment is to be used on an outpatient basis or continued in outpatient status after use as an inpatient, benefits will be provided as set forth in paragraph (d) of this section and cost-sharing will be on an outpatient basis (refer to paragraph (a)(4) of this section).

(vii) Diagnostic services. Includes clinical laboratory examinations, x-ray examinations, pathological examinations, and machine tests that produce hard-copy results. Also includes CT scanning under certain limited conditions.

(viii) Anesthesia. Includes both the anesthetic agent and its administration.

(ix) Blood. Includes blood, plasma and its derivatives, including equipment and supplies, and its administration.

(x) Radiation therapy. Includes radioisotopes.

(xi) Physical therapy.

- (xii) Oxygen. Includes equipment for its administration.
- (xiii) Intravenous injections. Includes solution.
- (xiv) Shock therapy.
- (xv) Chemotherapy.
- (xvi) Renal and peritoneal dialysis.
- (xvii) Psychological evaluation tests. When required by the diagnosis.
- (xviii) Other medical services. Includes such other medical services as may be authorized by the Director, OCHAMPUS, or a designee, provided they are related directly to the diagnosis or definitive set of symptoms and rendered by a member of the institution's medical or professional staff (either salaried or contractual) and billed for by the hospital.
- (xix) Medication assisted treatment. Covered drugs and medicines for the treatment of substance use disorder include the substitution of a therapeutic drug, with addictive potential, for a drug addiction when medically or psychologically necessary and appropriate medical care for a beneficiary undergoing supervised treatment for a substance use disorder.
- (xx) Withdrawal management (detoxification). For a beneficiary undergoing treatment for a substance use disorder, this includes management of a patient's withdrawal symptoms (detoxification).
- (3) Covered services and supplies provided by special medical treatment institutions or facilities, other than hospitals or RTCs--(i) Room and board. Includes special diets, laundry services, and other general housekeeping support services (inpatient only).
- (ii) General staff nursing services.
- (iii) Drugs and medicines. Includes sera, biologicals, and pharmaceutical preparations (including insulin) that are listed in the official formularies of the institution or facility at the time of use. (To be considered as an inpatient supply, drugs and medicines must be consumed during the specific period the beneficiary is a registered inpatient. Drugs and medicines prescribed for use outside the authorized institutional provider, even though prescribed and obtained while still a registered inpatient, will be considered outpatient supplies and the provisions of paragraph (d) of this section will apply.).
- (iv) Durable medical equipment, medical supplies, and dressings. Includes durable medical equipment, sterile trays, casts, orthopedic hardware and dressings. Use of durable medical equipment is restricted to an inpatient basis.

NOTE: If the durable medical equipment is to be used on an outpatient basis or continued in outpatient status after use as an inpatient, benefits will be provided as set forth in paragraph (d) of this section, and cost-sharing will be on an outpatient basis (refer to paragraph (a)(4) of this section).

- (v) Diagnostic services. Includes clinical laboratory examinations, x-ray examinations, pathological examination, and machine tests that produce hard-copy results.
- (vi) Blood. Includes blood, plasma and its derivatives, including equipment and supplies, and its administration.
- (vii) Physical therapy.
- (viii) Oxygen. Includes equipment for its administration.
- (ix) Intravenous injections. Includes solution.
- (x) Shock therapy.
- (xi) Chemotherapy.
- (xii) Psychological evaluation tests. When required by the diagnosis.
- (xiii) Renal and peritoneal dialysis.
- (xiv) Skilled nursing facility (SNF) services. Covered services in SNFs are the same as provided under Medicare under section 1861(h) and (i) of the Social Security Act (42 U.S.C. 1395x(h) and (i)) and 42 CFR part 409, subparts C and D, except that the Medicare limitation on the number of days of coverage under section 1812(a) and (b) of the Social Security Act (42 U.S.C. 1395d(a) and (b)) and 42 CFR 409.61(b) shall not be applicable under TRICARE. Skilled nursing facility care for each spell of illness shall continue to be provided for as long as medically necessary and appropriate. For a SNF admission to be covered under TRICARE, the beneficiary must have a qualifying hospital stay meaning an inpatient hospital stay of three consecutive days or more, not including the hospital leave day. The beneficiary must enter the SNF within 30 days of leaving the hospital, or within such time as it would be medically appropriate to begin an active course of treatment, where the individual's condition is such that SNF care would not be medically appropriate within 30 days after discharge from a hospital. The skilled services must be for a medical condition that was either treated during the qualifying three-day hospital stay, or started while the beneficiary was already receiving covered SNF care. Additionally, an individual shall be deemed not to have been discharged from a SNF, if within 30 days after discharge from a SNF, the individual is again admitted to a SNF. Adoption by TRICARE of most Medicare coverage standards does not include Medicare coinsurance amounts. Extended care services furnished to an inpatient of a SNF by such SNF (except as provided in paragraphs (b)(3)(xiv)(C), (b)(3)(xiv)(F), and (b)(3)(xiv)(G) of this section) include:
  - (A) Nursing care provided by or under the supervision of a registered professional nurse;
  - (B) Bed and board in connection with the furnishing of such nursing care;
  - (C) Physical or occupational therapy or speech-language pathology services furnished by the SNF or by others under arrangements with them by the facility;
  - (D) Medical social services;

(E) Such drugs, biological, supplies, appliances, and equipment, furnished for use in the SNF, as are ordinarily furnished for the care and treatment of inpatients;

(F) Medical services provided by an intern or resident-in-training of a hospital with which the facility has such an agreement in effect; and

(G) Such other services necessary to the health of the patients as are generally provided by SNFs, or by others under arrangements with them made by the facility.

(xv) Other medical services. Other medical services may be authorized by the Director, OCHAMPUS, or a designee, provided they are related directly to the diagnosis or definitive set of symptoms and rendered by a member of the institution's medical or professional staff (either salaried or contractual) and billed for by the authorized institutional provider of care.

(xvi) Medication assisted treatment. Covered drugs and medicines for the treatment of substance use disorder include the substitution of a therapeutic drug, with addictive potential, for a drug addiction when medically or psychologically necessary and appropriate medical care for a beneficiary undergoing supervised treatment for a substance use disorder.

(xvii) Withdrawal management (detoxification). For a beneficiary undergoing treatment for a substance use disorder, this includes management of a patient's withdrawal symptoms (detoxification).

(4) Services and supplies provided by RTCs--(i) Room and board. Includes use of residential facilities such as food service (including special diets), laundry services, supervised reasonable recreational and social activity services, and other general services as considered appropriate by the Director, OCHAMPUS, or a designee.

(ii) Patient assessment. Includes the assessment of each child or adolescent accepted by the RTC, including clinical consideration of each of his or her fundamental needs, that is, physical, psychological, chronological age, developmental level, family, educational, social, environmental, and recreational.

(iii) Diagnostic services. Includes clinical laboratory examinations, x-ray examinations, pathological examinations, and machine tests that produce hard-copy results.

(iv) Psychological evaluation tests.

(v) Treatment of mental disorders. Services and supplies that are medically or psychologically necessary to diagnose and treat the mental disorder for which the patient was admitted to the RTC. Covered services and requirements for qualifications of providers are as listed in paragraph (c)(3)(ix) of this section.

(vi) Other necessary medical care. Emergency medical services or other authorized medical care may be rendered by the RTC provided it is professionally capable of rendering such services and meets standards required by the Director, OCHAMPUS. It is intended, however, that CHAMPUS payments to an RTC should primarily cover those services and supplies directly related to the treatment of mental disorders that require residential care.

(vii) Criteria for determining medical or psychological necessity. In determining the medical or psychological necessity of services and supplies provided by RTCs, the evaluation conducted by the Director, OCHAMPUS (or designee) shall consider the appropriate level of care for the patient, the intensity of services required by the patient, and the availability of that care. In addition to the criteria set forth in this paragraph (b)(4) of this section, additional evaluation standards, consistent with such criteria, may be adopted by the Director, OCHAMPUS (or designee). RTC services and supplies shall not be considered medically or psychologically necessary unless, at a minimum, all the following criteria are clinically determined in the evaluation to be fully met:

- (A) Patient has a diagnosable psychiatric disorder.
- (B) Patient exhibits patterns of disruptive behavior with evidence of disturbances in family functioning or social relationships and persistent psychological and/or emotional disturbances.
- (C) RTC services involve active clinical treatment under an individualized treatment plan that provides for:
- (1) Specific level of care, and measurable goals/objectives relevant to each of the problems identified;
  - (2) Skilled interventions by qualified mental health professionals to assist the patient and/or family;
  - (3) Time frames for achieving proposed outcomes; and
  - (4) Evaluation of treatment progress to include timely reviews and updates as appropriate of the patient's treatment plan that reflects alterations in the treatment regimen, the measurable goals/objectives, and the level of care required for each of the patient's problems, and explanations of any failure to achieve the treatment goals/objectives.
- (D) Unless therapeutically contraindicated, the family and/or guardian must actively participate in the continuing care of the patient either through direct involvement at the facility or geographically distant family therapy. (In the latter case, the treatment center must document that there has been collaboration with the family and/or guardian in all reviews.)
- (5) Extent of institutional benefits--(i) Inpatient room accommodations--
- (A) Semiprivate. The allowable costs for room and board furnished an individual patient are payable for semiprivate accommodations in a hospital or other authorized institution, subject to appropriate cost-sharing provisions (refer to paragraph (f) of this section). A semiprivate accommodation is a room containing at least two beds. Therefore, if a room publicly is designated by the institution as a semiprivate accommodation and contains multiple beds, it qualifies as semiprivate for the purpose of CHAMPUS.
- (B) Private. A room with one bed that is designated as a private room by the hospital or other authorized institutional provider. The allowable cost of a private room accommodation is covered only under the following conditions:
- (1) When its use is required medically and when the attending physician certifies that a

private room is necessary medically for the proper care and treatment of a patient; or

(2) When a patient's medical condition requires isolation; or

(3) When a patient (in need of immediate inpatient care but not requiring a private room) is admitted to a hospital or other authorized institution that has semiprivate accommodations, but at the time of admission, such accommodations are occupied; or

(4) When a patient is admitted to an acute care hospital (general or special) without semiprivate rooms.

(C) Duration of private room stay. The allowable cost of private accommodations is covered under the circumstances described in paragraph (b)(5)(i)(B) of this section until the patient's condition no longer requires the private room for medical reasons or medical isolation; or, in the case of the patient not requiring a private room, when a semiprivate accommodation becomes available; or, in the case of an acute care hospital (general or special) which does not have semiprivate rooms, for the duration of an otherwise covered inpatient stay.

(D) Hospital (except an acute care hospital, general or special) or other authorized institutional provider without semiprivate accommodations. When a beneficiary is admitted to a hospital (except an acute care hospital, general or special) or other institution that has no semiprivate accommodations, for any inpatient day when the patient qualifies for use of a private room (as set forth in paragraphs (b)(5)(i)(B)(1) and (2) of this section) the allowable cost of private accommodations is covered. For any inpatient day in such a hospital or other authorized institution when the patient does not require medically the private room, the allowable cost of semiprivate accommodations is covered, such allowable costs to be determined by the Director, OCHAMPUS, or a designee.

(ii) General staff nursing services. General staff nursing services cover 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. Only nursing services provided by nursing personnel on the payroll of the hospital or other authorized institution are eligible under paragraph (b) of this section. If a nurse who is not on the payroll of the hospital or other authorized institution is called in specifically to care for a single patient (individual nursing) or more than one patient (group nursing), whether the patient is billed for the nursing services directly or through the hospital or other institution, such services constitute private duty (special) nursing services and are not eligible for benefits under this paragraph (the provisions of paragraph (c)(2)(xv) of this section would apply).

(iii) ICU. An ICU is 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 are available regularly and immediately within the unit, and patients are under continuous observation by a nursing staff specially trained and selected for the care of this type of patient. The unit is maintained on a continuing, rather than an intermittent or temporary, basis. It is not a postoperative recovery room or a postanesthesia room. In some large or highly specialized hospitals, the ICUs may be refined further for special purposes, such as for respiratory conditions, cardiac surgery, coronary

care, burn care, or neurosurgery. For purposes of CHAMPUS, these specialized units would be considered ICUs if they otherwise conformed to the definition of an ICU.

(iv) Treatment rooms. Standard treatment rooms include emergency rooms, operating rooms, recovery rooms, special treatment rooms, and hyperbaric chambers and all related necessary medical staff and equipment. To be recognized for purposes of CHAMPUS, treatment rooms must be so designated and maintained by the hospital or other authorized institutions on a continuing basis. A treatment room set up on an intermittent or temporary basis would not be so recognized.

(v) Drugs and medicines. Drugs and medicines are included as a supply of a hospital or other authorized institution only under the following conditions:

(A) They represent a cost to the facility rendering treatment;

(B) They are furnished to a patient receiving treatment, and are related directly to that treatment; and

(C) They are ordinarily furnished by the facility for the care and treatment of inpatients.

(vi) Durable medical equipment, medical supplies, and dressings. Durable medical equipment, medical supplies, and dressings are included as a supply of a hospital or other authorized institution only under the following conditions:

(A) If ordinarily furnished by the facility for the care and treatment of patients; and

(B) If specifically related to, and in connection with, the condition for which the patient is being treated; and

(C) If ordinarily furnished to a patient for use in the hospital or other authorized institution (except in the case of a temporary or disposable item); and

(D) Use of durable medical equipment is limited to those items provided while the patient is an inpatient. If such equipment is provided for use on an outpatient basis, the provisions of paragraph (d) of this section apply.

(vii) Transitional use items. Under certain circumstances, a temporary or disposable item may be provided for use beyond an inpatient stay, when such item is necessary medically to permit or facilitate the patient's departure from the hospital or other authorized institution, or which may be required until such time as the patient can obtain a continuing supply; or it would be unreasonable or impossible from a medical standpoint to discontinue the patient's use of the item at the time of termination of his or her stay as an inpatient.

(viii) Anesthetics and oxygen. Anesthetics and oxygen and their administration are considered a service or supply if furnished by the hospital or other authorized institution, or by others under arrangements made by the facility under which the billing for such services is made through the facility.

(6) Inpatient mental health services. Inpatient mental health services are those services furnished by institutional and professional providers for treatment of a nervous or mental

disorder (as defined in Sec. 199.2) to a patient admitted to a CHAMPUS-authorized acute care general hospital; a psychiatric hospital; or, unless otherwise exempted, a special institutional provider.

(i) Criteria for determining medical or psychological necessity. In determining the medical or psychological necessity of acute inpatient mental health services, the evaluation conducted by the Director, OCHAMPUS (or designee) shall consider the appropriate level of care for the patient, the intensity of services required by the patient, and the availability of that care. The purpose of such acute inpatient care is to stabilize a life-threatening or severely disabling condition within the context of a brief, intensive model of inpatient care in order to permit management of the patient's condition at a less intensive level of care. Such care is appropriate only if the patient requires services of an intensity and nature that are generally recognized as being effectively and safely provided only in an acute inpatient hospital setting. In addition to the criteria set forth in this paragraph (b)(6) of this section, additional evaluation standards, consistent with such criteria, may be adopted by the Director, OCHAMPUS (or designee). Acute inpatient care shall not be considered necessary unless the patient needs to be observed and assessed on a 24-hour basis by skilled nursing staff, and/or requires continued intervention by a multidisciplinary treatment team; and in addition, at least one of the following criteria is determined to be met:

- (A) Patient poses a serious risk of harm to self and/or others.
- (B) Patient is in need of high dosage, intensive medication or somatic and/or psychological treatment, with potentially serious side effects.
- (C) Patient has acute disturbances of mood, behavior, or thinking.

(ii) Emergency admissions. Admission to an acute inpatient hospital setting may be on an emergency or on a non-emergency basis. In order for an admission to qualify as an emergency, the following criteria, in addition to those in paragraph (b)(6)(i) of this section, must be met:

- (A) The patient must be at immediate risk of serious harm to self and or others based on a psychiatric evaluation performed by a physician (or other qualified mental health professional with hospital admission authority); and
- (B) The patient requires immediate continuous skilled observation and treatment at the acute psychiatric level of care.

(iii) (Reserved)

(iv) (Reserved)

(7) Emergency inpatient hospital services. In the case of a medical emergency, benefits can be extended for medically necessary inpatient services and supplies provided to a beneficiary by a hospital, including hospitals that do not meet CHAMPUS standards or comply with the nondiscrimination requirements under title VI of the Civil Rights Act and other nondiscrimination laws applicable to recipients of federal financial assistance, or satisfy other conditions herein set forth. In a medical emergency, medically necessary inpatient services and supplies are those that are necessary to prevent the death or serious impairment

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of the health of the patient, and that, because of the threat to the life or health of the patient, necessitate, the use of the most accessible hospital available and equipped to furnish such services. Emergency services are covered when medically necessary for the active medical treatment of the acute phases of substance withdrawal (detoxification), for stabilization and for treatment of medical complications for substance use disorder. The availability of benefits depends upon the following three separate findings and continues only as long as the emergency exists, as determined by medical review. If the case qualified as an emergency at the time of admission to an unauthorized institutional provider and the emergency subsequently is determined no longer to exist, benefits will be extended up through the date of notice to the beneficiary and provider that CHAMPUS benefits no longer are payable in that hospital.

(i) Existence of medical emergency. A determination that a medical emergency existed with regard to the patient's condition;

(ii) Immediate admission required. A determination that the condition causing the medical emergency required immediate admission to a hospital to provide the emergency care; and

(iii) Closest hospital utilized. A determination that diagnosis or treatment was received at the most accessible (closest) hospital available and equipped to furnish the medically necessary care.

(8) Residential treatment for substance use disorder--(i) In general. Rehabilitative care, to include withdrawal management (detoxification), in an inpatient residential setting of an authorized hospital or substance use disorder rehabilitative facility, whether free-standing or hospital-based, is covered on a residential basis. The medical necessity for the management of withdrawal symptoms must be documented. Any withdrawal management (detoxification) services provided by the substance use disorder rehabilitation facility must be under general medical supervision.

(ii) Criteria for determining medical or psychological necessity of residential treatment for substance use disorder. Residential treatment for substance use disorder will be considered necessary only if all of the following conditions are present:

(A) The patient has been diagnosed with a substance use disorder.

(B) The patient is experiencing withdrawal symptoms or potential symptoms severe enough to require inpatient care and physician management, or who have less severe symptoms that require 24-hour inpatient monitoring or the patient's addiction-related symptoms, or concomitant physical and emotional/behavioral problems reflect persistent dysfunction in several major life areas.

(iii) Services and supplies. The following services and supplies are included in the per diem rate approved for an authorized residential treatment for substance use disorder.

(A) Room and board. Includes use of the residential treatment program facilities such as food service (including special diets), laundry services, supervised therapeutically constructed recreational and social activities, and other general services as considered appropriate by the Director, or a designee.

(B) Patient assessment. Includes the assessment of each individual accepted by the facility, and must, at a minimum, consist of a physical examination; psychiatric examination; psychological assessment; assessment of physiological, biological and cognitive processes; case management assessment; developmental assessment; family history and assessment; social history and assessment; educational or vocational history and assessment; environmental assessment; and recreational/activities assessment. Assessments conducted within 30 days prior to admission to a residential treatment program for substance use disorder (SUD) may be used if approved and deemed adequate to permit treatment planning by the residential treatment program for SUD.

(C) Psychological testing. Psychological testing is provided based on medical and psychological necessity.

(D) Treatment services. All services, supplies, equipment and space necessary to fulfill the requirements of each patient's individualized diagnosis and treatment plan. All mental health services must be provided by a TRICARE authorized individual professional provider of mental health services. [Exception: Residential treatment programs that employ individuals with master's or doctoral level degrees in a mental health discipline who do not meet the licensure, certification, and experience requirements for a qualified mental health provider but are actively working toward licensure or certification may provide services within the all-inclusive per diem rate, but such individuals must work under the clinical supervision of a fully qualified mental health provider employed by the facility.]

(iv) Case management required. The facility must provide case management that helps to assure arrangement of community based support services, referral of suspected child or elder abuse or domestic violence to the appropriate state agencies, and effective after care arrangements, at a minimum.

(v) Professional mental health benefits. Professional mental health benefits are billed separately from the residential treatment program per diem rate only when rendered by an attending, TRICARE authorized mental health professional who is not an employee of, or under contract with, the program for purposes of providing clinical patient care.

(vi) Non-mental health related medical services. Separate billing will be allowed for otherwise covered non-mental health related services.

(9) Psychiatric and substance use disorder partial hospitalization services--(i) In general. Partial hospitalization services are those services furnished by a TRICARE authorized partial hospitalization program and authorized mental health providers for the active treatment of a mental disorder. All services must follow a medical model and vest patient care under the general direction of a licensed TRICARE authorized physician employed by the partial hospitalization program to ensure medication and physical needs of all the patients are considered. The primary or attending provider must be a TRICARE authorized mental health provider (see paragraph (c)(3)(ix) of this section), operating within the scope of his/her license. These categories include physicians, clinical psychologists, certified psychiatric nurse specialists, clinical social workers, marriage and family counselors, TRICARE certified mental health counselors, pastoral counselors, and supervised mental health counselors. All categories practice independently except pastoral counselors and supervised mental health counselors who must practice under the supervision of TRICARE authorized physicians. Partial hospitalization services and

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interventions are provided at a high degree of intensity and restrictiveness of care, with medical supervision and medication management. Partial hospitalization services are covered as a basic program benefit only if they are provided in accordance with paragraph (b)(9) of this section. Such programs must enter into a participation agreement with TRICARE; and be accredited and in substantial compliance with the specified standards of an accreditation organization approved by the Director.

(ii) Criteria for determining medical or psychological necessity of psychiatric and SUD partial hospitalization services. Partial hospitalization services will be considered necessary only if all of the following conditions are present:

(A) The patient is suffering significant impairment from a mental disorder (as defined in Sec. 199.2) which interferes with age appropriate functioning or the patient is in need of rehabilitative services for the management of withdrawal symptoms from alcohol, sedative-hypnotics, opioids, or stimulants that require medically-monitored ambulatory detoxification, with direct access to medical services and clinically intensive programming of rehabilitative care based on individual treatment plans.

(B) The patient is unable to maintain himself or herself in the community, with appropriate support, at a sufficient level of functioning to permit an adequate course of therapy exclusively on an outpatient basis, to include outpatient treatment program, outpatient office visits, or intensive outpatient services (but is able, with appropriate support, to maintain a basic level of functioning to permit partial hospitalization services and presents no substantial imminent risk of harm to self or others). These patients require medical support; however, they do not require a 24-hour medical environment.

(C) The patient is in need of crisis stabilization, acute symptom reduction, treatment of partially stabilized mental health disorders, or services as a transition from an inpatient program.

(D) The admission into the partial hospitalization program is based on the development of an individualized diagnosis and treatment plan expected to be effective for that patient and permit treatment at a less intensive level.

(iii) Services and supplies. The following services and supplies are included in the per diem rate approved for an authorized partial hospitalization program:

(A) Board. Includes use of the partial hospital facilities such as food service, supervised therapeutically constructed recreational and social activities, and other general services as considered appropriate by the Director, or a designee.

(B) Patient assessment. Includes the assessment of each individual accepted by the facility, and must, at a minimum, consist of a physical examination; psychiatric examination; psychological assessment; assessment of physiological, biological and cognitive processes; case management assessment; developmental assessment; family history and assessment; social history and assessment; educational or vocational history and assessment; environmental assessment; and recreational/activities assessment. Assessments conducted within 30 days prior to admission to a partial program may be used if approved and deemed adequate to permit treatment planning by the partial hospital program.

(C) Psychological testing. Treatment services. All services, supplies, equipment and space necessary to fulfill the requirements of each patient's individualized diagnosis and treatment plan. All mental health services must be provided by a TRICARE authorized individual professional provider of mental health services. [Exception: partial hospitalization programs that employ individuals with master's or doctoral level degrees in a mental health discipline who do not meet the licensure, certification, and experience requirements for a qualified mental health provider but are actively working toward licensure or certification, may provide services within the all-inclusive per diem rate, but such individuals must work under the clinical supervision of a fully qualified mental health provider employed by the partial hospitalization program.]

(iv) Case management required. The facility must provide case management that helps to assure the patient appropriate living arrangements after treatment hours, transportation to and from the facility, arrangement of community based support services, referral of suspected child or elder abuse or domestic violence to the appropriate state agencies, and effective after care arrangements, at a minimum.

(v) Educational services required. Programs treating children and adolescents must ensure the provision of a state certified educational component which assures that patients do not fall behind in educational placement while receiving partial hospital treatment. CHAMPUS will not fund the cost of educational services separately from the per diem rate. The hours devoted to education do not count toward the therapeutic intensive outpatient program or full day program.

(vi) Family therapy required. The facility must ensure the provision of an active family therapy treatment component, which assures that each patient and family participate at least weekly in family therapy provided by the institution and rendered by a TRICARE authorized individual professional provider of mental health services. There is no acceptable substitute for family therapy. An exception to this requirement may be granted on a case-by-case basis by the Clinical Director, or designee, only if family therapy is clinically contraindicated.

(vii) Professional mental health benefits. Professional mental health benefits are billed separately from the partial hospitalization per diem rate only when rendered by an attending, TRICARE authorized mental health professional who is not an employee of, or under contract with, the partial hospitalization program for purposes of providing clinical patient care.

(viii) Non-mental health related medical services. Separate billing will be allowed for otherwise covered, non-mental health related medical services.

(10) Intensive psychiatric and substance use disorder outpatient services--(i) In general. Intensive outpatient services are those services furnished by a TRICARE authorized intensive outpatient program and qualified mental health provider(s) for the active treatment of a mental disorder, to include substance use disorder.

(ii) Criteria for determining medical or psychological necessity of intensive outpatient services. In determining the medical or psychological necessity of intensive outpatient services, the evaluation conducted by the Director, or designee, shall consider the appropriate level of care, based on the patient's clinical needs and characteristics matched to

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a service's structure and intensity. In addition to the criteria set for this paragraph (b)(10) of this section, additional evaluation standards, consistent with such criteria, may be adopted by the Director, or designee. Treatment in an intensive outpatient setting shall not be considered necessary unless the patient requires care that is more intensive than an outpatient treatment program or outpatient office visits and less intensive than inpatient psychiatric care or a partial hospital program. Intensive outpatient services will be considered necessary only if the following conditions are present:

(A) The patient is suffering significant impairment from a mental disorder, to include a substance use disorder (as defined in Sec. 199.2), which interferes with age appropriate functioning. Patients receiving a higher intensity of treatment may be experiencing moderate to severe instability, exacerbation of severe/persistent disorder, or dangerousness with some risk of confinement. Patients receiving a lower intensity of treatment may be experiencing mild instability with limited dangerousness and low risk for confinement.

(B) The patient is unable to maintain himself or herself in the community, with appropriate support, at a sufficient level of functioning to permit an adequate course of therapy exclusively in an outpatient treatment program or an outpatient office basis (but is able, with appropriate support, to maintain a basic level of functioning to permit a level of intensive outpatient treatment and presents no substantial imminent risk of harm to self or others).

(C) The patient is in need of stabilization, symptom reduction, and prevention of relapse for chronic mental illness. The goal of maintenance of his or her functioning within the community cannot be met by outpatient office visits, but requires active treatment in a stable, staff-supported environment;

(D) The admission into the intensive outpatient program is based on the development of an individualized diagnosis and treatment plan expected to be effective for that patient and permit treatment at a less intensive level.

(iii) Services and supplies. The following services and supplies are included in the per diem rate approved for an authorized intensive outpatient program.

(A) Patient assessment. Includes the assessment of each individual accepted by the facility.

(B) Treatment services. All services, supplies, equipment, and space necessary to fulfill the requirements of each patient's individualized diagnosis and treatment plan. All mental health services must be provided by a TRICARE authorized individual qualified mental health provider. [Exception: Intensive outpatient programs that employ individuals with master's or doctoral level degrees in a mental health discipline who do not meet the licensure, certification, and experience requirements for a qualified mental health provider but are actively working toward licensure or certification, may provide services within the all-inclusive per diem rate but such individuals must work under the clinical supervision of a fully qualified mental health provider employed by the facility.]

(iv) Case management. When appropriate, and with the consent of the person served, the facility should coordinate the care, treatment, or services, including providing coordinated treatment with other services.

(v) Professional mental health benefits. Professional mental health benefits are billed separately from the intensive outpatient per diem rate only when rendered by an attending, TRICARE authorized qualified mental health provider who is not an employee of, or under contract with, the program for purposes of providing clinical patient care.

(vi) Non-mental health related medical services. Separate billing will be allowed for otherwise covered, non-mental health related medical services.

(11) Opioid treatment programs--(i) In general. Outpatient treatment and management of withdrawal symptoms for substance use disorder provided at a TRICARE authorized opioid treatment program are covered. If the patient is medically in need of management of withdrawal symptoms, but does not require the personnel or facilities of a general hospital setting, services for management of withdrawal symptoms are covered. The medical necessity for the management of withdrawal symptoms must be documented. Any services to manage withdrawal symptoms provided by the opioid treatment program must be under general medical supervision.

(ii) Criteria for determining medical or psychological necessity of an opioid treatment program are set forth in 42 CFR part 8.

(iii) Services and supplies. The following services and supplies are included in the reimbursement approved for an authorized opioid treatment program.

(A) Patient assessment. Includes the assessment of each individual accepted by the facility.

(B) Treatment services. All services, supplies, equipment, and space necessary to fulfill the requirements of each patient's individualized diagnosis and treatment plan. All mental health services must be provided by a TRICARE authorized individual professional provider of mental health services. [Exception: opioid treatment programs that employ individuals with degrees in a mental health discipline who do not meet the licensure, certification, and experience requirements for a qualified mental health provider but work under the clinical supervision of a fully qualified mental health provider employed by the facility.]

(iv) Case management. Care, treatment, or services should be coordinated among providers and between settings, independent of whether they are provided directly by the organization or by an organization or by an outside source, so that the individual's needs are addressed in a seamless, synchronized, and timely manner.

**(c) Professional services benefit--**(1) General. Benefits may be extended for those covered services described in paragraph (c) of this section that are provided in accordance with good medical practice and established standards of quality by physicians or other authorized individual professional providers, as set forth in Sec. 199.6 of this part. Such benefits are subject to all applicable definitions, conditions, exceptions, limitations, or exclusions as maybe otherwise set forth in this or other Sections of this part. Except as otherwise specifically authorized, to be considered for benefits under paragraph (c) of this section, the described services must be rendered by a physician, or prescribed, ordered, and referred medically by a physician to other authorized individual professional providers. Further, except under specifically defined circumstances, there should be an attending

physician in any episode of care. (For example, certain services of a clinical psychologist are exempt from this requirement. For these exceptions, refer to Sec. 199.6.)

(i) Billing practices. To be considered for benefits under paragraph (c) of this section, covered professional services must be performed personally by the physician or other authorized individual professional provider, who is other than a salaried or contractual staff member of a hospital or other authorized institution, and who ordinarily and customarily bills on a fee-for-service basis for professional services rendered. Such billings must be itemized fully and be sufficiently descriptive to permit CHAMPUS to determine whether benefits are authorized by this part. See paragraph (c)(3)(xiii) of this section for the requirements regarding the special circumstances for teaching physicians. For continuing professional care, claims should be submitted to the appropriate CHAMPUS fiscal intermediary at least every 30 days either by the beneficiary or sponsor, or directly by the physician or other authorized individual professional provider on behalf of a beneficiary (refer to Sec. 199.7).

(ii) Services must be related. Covered professional services must be rendered in connection with and directly related to a covered diagnosis or definitive set of symptoms requiring medically necessary treatment.

(2) Covered services of physicians and other authorized profession providers.

(i) Surgery. Surgery means operative procedures, including related preoperative and postoperative care; reduction of fractures and dislocations; injection and needling procedures of the joints; laser surgery of the eye; and the following procedures:

Bronchoscopy

Laryngoscopy

Thoracoscopy

Catheterization of the heart

Arteriograph thoracic lumbar

Esophagoscopy

Gastroscopy

Proctoscopy

Sigmoidoscopy

Peritoneoscopy

Cystoscopy

Colonscopy

Upper G.I. panendoscopy

Encephalograph

Myelography

Discography

Visualization of intracranial aneurysm by intracarotid injection of dye, with exposure of carotid artery, unilateral

Ventriculography

Insufflation of uterus and fallopian tubes for determination of tubal patency (Rubin's test of injection of radiopaque medium or for dilation)

Introduction of opaque media into the cranial arterial system, preliminary to cerebral arteriography, or into vertebral and subclavian systems

Intraspinal introduction of air preliminary to pneumoencephalography

Intraspinal introduction of opaque media preliminary to myelography

Intraventricular introduction of air preliminary to ventriculography

NOTE: The Director, OCHAMPUS, or a designee, shall determine such additional procedures that may fall within the intent of this definition of "surgery."

- (ii) Surgical assistance.
- (iii) Inpatient medical services.
- (iv) Outpatient medical services.
- (v) Psychiatric services.
- (vi) Consultation services.
- (vii) Anesthesia services.
- (viii) Radiation therapy services.
- (ix) X-ray services.
- (x) Laboratory and pathological services.
- (xi) Physical medicine services or physiatry services.
- (xii) Maternity care.
- (xiii) Well-child care.

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(xiv) Other medical care. Other medical care includes, but is not limited to, hemodialysis, inhalation therapy, shock therapy, and chemotherapy. The Director, OCHAMPUS, or a designee, shall determine those additional medical services for which benefits may be extended under this paragraph.

NOTE: A separate professional charge for the oral administration of approved antineoplastic drugs is not covered.

(xv) (Reserved)

(xvi) Routine eye examinations. Coverage for routine eye examinations is limited to dependents of active duty members, to one examination per calendar year per person, and to services rendered on or after October 1, 1984, except as provided under paragraph (c)(3)(xi) of this section.

(3) Extent of professional benefits--(i) Multiple Surgery. In cases of multiple surgical procedures performed during the same operative session, benefits shall be extended as follows:

(A) One hundred (100) percent of the CHAMPUS-determined allowable charge for the major surgical procedure (the procedure for which the greatest amount is payable under the applicable reimbursement method); and

(B) Fifty (50) percent of the CHAMPUS-determined allowable charge for each of the other surgical procedures;

(C) Except that:

(1) If the multiple surgical procedures include an incidental procedure, no benefits shall be allowed for the incidental procedure.

(2) If the multiple surgical procedures involve specific procedures identified by the Director, OCHAMPUS, benefits shall be limited as set forth in CHAMPUS instructions.

(ii) Different types of inpatient care, concurrent. If a beneficiary receives inpatient medical care during the same admission in which he or she also receives surgical care or maternity care, the beneficiary shall be entitled to the greater of the CHAMPUS-determined allowable charge for either the inpatient medical care or surgical or maternity care received, as the case may be, but not both; except that the provisions of this paragraph (c)(3)(ii) shall not apply if such inpatient medical care is for a diagnosed condition requiring inpatient medical care not related to the condition for which surgical care or maternity care is received, and is received from a physician other than the one rendering the surgical care or maternity care.

NOTE: This provision is not meant to imply that when extra time and special effort are required due to postsurgical or postdelivery complications, the attending physician may not request special consideration for a higher than usual charge.

(iii) Need for surgical assistance. Surgical assistance is payable only when the complexity of the procedure warrants a surgical assistant (other than the surgical nurse or

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other such operating room personnel), subject to utilization review. In order for benefits to be extended for surgical assistance service, the primary surgeon may be required to certify in writing to the nonavailability of a qualified intern, resident, or other house physician. When a claim is received for a surgical assistant involving the following circumstances, special review is required to ascertain whether the surgical assistance service meets the medical necessity and other requirements of paragraph (c) of this section.

(A) If the surgical assistance occurred in a hospital that has a residency program in a specialty appropriate to the surgery;

(B) If the surgery was performed by a team of surgeons;

(C) If there were multiple surgical assistants; or

(D) If the surgical assistant was a partner of or from the same group of practicing physicians as the attending surgeon.

(iv) Aftercare following surgery. Except for those diagnostic procedures classified as surgery in paragraph (c) of this section, and injection and needling procedures involving the joints, the benefit payments made for surgery (regardless of the setting in which it is rendered) include normal aftercare, whether the aftercare is billed for by the physician or other authorized individual professional provider on a global, all-inclusive basis, or billed for separately.

(v) Cast and sutures, removal. The benefit payments made for the application of a cast or of sutures normally covers the postoperative care including the removal of the cast or sutures. When the application is made in one geographical location and the removal of the cast or sutures must be done in another geographical location, a separate benefit payment may be provided for the removal. The intent of this provision is to provide a separate benefit only when it is impracticable for the beneficiary to use the services of the provider that applied the cast originally. Benefits are not available for the services of a second provider if those services reasonably could have been rendered by the individual professional provider who applied the cast or sutures initially.

(vi) Inpatient care, concurrent. Concurrent inpatient care by more than one individual professional provider is covered if required because of the severity and complexity of the beneficiary's condition or because the beneficiary has multiple conditions that require treatment by providers of different specialties. Any claim for concurrent care must be reviewed before extending benefits in order to ascertain the condition of the beneficiary at the time the concurrent care was rendered. In the absence of such determination, benefits are payable only for inpatient care rendered by one attending physician or other authorized individual professional provider.

(vii) Consultants who become the attending surgeon. A consultation performed within 3 days of surgery by the attending physician is considered a preoperative examination. Preoperative examinations are an integral part of the surgery and a separate benefit is not payable for the consultation. If more than 3 days elapse between the consultation and surgery (performed by the same physician), benefits may be extended for the consultation, subject to review.

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(viii) Anesthesia administered by the attending physician. A separate benefit is not payable for anesthesia administered by the attending physician (surgeon or obstetrician) or dentist, or by the surgical, obstetrical, or dental assistant.

(ix) Treatment of mental disorders, to include substance use disorder. In order to qualify for CHAMPUS mental health benefits, the patient must be diagnosed by a TRICARE authorized qualified mental health professional practicing within the scope of his or her license to be suffering from a mental disorder, as defined in Sec. 199.2.

(A) Covered diagnostic and therapeutic services. CHAMPUS benefits are payable for the following services when rendered in the diagnosis or treatment of a covered mental disorder by a TRICARE authorized qualified mental health provider practicing within the scope of his or her license. Qualified mental health providers are: Psychiatrists or other physicians; clinical psychologists, certified psychiatric nurse specialists, certified clinical social workers, certified marriage and family therapists, TRICARE certified mental health counselors, pastoral counselors under a physician's supervision, and supervised mental health counselors under a physician's supervision.

(1) Individual psychotherapy, adult or child. A covered individual psychotherapy session is no more than 60 minutes in length. An individual psychotherapy session of up to 120 minutes in length is payable for crisis intervention.

(2) Group psychotherapy. A covered group psychotherapy session is no more than 90 minutes in length.

(3) Family or conjoint psychotherapy. A covered family or conjoint psychotherapy session is no more than 90 minutes in length. A family or conjoint psychotherapy session of up to 180 minutes in length is payable for crisis intervention.

(4) Psychoanalysis. Psychoanalysis is covered when provided by a graduate or candidate of a psychoanalytic training institution recognized by the American Psychoanalytic Association and when preauthorized by the Director, or a designee.

(5) Psychological testing and assessment. Psychological testing and assessment is covered when medically or psychologically necessary. Psychological testing and assessment performed as part of an assessment for academic placement are not covered.

(6) Administration of psychotropic drugs. When prescribed by an authorized provider qualified by licensure to prescribe drugs.

(7) Electroconvulsive treatment. When provided in accordance with guidelines issued by the Director.

(8) Collateral visits. Covered collateral visits are those that are medically or psychologically necessary for the treatment of the patient.

(9) Medication assisted treatment. Medication assisted treatment, combining pharmacotherapy and holistic care, to include provision in office-based opioid treatment by an authorized TRICARE provider, is covered. The practice of an individual physician in office-based treatment is regulated by the Department of Health and Human Services' 42

CFR 8.12, the Center for Substance Abuse Treatment (CSAT), and the Drug Enforcement Administration (DEA), along with individual state and local regulations.

(B) Therapeutic settings--(1) Outpatient psychotherapy. Outpatient psychotherapy generally is covered for individual, family, conjoint, collateral, and/or group sessions.

(2) Inpatient psychotherapy. Coverage of inpatient psychotherapy is based on medical or psychological necessity for the services identified in the patient's treatment plan.

(C) Covered ancillary therapies. Includes art, music, dance, occupational, and other ancillary therapies, when included by the attending provider in an approved inpatient, SUDRF, residential treatment, partial hospital, or intensive outpatient program treatment plan and under the clinical supervision of a qualified mental health professional. These ancillary therapies are not separately reimbursed professional services but are included within the institutional reimbursement.

(D) Review of claims for treatment of mental disorder. The Director shall establish and maintain procedures for review, including professional review, of the services provided for the treatment of mental disorders.

(x) Physical and occupational therapy. Assessment and treatment services of a CHAMPUS-authorized physical or occupational therapist may be cost-shared when:

(A) The services are prescribed and monitored by a physician, certified physician assistant or certified nurse practitioner.

(B) The purpose of the prescription is to reduce the disabling effects of an illness, injury, or neuromuscular disorder; and

(C) The prescribed treatment increases, stabilizes, or slows the deterioration of the beneficiary's ability to perform specified purposeful activity in the manner, or within the range considered normal, for a human being.

(xi) Well-child care. Benefits routinely are covered for well-child care from birth to under six years of age. These periodic health examinations are designed for prevention, early detection and treatment of disease and consist of screening procedures, immunizations and risk counseling.

(A) The following services are covered when required as a part of the specific well-child care program and when rendered by the attending pediatrician, family physician, certified nurse practitioner, or certified physician assistant.

(1) Newborn examination, heredity and metabolic screening, and newborn circumcision.

(2) Periodic health supervision visits, in accordance with American Academy of Pediatrics (AAP) guidelines, intended to promote the optimal health for infants and children to include the following services:

(i) History and physical examination and mental health assessment.

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- (ii) Vision, hearing, and dental screening.
- (iii) Developmental appraisal to include body measurement.
- (iv) Immunizations as recommended by the Centers for Disease Control (CDC).
- (v) Pediatric risk assessment for lead exposure and blood lead level test.
- (vi) Tuberculosis screening.
- (vii) Blood pressure screening.
- (viii) Measurement of hemoglobin and hematocrit for anemia.
- (ix) Urinalysis.
- (x) Health guidance and counseling, including breastfeeding and nutrition counseling.
- (B) Additional services or visits required because of specific findings or because the particular circumstances of the individual case are covered if medically necessary and otherwise authorized for benefits under CHAMPUS.
- (C) The Deputy Assistant Secretary of Defense, Health Services Financing, will determine when such services are separately reimbursable apart from the health supervision visit.
- (xii) (Reserved)
- (xiii) Physicians in a teaching setting.
  - (A) Teaching physicians.
    - (1) General. The services of teaching physicians may be reimbursed on an allowable charge basis only when the teaching physician has established an attending physician relationship between the teaching physician and the patient or when the teaching physician provides distinct, identifiable, personal services (e.g., services rendered as a consultant, assistant surgeon, etc.). Attending physician services may include both direct patient care services or direct supervision of care provided by a physician in training. In order to be considered an attending physician, the teaching physician must:
      - (i) Review the patient's history and the record of examinations and tests in the institution, and make frequent reviews of the patient's progress; and
      - (ii) Personally examine the patient; and
      - (iii) Confirm or revise the diagnosis and determine the course of treatment to be followed; and
      - (iv) Either perform the physician's services required by the patient or supervise the treatment so as to assure that appropriate services are provided by physicians in training and

that the care meets a proper quality level; and

(v) Be present and ready to perform any service performed by an attending physician in a nonteaching setting when a major surgical procedure or a complex or dangerous medical procedure is performed; and

(vi) Be personally responsible for the patient's care, at least throughout the period of hospitalization.

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

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

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

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

(1) The physician in training is fully licensed to practice medicine by the state in which the services are performed, and

(2) The services are rendered outside the scope and requirements of the approved training program to which the physician in training is assigned.

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

licensure may also prescribe and order these services and supplies unless otherwise specified in paragraph (d) of this section.

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

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

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

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

(ii) Is not otherwise excluded by this part.

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

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

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

(iii) Iron lungs.

(iv) Hospital beds.

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

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

- (i) Achieving therapeutic benefit for the patient;
- (ii) Making the equipment serviceable; or
- (iii) Otherwise assuring the proper functioning of the equipment.

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

- (i) An infant beneficiary who has had an apparent life-threatening event, as defined in guidelines issued by the Director, OCHAMPUS, or a designee, or
- (ii) An infant beneficiary who is a subsequent or multiple birth biological sibling of a victim of sudden infant death syndrome (SIDS), or
- (iii) An infant beneficiary whose birth weight was 1,500 grams or less, or
- (iv) An infant beneficiary who is a pre-term infant with pathologic apnea, as defined in guidelines issued by the Director, OCHAMPUS, or a designee, or
- (v) Any beneficiary who has a condition or suspected condition designated in guidelines issued by the Director, OCHAMPUS, or a designee, for which the in-home use of the cardiorespiratory monitor otherwise meets Basic Program requirements.

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

- (i) Trend-event recorder, including technical support necessary for the proper use of the recorder.
- (ii) Analysis of recorded physiological data associated with monitor alarms.
- (iii) Professional visits for services otherwise authorized by this part, and for family training on how to respond to an apparent life threatening event.
- (iv) Diagnostic testing otherwise authorized by this part.

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

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

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

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

(2) In general, repairs of beneficiary owned durable equipment are covered when necessary to make the equipment serviceable and replacement of durable equipment is allowed when the durable equipment is not serviceable because of normal wear, accidental damage or when necessitated by a change in the beneficiary's condition. However, repairs of durable equipment damaged while using the equipment in a manner inconsistent with its common use, and replacement of lost or stolen rental durable equipment are excluded from coverage. In addition, repairs of deluxe, luxury, or immaterial features of durable equipment are excluded from coverage.

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

NOTE: Generally, the allowable charge of a medical supply item will be under \$100. Any item over this amount must be reviewed to determine whether it would not qualify as a DME

item. If it is, in fact, a medical supply item and does not represent an excessive charge, it can be considered for benefits under paragraph (d)(3)(iii) of this section.

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

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

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

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

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

(C) Except as described in paragraph (d)(3)(v)(C)(1)(i) of this section, ambulance services by other than land vehicles (such as a boat or airplane) may be considered only when the pickup point is inaccessible by a land vehicle, or when great distance or other obstacles are involved in transporting the patient to the nearest hospital with appropriate facilities and the patient's medical condition warrants speedy admission or is such that transfer by other means is contraindicated.

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

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

(vi) Drugs and medicines. Drugs and medicines that by United States law require a prescription are also referred to as "legend drugs." Legend drugs are covered when prescribed by a physician or other authorized individual professional provider acting within the scope of the provider's license and ordered or prescribed in connection with an otherwise

covered condition or treatment, and not otherwise excluded by TRICARE. This includes Rh immune globulin.

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

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

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

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

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

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

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

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

(viii) Orthopedic braces and appliances. The purchase of leg braces (including attached shoes), arm braces, back braces, and neck braces is covered, orthopedic shoes, arch supports, shoe inserts, and other supportive devices for the feet, including special-ordered, custom-made built-up shoes or regular shoes subsequently built up, are not covered.

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

**(e) Special benefit information--(1) General.** There are certain circumstances, conditions, or limitations that impact the extension of benefits and that require special emphasis and explanation. This paragraph (e) sets forth those benefits and limitations

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recognized to be in this category. The benefits and limitations herein described also are subject to all applicable definitions, conditions, limitations, exceptions, and exclusions as set forth in this or other sections of this part, except as otherwise may be provided specifically in this paragraph (e).

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

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

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

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

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

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

(3) Prescription contraceptives.

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

(B) Exclusions. The family planning benefit does not include the following:

(1) Prophylactics (condoms).

(2) Spermicidal foams, jellies, and sprays not requiring a prescription.

(3) Services and supplies related to noncoital reproductive technologies, including but not limited to artificial insemination (including any costs related to donors or semen banks), in-vitro fertilization and gamete intrafallopian transfer.

(4) Reversal of a surgical sterilization procedure (male or female).

(ii) Genetic testing. Genetic testing essentially is preventive rather than related to active medical treatment of an illness or injury. However, under the family planning benefit, genetic testing is covered when performed in certain high risk situations. For the purpose of

CHAMPUS, genetic testing includes to detect developmental abnormalities as well as purely genetic defects.

(A) Benefits provided. Benefits may be extended for genetic testing performed on a pregnant beneficiary under the following prescribed circumstances. The tests must be appropriate to the specific risk situation and must meet one of the following criteria:

- (1) The mother-to-be is 35 years old or older; or
- (2) The mother- or father-to-be has had a previous child born with a congenital abnormality; or
- (3) Either the mother- or father-to-be has a family history of congenital abnormalities; or
- (4) The mother-to-be contracted rubella during the first trimester of the pregnancy; or
- (5) Such other specific situations as may be determined by the Director, OCHAMPUS, or a designee, to fall within the intent of paragraph (e)(3)(ii) of this section.

(B) Exclusions. It is emphasized that routine or demand genetic testing is not covered. Further, genetic testing does not include the following:

- (1) Tests performed to establish paternity of a child.
- (2) Tests to determine the sex of an unborn child.
- (4) (Reserved)

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

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

- (i) Evaluation of potential candidate's suitability for an organ transplant, whether or not the patient is ultimately accepted as a candidate for transplant.
- (ii) Pre- and post-transplant inpatient hospital and outpatient services.
- (iii) Pre- and post-operative services of the transplant team.
- (iv) Blood and blood products.
- (v) FDA approved immunosuppression drugs to include off-label uses when determined to be medically necessary for the treatment of the condition for which it is administered, according to accepted standards of medical practice.
- (vi) Complications of the transplant procedure, including inpatient care, management of

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infection and rejection episodes.

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

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

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

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

(3) Donor costs are payable when:

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

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

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

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

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

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

(B) (Reserved)

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

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

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

(A) Eyeglasses or lenses that perform the function of the human lens, lost as a result of intraocular surgery or ocular injury or congenital absence.

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

- (B) "Pinhole" glasses prescribed for use after surgery for detached retina.
- (C) Lenses prescribed as "treatment" instead of surgery for the following conditions:
  - (1) Contact lenses used for treatment of infantile glaucoma.
  - (2) Corneal or scleral lenses prescribed in connection with treatment of keratoconus.
  - (3) Scleral lenses prescribed to retain moisture when normal tearing is not present or is inadequate.
  - (4) Corneal or scleral lenses prescribed to reduce a corneal irregularity other than astigmatism.
- (ii) Limitations. The specified benefits are limited further to one set of lenses related to one of the qualifying eye conditions set forth in paragraph (e)(6)(i) of this section. If there is a prescription change requiring a new set of lenses (but still related to the qualifying eye condition), benefits may be extended for a second set of lenses, subject to specific medical review.
- (7) (Reserved)
- (8) Cosmetic, reconstructive, or plastic surgery. For the purposes of CHAMPUS, cosmetic, reconstructive, or plastic surgery is surgery that can be expected primarily to improve physical appearance or that is performed primarily for psychological purposes or that restores form, but does not correct or improve materially a bodily function.

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

- (i) Limited benefits under CHAMPUS. Benefits under the Basic Program generally are not available for cosmetic, reconstructive, or plastic surgery. However, under certain limited circumstances, benefits for otherwise covered services and supplies may be provided in connection with cosmetic, reconstructive, or plastic surgery as follows:
  - (A) Correction of a congenital anomaly; or
  - (B) Restoration of body form following an accidental injury; or
  - (C) Revision of disfiguring and extensive scars resulting from neoplastic surgery.
  - (D) Reconstructive breast surgery following a medically necessary mastectomy performed for the treatment of carcinoma, severe fibrocystic disease, other nonmalignant tumors or traumatic injuries.

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(E) Penile implants and testicular prostheses for conditions resulting from organic origins (i.e., trauma, radical surgery, disease process, for correction of congenital anomaly, etc.). Also, penile implants for organic impotency.

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

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

(ii) General exclusions. (A) For purposes of CHAMPUS, dental congenital anomalies such as absent tooth buds or malocclusion specifically are excluded.

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

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

(D) Any procedures related to sex gender changes, except as provided in paragraph (g)(29) of this section, are excluded.

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

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

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

(B) Cosmetic, reconstructive, or plastic surgical procedures that are justified primarily on the basis of a psychological or psychiatric need.

(C) Augmentation mammoplasties. Augmentation mammoplasties, except for breast reconstruction following a covered mastectomy and those specifically authorized in paragraph (e)(8)(i) of this section.

(D) Face lifts and other procedures related to the aging process.

(E) Reduction mammoplasties. Reduction mammoplasties (unless there is medical documentation of intractable pain, not amenable to other forms of treatment, resulting from large, pendulous breasts or unless performed as an integral part of an authorized breast reconstruction procedure under paragraph (e)(8)(i) of this section, including reduction of the collateral breast for purposes of ensuring breast symmetry)

(F) Panniculectomy; body sculpture procedures.

(G) Repair of sagging eyelids (without demonstrated and medically documented significant impairment of vision).

(H) Rhinoplasties (without evidence of accidental injury occurring within the previous 6 months that resulted in significant obstruction of breathing).

(I) Chemical peeling for facial wrinkles.

(J) Dermabrasion of the face.

(K) Elective correction of minor dermatological blemishes and marks or minor anatomical anomalies.

(L) Revision of scars resulting from surgery or a disease process, except disfiguring and extensive scars resulting from neoplastic surgery.

(M) Removal of tattoos.

(N) Hair transplants.

(O) Electrolysis.

(P) [Reserved]

(Q) Penile implant procedure for psychological impotency or as related to sex gender changes, as prohibited by section 1079 of title 10, United States Code.

(R) Insertion of prosthetic testicles as related to sex gender changes, as prohibited by section 1079 of title 10, United States Code.

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

(ii) Benefits are available for otherwise covered services and supplies required in the treatment of complications (unfortunate sequelae) and any necessary follow-on care

resulting from a non-covered incident of treatment provided in an MTF, when the initial non-covered service has been authorized by the MTF Commander and the MTF is unable to provide the necessary treatment of the complications or required follow-on care, according to the guidelines adopted by the Director, DHA, or a designee.

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

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

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

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

- (1) Intraoral abscesses which extend beyond the dental alveolus.
- (2) Extraoral abscesses.
- (3) Cellulitis and osteitis which is clearly exacerbating and directly affecting a medical condition currently under treatment.
- (4) Removal of teeth and tooth fragments in order to treat and repair facial trauma resulting from an accidental injury.
- (5) Myofacial Pain Dysfunction Syndrome.
- (6) Total or complete ankyloglossia.
- (7) Adjunctive dental and orthodontic support for cleft palate.
- (8) The prosthetic replacement of either the maxilla or the mandible due to the reduction of body tissues associated with traumatic injury (e.g., impact, gun shot wound), in addition to services related to treating neoplasms or iatrogenic dental trauma.

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

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

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injury or disease (iatrogenic).

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

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

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

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

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

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

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

(iv) Covered oral surgery. Notwithstanding the above limitations on dental care, there are certain oral surgical procedures that are performed by both physicians and dentists, and that are essentially medical rather than dental care. For the purposes of CHAMPUS, the following procedures, whether performed by a physician or dentist, are considered to be in this category and benefits may be extended for otherwise covered services and supplies without preauthorization:

(A) Excision of tumors and cysts of the jaws, cheeks, lips, tongue, and roof and floor of the mouth, when such conditions require a pathological (histological) examination.

(B) Surgical procedures required to correct accidental injuries of the jaws, cheeks, lips, tongue, and roof and floor of the mouth.

(C) Treatment of oral or facial cancer.

(D) Treatment of fractures of facial bones.

- (E) External (extra-oral) incision and drainage of cellulitis.
- (F) Surgery of accessory sinuses, salivary glands, or ducts.
- (G) Reduction of dislocations and the excision of the temporomandibular joints, when surgery is a necessary part of the reduction.
- (H) Any oral surgical procedure that falls within the cosmetic, reconstructive, or plastic surgery definition is subject to the limitations and requirements set forth in paragraph (e)(8) of this section.

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

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

(vi) Anesthesia and institutional costs for dental care for children and certain other patients. Institutional benefits specified in paragraph (b) of this section may be extended for hospital and in-out surgery settings related to noncovered, nonadjunctive dental care when such outpatient care or inpatient stay is in conjunction with dental treatment for patients with developmental, mental, or physical disabilities or for pediatric patients age 5 or under. For these patients, anesthesia services will be limited to the administration of general anesthesia only. Patients with developmental, mental, or physical disabilities are those patients with conditions that prohibit dental treatment in a safe and effective manner. Therefore, it is medically or psychologically necessary for these patients to require general anesthesia for dental treatment. Patients with physical disabilities include those patients having disabilities as defined in Sec. 199.2 as a serious physical disability. Preauthorization by the Director, TRICARE Management Activity, or a designee, is required for such outpatient care or inpatient stays to be covered in the same manner as required for adjunctive dental care described in paragraph (e)(10)(iii) of this section. Regardless of whether or not the preauthorization request for outpatient care or hospital admission is approved and thus qualifies for institutional benefits, the professional service related to the nonadjunctive dental care is not covered, with the exception of coverage for anesthesia services.

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

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

(ii) (Reserved).

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

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

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

(D) Barbiturates. Examples are Seconal and Nembuttal.

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

(F) Stimulants. Examples are amphetamines.

(iv) CHAMPUS fiscal intermediary responsibilities. CHAMPUS fiscal intermediaries are responsible for implementing utilization control and quality assurance procedures designed to identify possible drug abuse situations. The CHAMPUS fiscal intermediary is directed to screen all drug claims for potential overutilization and irrational prescribing of drugs, and to subject any such cases to extensive review to establish the necessity for the drugs and their appropriateness on the basis of diagnosis or definitive symptoms.

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

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

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

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

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

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

(12) (Reserved)

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

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

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

(B) Home care is not suitable. Institutionalization of a child because a parent (or parents) is unable to provide a safe and nurturing environment due to a mental or substance use disorder, or because someone in the home has a contagious disease, are examples of why domiciliary care is being provided because the home setting is unsuitable.

(C) Family unwilling to care for a person in the home. A child who is difficult to manage may be placed in an institution, not because institutional care is medically necessary, but because the family does not want to handle him or her in the home. Such institutionalization would represent domiciliary care, that is, the family being unwilling to assume responsibility for the child.

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

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

may be necessary for the beneficiary, domiciliary care does not represent the kind of care for which CHAMPUS benefits can be provided.

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

- (A) The patient is referred for the diagnostic procedure by a physician.
- (B) The CT scan procedure is consistent with the preliminary diagnosis or symptoms.
- (C) Other noninvasive and less costly means of diagnosis have been attempted or are not appropriate.
- (D) The CT scan equipment is licensed or registered by the appropriate state agency responsible for licensing or registering medical equipment that emits ionizing radiation.
- (E) The CT scan equipment is operated under the general supervision and direction of a physician.
- (F) The results of the CT scan diagnostic procedure are interpreted by a physician.

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

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

- (i) Conditions for coverage.
  - (A) Payment for bariatric surgical procedures is determined by the requirements specified in paragraph (g)(15) of this section, and as defined in Sec. 199.2(b) of this part.
  - (B) Covered bariatric surgical procedures are payable only when the patient has completed growth (18 years of age or documentation of completion of bone growth) and has met one of the following selection criteria:

(1) The patient has a BMI that is equal to or exceeds 40 kg/m<sup>2</sup> and has previously been unsuccessful with medical treatment for obesity.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(5) If an election of hospice benefits has been revoked, the individual, or his or her representative may at any time file a hospice election for any period of time still available to the individual, in accordance with Sec. 199.4(e)(19)(vi)(B).

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

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

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

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

- (i) Identification of the particular hospice that will provide care to the individual.
- (ii) The individual's or representative's acknowledgment that he or she has been given a full understanding of the palliative rather than curative nature of hospice care, as it relates to the individual's terminal illness.
- (iii) The individual's or representative's acknowledgment that he or she understands that certain other CHAMPUS services are waived by the election.
- (iv) The effective date of the election.
- (v) The signature of the individual or representative, and the date signed.
- (8) The hospice must notify the CHAMPUS contractor of the initiation, change or revocation of any election.
- (C) The beneficiary must waive all rights to other CHAMPUS payments for the duration of the election period for:
- (1) Care provided by any hospice program other than the elected hospice unless provided under arrangements made by the elected hospice; and
- (2) Other CHAMPUS basic program services/benefits related to the treatment of the terminal illness for which hospice care was elected, or to a related condition, or that are equivalent to hospice care, except for services provided by:
- (i) The designated hospice;
- (ii) Another hospice under arrangement made by the designated hospice; or
- (iii) An attending physician who is not employed by or under contract with the hospice program.
- (3) Basic CHAMPUS coverage will be reinstated upon revocation of the hospice election.
- (D) A written plan of care must be established by a member of the basic interdisciplinary group assessing the patient's needs. This group must have at least one physician, one registered professional nurse, one social worker, and one pastoral or other counselor.
- (1) In establishing the initial plan of care the member of the basic interdisciplinary group who assesses the patient's needs must meet or call at least one other group member before writing the initial plan of care.
- (2) At least one of the persons involved in developing the initial plan must be a nurse or physician.
- (3) The plan must be established on the same day as the assessment if the day of assessment is to be a covered day of hospice care.
- (4) The other two members of the basic interdisciplinary group--the attending physician

and the medical director or physician designee--must review the initial plan of care and provide their input to the process of establishing the plan of care within two calendar days following the day of assessment. A meeting of group members is not required within this 2-day period. Input may be provided by telephone.

(5) Hospice services must be consistent with the plan of care for coverage to be extended.

(6) The plan must be reviewed and updated, at intervals specified in the plan, by the attending physician, medical director or physician designee and interdisciplinary group. These reviews must be documented in the medical records.

(7) The hospice must designate a registered nurse to coordinate the implementation of the plan of care for each patient.

(8) The plan must include an assessment of the individual's needs and identification of the services, including the management of discomfort and symptom relief. It must state in detail the scope and frequency of services needed to meet the patient's and family's needs.

(E) Complete medical records and all supporting documentation must be submitted to the CHAMPUS contractor within 30 days of the date of its request. If records are not received within the designated time frame, authorization of the hospice benefit will be denied and any prior payments made will be recouped. A denial issued for this reason is not an initial determination under Sec. 199.10, and is not appealable.

(vii) Appeal rights under hospice benefit. A beneficiary or provider is entitled to appeal rights for cases involving a denial of benefits in accordance with the provisions of this part and Sec. 199.10.

(20) (Reserved)

(21) Home health services. Home health services are covered when furnished by, or under arrangement with, a home health agency (HHA) that participates in the TRICARE program, and provides care on a visiting basis in the beneficiary's home. Covered HHA services are the same as those provided under Medicare under section 1861(m) of the Social Security Act (42 U.S.C. 1395x(m)) and 42 CFR part 409, subpart E.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) The orders on the plan of care must specify the type of services to be provided to the beneficiary, both with respect to the professional who will provide them and the nature of the individual services, as well as the frequency of the services.

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

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

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

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

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

(G) TRICARE is the appropriate payer.

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

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

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

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

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

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

(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 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.

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

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

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

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

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

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

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

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

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

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

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

(iii) Other types of physical examinations not listed above are excluded including routine, annual, or employment-requested physical examinations and routine screening procedures

that are not part of medically necessary care or treatment or otherwise specifically authorized by statute.

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

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

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

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

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

(C) Toll-free quit line. Access to a non-medical toll-free quit line 7 days a week, 24 hours a day will be available. The quit line will be staffed with smoking cessation counselors trained to assess a beneficiary's readiness to quit, identify barriers to quitting, and provide specific suggested actions and motivational counseling to enhance the chances of a successful quit attempt. When appropriate, quit line counselors will refer beneficiaries to a TRICARE-authorized provider for medical intervention. The quit line may, at the discretion of the Director, TMA, include the opportunity for the beneficiary to request individual follow-up contact initiated by quit line personnel; however, the beneficiary is not required to participate

in the quit line initiated follow-up. Printed educational materials on the effects of tobacco use will be provided to the beneficiary upon request. This benefit may be made available to overseas Prime beneficiaries should the ASD(HA) exercise his authority to do so and provide appropriate notice in the **Federal Register**.

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

**(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 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

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authorized NATO dependents.

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

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

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

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

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

(ii) **Inpatient cost-sharing.** Dependents of members of the Uniformed Services are responsible for the payment of the first \$25 of the allowable institutional costs incurred with each covered inpatient admission to a hospital or other authorized institutional provider (refer to Sec. 199.6, including inpatient admission to a residential treatment center, substance use disorder rehabilitation facility residential treatment program, or skilled nursing facility), 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.

(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) (Reserved)

(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).

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(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. Inpatient admissions to a hospital or other authorized institutional provider (refer to Sec. 199.6, including inpatient admission to a residential treatment center, substance use disorder rehabilitation facility residential treatment program, or skilled nursing facility) shall be cost-shared on an inpatient basis. The cost-sharing for inpatient services subject to the TRICARE DRG-based payment system and the TRICARE per diem system shall be the lesser of the respective per diem copayment amount multiplied by the total number of days in the hospital (except for the day of discharge under the DRG payment system), or 25 percent of the hospital's billed charges. For other inpatient services, the cost-share shall be 25% of the CHAMPUS-determined allowable charges.**

(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.

(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.

(12) Elimination of cost-sharing for certain preventive services.(i) (i) Effective for dates

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

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

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

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

**(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, to include substance use 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

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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.

(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) Sex gender changes. Services and supplies related to sex gender change, also referred to as sex reassignment surgery, as prohibited by section 1079 of title 10, United States Code. This exclusion does not apply to surgery and related medically necessary services performed to correct sex gender confusion/intersex conditions (that is, ambiguous genitalia) which has been documented to be present at birth.

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

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

(32) Dyslexia.

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

(34) Noncoital reproductive procedures including artificial insemination, in-vitro fertilization, gamete intrafallopian transfer and all other such reproductive

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

(35) Nonprescription contraceptives.

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

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

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

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

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

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

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

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

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

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

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

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

- (ii) Exclusions. The wig or hairpiece benefit does not include coverage for the following:
- (A) Alopecia resulting from conditions other than treatment of malignant disease.
  - (B) Maintenance, wig or hairpiece supplies, or replacement of the wig or hairpiece.
  - (C) Hair transplants or any other surgical procedure involving the attachment of hair or a wig or hairpiece to the scalp.
  - (D) Any diagnostic or therapeutic method or supply intended to encourage hair regrowth.
- (42) Education or training. Self-help, academic education or vocational training services and supplies, unless the provisions of Sec. 199.4, paragraph (b)(1)(v) relating to general or special education, apply.
- (43) Exercise/relaxation/comfort/sporting items or sporting devices. Exercise equipment, to include items primarily and customarily designed for use in sports or recreational activities, spas, whirlpools, hot tubs, swimming pools health club memberships or other such charges or items.
- (44) Exercise. General exercise programs, even if recommended by a physician and regardless of whether or not rendered by an authorized provider. In addition, passive exercises and range of motion exercises also are excluded, except when prescribed by a physician and rendered by a physical therapist concurrent to, and as an integral part of, a comprehensive program of physical therapy.
- (45) (Reserved).
- (46) Vision care. Eye exercises or visual training (orthoaptics).
- (47) Eye and hearing examinations. Eye and hearing examinations except as specifically provided in paragraphs (c)(2)(xvi), (c)(3)(xi), and (e)(24) of this section, or except when rendered in connection with medical or surgical treatment of a covered illness or injury.
- (48) Prosthetic devices. Prostheses other than those determined by the Director, OCHAMPUS to be necessary because of significant conditions resulting from trauma, congenital anomalies, or disease. All dental prostheses are excluded, except for those specifically required in connection with otherwise covered orthodontia directly related to the surgical correction of a cleft palate anomaly.
- (49) Orthopedic shoes. Orthopedic shoes, arch supports, shoe inserts, and other supportive devices for the feet, including special-ordered, custom-made built-up shoes, or regular shoes later built up.
- (50) Eyeglasses. Eyeglasses, spectacles, contact lenses, or other optical devices, except as specifically provided under paragraph (e)(6) of this section.
- (51) Hearing aids. Hearing aids or other auditory sensory enhancing devices, except those allowed in paragraph (e)(24) of this section.

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

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

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

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

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

(54) Elevators or chair lifts.

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

(56) Clothing. Items of clothing or shoes, even if required by virtue of an allergy (such as cotton fabric as against synthetic fabric and vegetable-dyed shoes).

(57) Food, food substitutes. Food, food substitutes, vitamins, or other nutritional supplements, including those related to prenatal care.

(58) Enuretic. Enuretic conditioning programs, but enuretic alarms may be cost-shared when determined to be medically necessary in the treatment of enuresis.

(59) Duplicate equipment. As defined in Sec. 199.2, duplicate equipment is excluded.

(60) Autopsy and postmortem.

(61) Camping. All camping even though organized for a specific therapeutic purpose (such as diabetic camp or a camp for emotionally disturbed children), and even though offered as a part of an otherwise covered treatment plan or offered through a CHAMPUS-approved facility.

(62) Housekeeper, companion. Housekeeping, homemaker, or attendant services; sitter or companion.

(63) Noncovered condition/treatment, unauthorized provider. All services and supplies (including inpatient institutional costs) related to a non-covered condition or treatment, including any necessary follow-on care or the treatment of complications, are

excluded from coverage except as provided under paragraph (e)(9) of this section. In addition, all services and supplies provided by an unauthorized provider are excluded.

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

(65) (Reserved)

(66) Megavitamin psychiatric therapy, orthomolecular psychiatric therapy.

(67) Transportation. All transportation except by ambulance, as specifically provided under paragraph (d), and except as authorized in paragraph (e)(5) of this section.

(68) Travel. All travel even though prescribed by a physician and even if its purpose is to obtain medical care, except as specified in paragraph (a)(6) of this section in connection with a CHAMPUS-required physical examination and as specified in Sec. 199.17(n)(2)(vi).

(69) Institutions. Services and supplies provided by other than a hospital, unless the institution has been approved specifically by OCHAMPUS. Nursing homes, intermediate care facilities, halfway houses, homes for the aged, or institutions of similar purpose are excluded from consideration as approved facilities under the Basic Program.

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

(70) (Reserved)

(71) (Reserved)

(72) (Reserved)

(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. 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.

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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; 76 FR 57642, Sep 16, 2011; 76 FR 80743, Dec 27, 2011; 76 FR 81370, Dec 28, 2011; 77 FR 38175, Jun 27, 2012; 77 FR 38178, Jun 27, 2012; 78 FR 12952, Feb 26, 2013; 78 FR 13240, Feb 27, 2013; 78 FR 62430, Oct 22, 2013; 79 FR 41641, Jul 17, 2014; 79 FR 78707, Dec 31, 2014; 79 FR 78712, Dec 31, 2014; 81 FR 27328, May 6, 2016; 81 FR 61086, Sep 2, 2106]

**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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Social Security Act (Medicare), may be deemed to meet CHAMPUS requirements. The facility must be providing a type and level of service that is authorized by this part.

(ii) Required to comply with criteria. Facilities seeking CHAMPUS approval will be expected to comply with appropriate criteria set forth in paragraph (b)(4) of this section. They also are required to complete and submit CHAMPUS Form 200, "Required Information, Facility Determination Instructions," and provide such additional information as may be requested by OCHAMPUS. An onsite evaluation, either scheduled or unscheduled, may be conducted at the discretion of the Director, OCHAMPUS, or a designee. The final determination regarding approval, reapproval, or disapproval of a facility will be provided in writing to the facility and the appropriate CHAMPUS fiscal intermediary.

(iii) Notice of peer review rights. All health care facilities subject to the DRG-based payment system shall provide CHAMPUS beneficiaries, upon admission, with information about peer review including their appeal rights. The notices shall be in a form specified by the Director, OCHAMPUS.

(iv) Surveying of facilities. The surveying of newly established institutional providers and the periodic resurveying of all authorized institutional providers is a continuing process conducted by OCHAMPUS.

(v) Institutions not in compliance with CHAMPUS standards. If a determination is made that an institution is not in compliance with one or more of the standards applicable to its specific category of institution, CHAMPUS shall take immediate steps to bring about compliance or terminate the approval as an authorized institution in accordance with Sec. 199.9(f)(2).

(vi) Participation agreements required for some hospitals which are not Medicare-participating. Notwithstanding the provisions of this paragraph (B)(3), a hospital which is subject to the CHAMPUS DRG-based payment system but which is not a Medicare-participating hospital must request and sign an agreement with OCHAMPUS. By signing the agreement, the hospital agrees to participate on all CHAMPUS inpatient claims and accept the requirements for a participating provider as contained in paragraph (a)(8) of Sec. 199.6. Failure to sign such an agreement shall disqualify such hospital as a CHAMPUS-approved institutional provider.

(4) Categories of institutional providers. The following categories of institutional providers may be reimbursed by CHAMPUS for services provided CHAMPUS beneficiaries subject to any and all definitions, conditions, limitation, and exclusions specified or enumerated in this part.

(i) Hospitals, acute care, general and special. An institution that provides inpatient services, that also may provide outpatient services (including clinical and ambulatory surgical services), and that:

(A) Is engaged primarily in providing to inpatients, by or under the supervision of physicians, diagnostic and therapeutic services for the medical or surgical diagnosis and treatment of illness, injury, or bodily malfunction (including maternity).

(B) Maintains clinical records on all inpatients (and outpatients if the facility operates an

outpatient department or emergency room).

- (C) Has bylaws in effect with respect to its operations and medical staff.
- (D) Has a requirement that every patient be under the care of a physician.
- (E) Provides 24-hour nursing service rendered or supervised by a registered professional nurse, and has a licensed practical nurse or registered professional nurse on duty at all times.
- (F) Has in effect a hospital utilization review plan that is operational and functioning.
- (G) In the case of an institution in a state in which state or applicable local law provides for the licensing of hospitals, the hospital:
  - (1) Is licensed pursuant to such law, or
  - (2) Is approved by the agency of such state or locality responsible for licensing hospitals as meeting the standards established for such licensing.
- (H) Has in effect an operating plan and budget.
- (I) Is accredited by the JCAH or meets such other requirements as the Secretary of Health and Human Services, the Secretary of Transportation, or the Secretary of Defense finds necessary in the interest of the health and safety of patients who are admitted to and furnished services in the institution.
  - (ii) Organ transplant centers. To obtain TRICARE approval as an organ transplant center, the center must be a Medicare approved transplant center or meet the criteria as established by the Executive Director, TMA, or a designee.
  - (iii) Organ transplant consortia. TRICARE shall approve individual pediatric organ transplant centers that meet the criteria established by the Executive Director, TMA, or a designee.
  - (iv) Hospitals, psychiatric. A psychiatric hospital is an institution which is engaged primarily in providing services to inpatients for the diagnosis and treatment of mental disorders.
    - (A) There are two major categories of psychiatric hospitals:
      - (1) The private psychiatric hospital category includes both proprietary and the not-for-profit nongovernmental institutions.
      - (2) The second category is those psychiatric hospitals that are controlled, financed, and operated by departments or agencies of the local, state, or Federal Government and always are operated on a not-for-profit basis.
    - (B) In order for the services of a psychiatric hospital to be covered, the hospital shall comply with the provisions outlined in paragraph (b)(4)(i) of this section. All psychiatric hospitals shall be accredited under an accrediting organization approved by the Director, in

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order for their services to be cost-shared under CHAMPUS. In the case of those psychiatric hospitals that are not accredited because they have not been in operation a sufficient period of time to be eligible to request an accreditation survey, the Director, or a designee, may grant temporary approval if the hospital is certified and participating under Title XVIII of the Social Security Act (Medicare, Part A). This temporary approval expires 12 months from the date on which the psychiatric hospital first becomes eligible to request an accreditation survey by an accrediting organization approved by the Director.

(C) Factors to be considered in determining whether CHAMPUS will cost-share care provided in a psychiatric hospital include, but are not limited to, the following considerations:

(1) Is the prognosis of the patient such that care provided will lead to resolution or remission of the mental illness to the degree that the patient is of no danger to others, can perform routine daily activities, and can be expected to function reasonably outside the inpatient setting?

(2) Can the services being provided be provided more economically in another facility or on an outpatient basis?

(3) Are the charges reasonable?

(4) Is the care primarily custodial or domiciliary? (Custodial or domiciliary care of the permanently mentally ill or retarded is not a benefit under the Basic Program.)

(D) Although psychiatric hospitals are accredited under an accrediting organization approved by Director, their medical records must be maintained in accordance with accrediting organization's current standards manual, along with the requirements set forth in Sec. 199.7(b)(3). The hospital is responsible for assuring that patient services and all treatment are accurately documented and completed in a timely manner.

(v) Hospitals, long-term (tuberculosis, chronic care, or rehabilitation). To be considered a long-term hospital, an institution for patients that have tuberculosis or chronic diseases must be an institution (or distinct part of an institution) primarily engaged in providing by or under the supervision of a physician appropriate medical or surgical services for the diagnosis and active treatment of the illness or condition in which the institution specializes.

(A) In order for the service of long-term hospitals to be covered, the hospital must comply with the provisions outlined in paragraph (b)(4)(i) of this section. In addition, in order for services provided by such hospitals to be covered by CHAMPUS, they must be primarily for the treatment of the presenting illness.

(B) Custodial or domiciliary care is not coverable under CHAMPUS, even if rendered in an otherwise authorized long-term hospital.

(C) The controlling factor in determining whether a beneficiary's stay in a long-term hospital is coverable by CHAMPUS is the level of professional care, supervision, and skilled nursing care that the beneficiary requires, in addition to the diagnosis, type of condition, or degree of functional limitations. The type and level of medical services required or rendered

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is controlling for purposes of extending CHAMPUS benefits; not the type of provider or condition of the beneficiary.

(vi) Skilled nursing facility. A skilled nursing facility is an institution (or a distinct part of an institution) that is engaged primarily in providing to inpatients medically necessary skilled nursing care, which is other than a nursing home or intermediate facility, and which:

(A) Has policies that are developed with the advice of (and with provisions for review on a periodic basis by) a group of professionals, including one or more physicians and one or more registered nurses, to govern the skilled nursing care and related medical services it provides.

(B) Has a physician, a registered nurse, or a medical staff responsible for the execution of such policies.

(C) Has a requirement that the medical care of each patient must be under the supervision of a physician, and provides for having a physician available to furnish necessary medical care in case of an emergency.

(D) Maintains clinical records on all patients.

(E) Provides 24-hour skilled nursing service that is sufficient to meet nursing needs in accordance with the policies developed as provided in paragraph (b)(4)(iv)(A) of this section, and has at least one registered professional nurse employed full-time.

(F) Provides appropriate methods and procedures for the dispensing and administering of drugs and biologicals.

(G) Has in effect a utilization review plan that is operational and functioning.

(H) In the case of an institution in a state in which state or applicable local law provides for the licensing of this type facility, the institution:

(1) Is licensed pursuant to such law, or

(2) Is approved by the agency of such state or locality responsible for licensing such institutions as meeting the standards established for such licensing.

(I) Has in effect an operating plan and budget.

(J) Meets such provisions of the most current edition of the Life Safety Code<sup>1</sup> as are applicable to nursing facilities; except that if the Secretary of Health and Human Services has waived, for such periods, as deemed appropriate, specific provisions of such code which, if rigidly applied, would result in unreasonable hardship upon a nursing facility.

(K) Is an authorized provider under the Medicare program, and meets the requirements of Title 18 of the social Security Act, sections 1819(a), (b), (c), and (d) (42 U.S.C. 1395i-3(a)-(d)).

<sup>1</sup> Compiled and published by the National Fire Protection Association, Batterymarch Park, Quincy, Massachusetts 02269.

NOTE: If a pediatric SNF is certified by Medicaid, it will be considered to meet the Medicare certification requirement in order to be an authorized provider under TRICARE.

(vii) Residential treatment centers. This paragraph (b)(4)(vii) establishes the definition of and eligibility standards and requirements for residential treatment centers (RTCs).

(A) Organization and administration—(1) Definition. A Residential Treatment Center (RTC) is a facility or a distinct part of a facility that provides to beneficiaries under 21 years of age a medically supervised, interdisciplinary program of mental health treatment. An RTC is appropriate for patients whose predominant symptom presentation is essentially stabilized, although not resolved, and who have persistent dysfunction in major life areas. Residential treatment may be complemented by family therapy and case management for community based resources. Discharge planning should support transitional care for the patient and family, to include resources available in the geographic area where the patient will be residing. The extent and pervasiveness of the patient's problems require a protected and highly structured therapeutic environment. Residential treatment is differentiated from:

(i) Acute psychiatric care, which requires medical treatment and 24-hour availability of a full range of diagnostic and therapeutic services to establish and implement an effective plan of care which will reverse life-threatening and/or severely incapacitating symptoms;

(ii) Partial hospitalization, which provides a less than 24-hour-per-day, seven-day-per-week treatment program for patients who continue to exhibit psychiatric problems but can function with support in some of the major life areas;

(iii) A group home, which is a professionally directed living arrangement with the availability of psychiatric consultation and treatment for patients with significant family dysfunction and/or chronic but stable psychiatric disturbances;

(iv) Therapeutic school, which is an educational program supplemented by psychological and psychiatric services;

(v) Facilities that treat patients with a primary diagnosis of substance use disorder; and

(vi) Facilities providing care for patients with a primary diagnosis of mental retardation or developmental disability.

(2) Eligibility. (i) In order to qualify as a TRICARE authorized provider, every RTC must meet the minimum basic standards set forth in paragraphs (b)(4)(vii)(A) through (C) of this section, and as well as such additional elaborative criteria and standards as the Director determines are necessary to implement the basic standards.

(ii) To qualify as a TRICARE authorized provider, the facility is required to be licensed and operate in substantial compliance with state and federal regulations.

(iii) The facility is currently accredited by an accrediting organization approved by the Director.

(iv) The facility has a written participation agreement with OCHAMPUS. The RTC is not a CHAMPUS-authorized provider and CHAMPUS benefits are not paid for services provided

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until the date upon which a participation agreement is signed by the Director.

(B) Participation agreement requirements. In addition to other requirements set forth in this paragraph (b)(4)(vii), for the services of an RTC to be authorized, the RTC shall have entered into a Participation Agreement with OCHAMPUS. The period of a participation agreement shall be specified in the agreement, and will generally be for not more than five years. In addition to review of a facility's application and supporting documentation, an on-site inspection by OCHAMPUS authorized personnel may be required prior to signing a Participation Agreement. Retroactive approval is not given. In addition, the Participation Agreement shall include provisions that the RTC shall, at a minimum:

(1) Render residential treatment center inpatient services to eligible CHAMPUS beneficiaries in need of such services, in accordance with the participation agreement and CHAMPUS regulation;

(2) Accept payment for its services based upon the methodology provided in Sec. 199.14(f) or such other method as determined by the Director;

(3) Accept the CHAMPUS all-inclusive per diem rate as payment in full and collect from the CHAMPUS beneficiary or the family of the CHAMPUS beneficiary only those amounts that represent the beneficiary's liability, as defined in Sec. 199.4, and charges for services and supplies that are not a benefit of CHAMPUS;

(4) Make all reasonable efforts acceptable to the Director, to collect those amounts, which represents the beneficiary's liability, as defined in Sec. 199.4;

(5) Comply with the provisions of Sec. 199.8, and submit claims first to all health insurance coverage to which the beneficiary is entitled that is primary to CHAMPUS;

(6) Submit claims for services provided to CHAMPUS beneficiaries at least every 30 days (except to the extent a delay is necessitated by efforts to first collect from other health insurance). If claims are not submitted at least every 30 days, the RTC agrees not to bill the beneficiary or the beneficiary's family for any amounts disallowed by CHAMPUS;

(7) Certify that:

(i) It is and will remain in compliance with the TRICARE standards and provisions of paragraph (b)(4)(vii) of this section establishing standards for Residential Treatment Centers; and

(ii) It will maintain compliance with the CHAMPUS Standards for Residential Treatment Centers Serving Children and Adolescents with Mental Disorders, as issued by the Director, except for any such standards regarding which the facility notifies the Director that it is not in compliance.

(8) Designate an individual who will act as liaison for CHAMPUS inquiries. The RTC shall inform OCHAMPUS in writing of the designated individual;

(9) Furnish OCHAMPUS, as requested by OCHAMPUS, with cost data certified by an independent accounting firm or other agency as authorized by the Director, OCHAMPUS;

(10) Comply with all requirements of this section applicable to institutional providers generally concerning accreditation requirements, preauthorization, concurrent care review, claims processing, beneficiary liability, double coverage, utilization and quality review, and other matters;

(11) Grant the Director, or designee, the right to conduct quality assurance audits or accounting audits with full access to patients and records (including records relating to patients who are not CHAMPUS beneficiaries) to determine the quality and cost-effectiveness of care rendered. The audits may be conducted on a scheduled or unscheduled (unannounced) basis. This right to audit/review includes, but is not limited to:

(i) Examination of fiscal and all other records of the RTC which would confirm compliance with the participation agreement and designation as a TRICARE authorized RTC;

(ii) Conducting such audits of RTC records including clinical, financial, and census records, as may be necessary to determine the nature of the services being provided, and the basis for charges and claims against the United States for services provided CHAMPUS beneficiaries;

(iii) Examining reports of evaluations and inspections conducted by federal, state and local government, and private agencies and organizations;

(iv) Conducting on-site inspections of the facilities of the RTC and interviewing employees, members of the staff, contractors, board members, volunteers, and patients, as required;

(v) Audits conducted by the United States Government Accountability Office.

(C) Other requirements applicable to RTCs. (1) Even though an RTC may qualify as a TRICARE authorized provider and may have entered into a participation agreement with CHAMPUS, payment by CHAMPUS for particular services provided is contingent upon the RTC also meeting all conditions set forth in Sec. 199.4 especially all requirements of Sec. 199.4(b)(4).

(2) The RTC shall provide inpatient services to CHAMPUS beneficiaries in the same manner it provides inpatient services to all other patients. The RTC may not discriminate against CHAMPUS beneficiaries in any manner, including admission practices, placement in special or separate wings or rooms, or provisions of special or limited treatment.

(3) The RTC shall assure that all certifications and information provided to the Director, incident to the process of obtaining and retaining authorized provider status is accurate and that it has no material errors or omissions. In the case of any misrepresentations, whether by inaccurate information being provided or material facts withheld, authorized status will be denied or terminated, and the RTC will be ineligible for consideration for authorized provider status for a two year period.

(viii) Christian Science sanatoriums. The services obtained in Christian Science sanatoriums are covered by CHAMPUS as inpatient care. To qualify for coverage, the sanatorium either must be operated by, or be listed and certified by the First Church of Christ, Scientist.

(ix) Infirmaries. Infirmaries are facilities operated by student health departments of colleges and universities to provide inpatient or outpatient care to enrolled students. Charges for care provided by such facilities will not be cost-shared by CHAMPUS if the student would not be charged in the absence of CHAMPUS, or if student is covered by a mandatory student health insurance plan, in which enrollment is required as a part of the student's school registration and the charges by the college or university include a premium for the student health insurance coverage. CHAMPUS will cost-share only if enrollment in the student health program or health insurance plan is voluntary.

NOTE: An infirmary in a boarding school also may qualify under this provision, subject to review and approval by the Director, OCHAMPUS or a designee.

(x) Other special institution providers. (A) General. (1) Care provided by certain special institutional providers (on either an inpatient or outpatient basis), may be cost-shared by CHAMPUS under specified circumstances and only if the provider is specifically identified in paragraph (b)(4)(x) of this section.

(i) The course of treatment is prescribed by a doctor of medicine or osteopathy.

(ii) The patient is under the supervision of a physician during the entire course of the inpatient admission or the outpatient treatment.

(iii) The type and level of care and service rendered by the institution are otherwise authorized by this part.

(iv) The facility meets all licensing or other certification requirements that are extant in the jurisdiction in which the facility is located geographically.

(v) Is other than a nursing home, intermediate care facility, home for the aged, halfway house, or other similar institution.

(vi) Is accredited by the JCAH or other CHAMPUS-approved accreditation organization, if an appropriate accreditation program for the given type of facility is available. As future accreditation programs are developed to cover emerging specialized treatment programs, such accreditation will be a prerequisite to coverage by CHAMPUS for services provided by such facilities.

(2) To ensure that CHAMPUS beneficiaries are provided quality care at a reasonable cost when treated by a special institutional provider, the Director, OCHAMPUS may:

(i) Require prior approval of all admissions to special institutional providers.

(ii) Set appropriate standards for special institutional providers in addition to or in the absence of JCAHO accreditation.

(iii) Monitor facility operations and treatment programs on a continuing basis and conduct onsite inspections on a scheduled and unscheduled basis.

(iv) Negotiate agreements of participation.

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(v) Terminate approval of a case when it is ascertained that a departure from the facts upon which the admission was based originally has occurred.

(vi) Declare a special institutional provider not eligible for CHAMPUS payment if that facility has been found to have engaged in fraudulent or deceptive practices.

(3) In general, the following disclaimers apply to treatment by special institutional providers:

(i) Just because one period or episode of treatment by a facility has been covered by CHAMPUS may not be construed to mean that later episodes of care by the same or similar facility will be covered automatically.

(ii) The fact that one case has been authorized for treatment by a specific facility or similar type of facility may not be construed to mean that similar cases or later periods of treatment will be extended CHAMPUS benefits automatically.

(B) Types of providers. The following is a list of facilities that have been designated specifically as special institutional providers.

(1) Free-standing ambulatory surgical centers. Care provided by freestanding ambulatory surgical centers may be cost-shared by CHAMPUS under the following circumstances:

(i) The treatment is prescribed and supervised by a physician.

(ii) The type and level of care and services rendered by the center are otherwise authorized by this part.

(iii) The center meets all licensing or other certification requirements of the jurisdiction in which the facility is located.

(iv) The center is accredited by the JCAH, the Accreditation Association for Ambulatory Health Care, Inc. (AAAHC), or such other standards as authorized by the Director, OCHAMPUS.

(v) A childbirth procedure provided by a CHAMPUS-approved free-standing ambulatory surgical center shall not be cost-shared by the CHAMPUS unless the surgical center is also a CHAMPUS-approved birthing center institutional provider as established by the birthing center provider certification requirement of this Regulation.

(2) (Reserved)

(xi) Birthing centers. A birthing center is a freestanding or institution-affiliated outpatient maternity care program which principally provides a planned course of outpatient prenatal care and outpatient childbirth service limited to low-risk pregnancies; excludes care for high-risk pregnancies; limits childbirth to the use of natural childbirth procedures; and provides immediate newborn care.

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(A) Certification requirements. A birthing center which meets the following criteria may be designated as an authorized CHAMPUS institutional provider:

(1) The predominant type of service and level of care rendered by the center is otherwise authorized by this part.

(2) The center is licensed to operate as a birthing center where such license is available, or is specifically licensed as a type of ambulatory health care facility where birthing center specific license is not available, and meets all applicable licensing or certification requirements that are extant in the state, county, municipality, or other political jurisdiction in which the center is located.

(3) The center is accredited by a nationally recognized accreditation organization whose standards and procedures have been determined to be acceptable by the Director, OCHAMPUS, or a designee.

(4) The center complies with the CHAMPUS birthing center standards set forth in this part.

(5) The center has entered into a participation agreement with OCHAMPUS in which the center agrees, in part, to:

(i) Participate in CHAMPUS and accept payment for maternity services based upon the reimbursement methodology for birthing centers;

(ii) Collect from the CHAMPUS beneficiary only those amounts that represent the beneficiary's liability under the participation agreement and the reimbursement methodology for birthing centers, and the amounts for services and supplies that are not a benefit of the CHAMPUS;

(iii) Permit access by the Director, OCHAMPUS, or a designee, to the clinical record of any CHAMPUS beneficiary, to the financial and organizational records of the center, and to reports of evaluations and inspections conducted by state or private agencies or organizations;

(iv) Submit claims first to all health benefit and insurance plans primary to the CHAMPUS to which the beneficiary is entitled and to comply with the double coverage provisions of this part;

(v) Notify CHAMPUS in writing within 7 days of the emergency transport of any CHAMPUS beneficiary from the center to an acute care hospital or of the death of any CHAMPUS beneficiary in the center.

(6) A birthing center shall not be a CHAMPUS-authorized institutional provider and CHAMPUS benefits shall not be paid for any service provided by a birthing center before the date the participation agreement is signed by the Director, OCHAMPUS, or a designee.

(B) CHAMPUS birthing center standards. (1) Environment: The center has a safe and sanitary environment, properly constructed, equipped, and maintained to protect health and safety and meets the applicable provisions of the "Life Safety Code" of the National Fire Protection Association.

(2) Policies and procedures: The center has written administrative, fiscal, personnel and clinical policies and procedures which collectively promote the provision of high-quality maternity care and childbirth services in an orderly, effective, and safe physical and organizational environment.

(3) Informed consent: Each CHAMPUS beneficiary admitted to the center will be informed in writing at the time of admission of the nature and scope of the center's program and of the possible risks associated with maternity care and childbirth in the center.

(4) Beneficiary care: Each woman admitted will be cared for by or under the direct supervision of a specific physician or a specific certified nurse-midwife who is otherwise eligible as a CHAMPUS individual professional provider.

(5) Medical direction: The center has written memoranda of understanding (MOU) for routine consultation and emergency care with an obstetrician-gynecologist who is certified or is eligible for certification by the American Board of Obstetrics and Gynecology or the American Osteopathic Board of Obstetrics and Gynecology and with a pediatrician who is certified or eligible for certification by the American Board of Pediatrics or by the American Osteopathic Board of Pediatrics, each of whom have admitting privileges to at least one backup hospital. In lieu of a required MOU, the center may employ a physician with the required qualifications. Each MOU must be renewed annually.

(6) Admission and emergency care criteria and procedures. The center has written clinical criteria and administrative procedures, which are reviewed and approved annually by a physician related to the center as required by paragraph (b)(4)(xi)(B)(5) above, for the exclusion of a woman with a high-risk pregnancy from center care and for management of maternal and neonatal emergencies.

(7) Emergency treatment. The center has a written memorandum of understanding (MOU) with at least one backup hospital which documents that the hospital will accept and treat any woman or newborn transferred from the center who is in need of emergency obstetrical or neonatal medical care. In lieu of this MOU with a hospital, a birthing center may have an MOU with a physician, who otherwise meets the requirements as a CHAMPUS individual professional provider, and who has admitting privileges to a backup hospital capable of providing care for critical maternal and neonatal patients as demonstrated by a letter from that hospital certifying the scope and expected duration of the admitting privileges granted by the hospital to the physician. The MOU must be reviewed annually.

(8) Emergency medical transportation. The center has a written memorandum of understanding (MOU) with at least one ambulance service which documents that the ambulance service is routinely staffed by qualified personnel who are capable of the management of critical maternal and neonatal patients during transport and which specifies the estimated transport time to each backup hospital with which the center has arranged for emergency treatment as required in paragraph (b)(4)(xi)(B)(7) above. Each MOU must be renewed annually.

(9) Professional staff. The center's professional staff is legally and professionally qualified for the performance of their professional responsibilities.

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(10) Medical records. The center maintains full and complete written documentation of the services rendered to each woman admitted and each newborn delivered. A copy of the informed consent document required by paragraph (b)(4)(xi)(B)(3), above, which contains the original signature of the CHAMPUS beneficiary, signed and dated at the time of admission, must be maintained in the medical record of each CHAMPUS beneficiary admitted.

(11) Quality assurance. The center has an organized program for quality assurance which includes, but is not limited to, written procedures for regularly scheduled evaluation of each type of service provided, of each mother or newborn transferred to a hospital, and of each death within the facility.

(12) Governance and administration. The center has a governing body legally responsible for overall operation and maintenance of the center and a full-time employee who has authority and responsibility for the day-to-day operation of the center.

(xii) Psychiatric and substance use disorder partial hospitalization programs. This paragraph (b)(4)(xii) establishes the definition of and eligibility standards and requirements for psychiatric and substance use disorder partial hospitalization programs.

(A) Organization and administration—(1) Definition. Partial hospitalization is defined as a time-limited, ambulatory, active treatment program that offers therapeutically intensive, coordinated, and structured clinical services within a stable therapeutic milieu. Partial hospitalization programs serve patients who exhibit psychiatric symptoms, disturbances of conduct, and decompensating conditions affecting mental health. Partial hospitalization is appropriate for those whose psychiatric and addiction-related symptoms or concomitant physical and emotional/behavioral problems can be managed outside the hospital for defined periods of time with support in one or more of the major life areas. A partial hospitalization program for the treatment of substance use disorders is an addiction-focused service that provides active treatment to children and adolescents, or adults aged 18 and over.

(2) Eligibility. (i) To qualify as a TRICARE authorized provider, every partial hospitalization program must meet minimum basic standards set forth in paragraphs (b)(4)(xii)(A) through (D) of this section, as well as such additional elaborative criteria and standards as the Director determines are necessary to implement the basic standards. Each partial hospitalization program must be either a distinct part of an otherwise-authorized institutional provider or a free-standing program. Approval of a hospital by TRICARE is sufficient for its partial hospitalization program to be an authorized TRICARE provider. Such hospital-based partial hospitalization programs are not required to be separately authorized by TRICARE.

(ii) To be approved as a TRICARE authorized provider, the facility is required to be licensed and operate in substantial compliance with state and federal regulations.

(iii) The facility is required to be currently accredited by an accrediting organization approved by the Director. Each PHP authorized to treat substance use disorder must be accredited to provide the level of required treatment by an accreditation body approved by the Director.

(iv) The facility is required to have a written participation agreement with OCHAMPUS. The PHP is not a CHAMPUS-authorized provider and CHAMPUS benefits are not paid for services provided until the date upon which a participation agreement is signed by the Director.

(B) Participation agreement requirements. In addition to other requirements set forth in this paragraph (b)(4)(xii), in order for the services of a PHP to be authorized, the PHP shall have entered into a Participation Agreement with OCHAMPUS. A single consolidated participation agreement is acceptable for all units of the TRICARE authorized facility granted that all programs meet the requirements of this part. The period of a Participation Agreement shall be specified in the agreement, and will generally be for not more than five years. The PHP shall not be considered to be a CHAMPUS authorized provider and CHAMPUS payments shall not be made for services provided by the PHP until the date the participation agreement is signed by the Director. In addition to review of a facility's application and supporting documentation, an on-site inspection by OCHAMPUS authorized personnel may be required prior to signing a participation agreement. The Participation Agreement shall include at least the following requirements:

(1) Render partial hospitalization program services to eligible CHAMPUS beneficiaries in need of such services, in accordance with the participation agreement and CHAMPUS regulation.

(2) Accept payment for its services based upon the methodology provided in Sec. 199.14, or such other method as determined by the Director;

(3) Accept the CHAMPUS all-inclusive per diem rate as payment in full and collect from the CHAMPUS beneficiary or the family of the CHAMPUS beneficiary only those amounts that represent the beneficiary's liability, as defined in Sec. 199.4, and charges for services and supplies that are not a benefit of CHAMPUS;

(4) Make all reasonable efforts acceptable to the Director to collect those amounts, which represent the beneficiary's liability, as defined in Sec. 199.4;

(5) Comply with the provisions of Sec. 199.8, and submit claims first to all health insurance coverage to which the beneficiary is entitled that is primary to CHAMPUS;

(6) Submit claims for services provided to CHAMPUS beneficiaries at least every 30 days (except to the extent a delay is necessitated by efforts to first collect from other health insurance). If claims are not submitted at least every 30 days, the PHP agrees not to bill the beneficiary or the beneficiary's family for any amounts disallowed by CHAMPUS;

(7) Certify that:

(i) It is and will remain in compliance with the TRICARE standards and provisions of paragraph (b)(4)(xii) of this section establishing standards for psychiatric and substance use disorder partial hospitalization programs; and

(ii) It will maintain compliance with the CHAMPUS Standards for Psychiatric Substance Use Disorder Partial Hospitalization Programs, as issued by the Director, except for any such standards regarding which the facility notifies the Director, or designee, that it is not in

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compliance.

(8) Designate an individual who will act as liaison for CHAMPUS inquiries. The PHP shall inform the Director, or designee, in writing of the designated individual;

(9) Furnish OCHAMPUS, as requested by OCHAMPUS, with cost data certified by an independent accounting firm or other agency as authorized by the Director;

(10) Comply with all requirements of this section applicable to institutional providers generally concerning accreditation requirements, preauthorization, concurrent care review, claims processing, beneficiary liability, double coverage, utilization and quality review, and other matters;

(11) Grant the Director, or designee, the right to conduct quality assurance audits or accounting audits with full access to patients and records (including records relating to patients who are not CHAMPUS beneficiaries) to determine the quality and cost-effectiveness of care rendered. The audits may be conducted on a scheduled or unscheduled (unannounced) basis. This right to audit/review includes, but is not limited to:

(i) Examination of fiscal and all other records of the PHP which would confirm compliance with the participation agreement and designation as a TRICARE authorized PHP provider;

(ii) Conducting such audits of PHP records including clinical, financial, and census records, as may be necessary to determine the nature of the services being provided, and the basis for charges and claims against the United States for services provided CHAMPUS beneficiaries;

(iii) Examining reports of evaluations and inspections conducted by federal, state and local government, and private agencies and organizations;

(iv) Conducting on-site inspections of the facilities of the PHP and interviewing employees, members of the staff, contractors, board members, volunteers, and patients, as required;

(v) Audits conducted by the United States General Account Office.

(C) Other requirements applicable to PHPs. (1) Even though a PHP may qualify as a TRICARE authorized provider and may have entered into a participation agreement with CHAMPUS, payment by CHAMPUS for particular services provided is contingent upon the PHP also meeting all conditions set forth in Sec. 199.4.

(2) The PHP may not discriminate against CHAMPUS beneficiaries in any manner, including admission practices, placement in special or separate wings or rooms, or provisions of special or limited treatment.

(3) The PHP shall assure that all certifications and information provided to the Director incident to the process of obtaining and retaining authorized provider status is accurate and that it has no material errors or omissions. In the case of any misrepresentations, whether by inaccurate information being provided or material facts withheld, authorized provider status will be denied or terminated, and the PHP will be ineligible for consideration for authorized

provider status for a two year period.

(xiii) Hospice programs. Hospice programs must be Medicare approved and meet all Medicare conditions of participation (42 CFR part 418) in relation to CHAMPUS patients in order to receive payment under the CHAMPUS program. A hospice program may be found to be out of compliance with a particular Medicare condition of participation and still participate in the CHAMPUS as long as the hospice is allowed continued participation in Medicare while the condition of noncompliance is being corrected. The hospice program can be either a public agency or private organization (or a subdivision thereof) which:

(A) Is primarily engaged in providing the care and services described under Sec. 199.4(e)(19) and makes such services available on a 24-hour basis.

(B) Provides bereavement counseling for the immediate family or terminally ill individuals.

(C) Provides for such care and services in individuals' homes, on an outpatient basis, and on a short-term inpatient basis, directly or under arrangements made by the hospice program, except that the agency or organization must:

(1) Ensure that substantially all the core services are routinely provided directly by hospice employees.

(2) Maintain professional management responsibility for all services which are not directly furnished to the patient, regardless of the location or facility in which the services are rendered.

(3) Provide assurances that the aggregate number of days of inpatient care provided in any 12-month period does not exceed 20 percent of the aggregate number of days of hospice care during the same period.

(4) Have an interdisciplinary group composed of the following personnel who provide the care and services described under Sec. 199.4(e)(19) and who establish the policies governing the provision of such care/services:

(i) A physician;

(ii) A registered professional nurse;

(iii) A social worker; and

(iv) A pastoral or other counselor.

(5) Maintain central clinical records on all patients.

(6) Utilize volunteers.

(7) The hospice and all hospice employees must be licensed in accordance with applicable Federal, State and local laws and regulations.

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(8) The hospice must enter into an agreement with CHAMPUS in order to be qualified to participate and to be eligible for payment under the program. In this agreement the hospice and CHAMPUS agree that the hospice will:

(i) Not charge the beneficiary or any other person for items or services for which the beneficiary is entitled to have payment made under the CHAMPUS hospice benefit.

(ii) Be allowed to charge the beneficiary for items or services requested by the beneficiary in addition to those that are covered under the CHAMPUS hospice benefit.

(9) Meet such other requirements as the Secretary of Defense may find necessary in the interest of the health and safety of the individuals who are provided care and services by such agency or organization.

(xiv) Substance use disorder rehabilitation facilities. This paragraph (b)(4)(xiv) establishes the definition of eligibility standards and requirements for residential substance use disorder rehabilitation facilities (SUDRF).

(A) Organization and administration--(1) Definition. A SUDRF is a residential or rehabilitation facility, or distinct part of a facility, that provides medically monitored, interdisciplinary addiction-focused treatment to beneficiaries who have psychoactive substance use disorders. Qualified health care professionals provide 24-hour, seven-day-per-week, assessment, treatment, and evaluation. A SUDRF is appropriate for patients whose addiction-related symptoms, or concomitant physical and emotional/behavioral problems reflect persistent dysfunction in several major life areas. Residential or inpatient rehabilitation is differentiated from:

(i) Acute psychoactive substance use treatment and from treatment of acute biomedical/emotional/behavioral problems; which problems are either life-threatening and/or severely incapacitating and often occur within the context of a discrete episode of addiction-related biomedical or psychiatric dysfunction;

(ii) A partial hospitalization center, which serves patients who exhibit emotional/behavioral dysfunction but who can function in the community for defined periods of time with support in one or more of the major life areas;

(iii) A group home, sober-living environment, halfway house, or three-quarter way house;

(iv) Therapeutic schools, which are educational programs supplemented by addiction-focused services;

(v) Facilities that treat patients with primary psychiatric diagnoses other than psychoactive substance use or dependence; and

(vi) Facilities that care for patients with the primary diagnosis of mental retardation or developmental disability.

(2) Eligibility. (i) In order to become a TRICARE authorized provider, every SUDRF must meet minimum basic standards set forth in paragraphs (b)(4)(xiv)(A) through (C) of this section, as well as such additional elaborative criteria and standards as the Director

determines are necessary to implement the basic standards.

(ii) To be approved as a TRICARE authorized provider, the SUDRF is required to be licensed and operate in substantial compliance with state and federal regulations.

(iii) The SUDRF is currently accredited by an accrediting organization approved by the Director. Each SUDRF must be accredited to provide the level of required treatment by an accreditation body approved by the Director.

(iv) The SUDRF has a written participation agreement with OCHAMPUS. The SUDRF is not considered a TRICARE authorized provider, and CHAMPUS benefits are not paid for services provided until the date upon which a participation agreement is signed by the Director.

(B) Participation agreement requirements. In addition to other requirements set forth in this paragraph (b)(4)(xiv), in order for the services of an inpatient rehabilitation center for the treatment of substance use disorders to be authorized, the center shall have entered into a Participation Agreement with OCHAMPUS. A single consolidated participation agreement is acceptable for all units of the TRICARE authorized facility. The period of a Participation Agreement shall be specified in the agreement, and will generally be for not more than five years. The SUDRF shall not be considered to be a CHAMPUS authorized provider and CHAMPUS payments shall not be made for services provided by the SUDRF until the date the participation agreement is signed by the Director. In addition to review of the SUDRF's application and supporting documentation, an on-site visit by OCHAMPUS representatives may be part of the authorization process. In addition, such a Participation Agreement may not be signed until an SUDRF has been licensed and operational for at least six months. The Participation Agreement shall include at least the following requirements:

(1) Render applicable services to eligible CHAMPUS beneficiaries in need of such services, in accordance with the participation agreement and CHAMPUS regulation;

(2) Accept payment for its services based upon the methodology provided in Sec. 199.14, or such other method as determined by the Director;

(3) Accept the CHAMPUS-determined rate as payment in full and collect from the CHAMPUS beneficiary or the family of the CHAMPUS beneficiary only those amounts that represent the beneficiary's liability, as defined in Sec. 199.4, and charges for services and supplies that are not a benefit of CHAMPUS;

(4) Make all reasonable efforts acceptable to the Director to collect those amounts which represent the beneficiary's liability, as defined in Sec. 199.4;

(5) Comply with the provisions of Sec. 199.8, and submit claims first to all health insurance coverage to which the beneficiary is entitled that is primary to CHAMPUS;

(6) Furnish OCHAMPUS with cost data, as requested by OCHAMPUS, certified to by an independent accounting firm or other agency as authorized by the Director;

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- (7) Certify that:
- (i) It is and will remain in compliance with the provisions of paragraph (b)(4)(xiv) of the section establishing standards for substance use disorder rehabilitation facilities; and
  - (ii) It has conducted a self-assessment of the facility's compliance with the CHAMPUS Standards for Substance Use Disorder Rehabilitation Facilities, as issued by the Director and notified the Director of any matter regarding which the facility is not in compliance with such standards; and
  - (iii) It will maintain compliance with the CHAMPUS Standards for Substance Use Disorder Rehabilitation Facilities, as issued by the Director, except for any such standards regarding which the facility notifies the Director that it is not in compliance.
- (8) Designate an individual who will act as liaison for CHAMPUS inquiries. The SUDRF shall inform OCHAMPUS in writing of the designated individual;
- (9) Furnish OCHAMPUS, as requested by OCHAMPUS, with cost data certified by an independent accounting firm or other agency as authorized by the Director;
- (10) Comply with all requirements of this section applicable to institutional providers generally concerning accreditation requirements, preauthorization, concurrent care review, claims processing, beneficiary liability, double coverage, utilization and quality review, and other matters;
- (11) Grant the Director, or designee, the right to conduct quality assurance audits or accounting audits with full access to patients and records (including records relating to patients who are not CHAMPUS beneficiaries) to determine the quality and cost effectiveness of care rendered. The audits may be conducted on a scheduled or unscheduled (unannounced) basis. This right to audit/review included, but is not limited to:
- (i) Examination of fiscal and all other records of the center which would confirm compliance with the participation agreement and designation as an authorized TRICARE provider;
  - (ii) Conducting such audits of center records including clinical, financial, and census records, as may be necessary to determine the nature of the services being provided, and the basis for charges and claims against the United States for services provided CHAMPUS beneficiaries;
  - (iii) Examining reports of evaluations and inspection conducted by federal, state and local government, and private agencies and organizations;
  - (iv) Conducting on-site inspections of the facilities of the SUDRF and interviewing employees, members of the staff, contractors, board members, volunteers, and patients, as required.
  - (v) Audits conducted by the United States Government Accountability Office.

(C) Other requirements applicable to substance use disorder rehabilitation facilities.  
(1) Even though a SUDRF may qualify as a TRICARE authorized provider and may have entered into a participation agreement with CHAMPUS, payment by CHAMPUS for particular services provided is contingent upon the SUDRF also meeting all conditions set forth in Sec. 199.4.

(2) The center shall provide inpatient services to CHAMPUS beneficiaries in the same manner it provides services to all other patients. The center may not discriminate against CHAMPUS beneficiaries in any manner, including admission practices, placement in special or separate wings or rooms, or provisions of special or limited treatment.

(3) The substance use disorder facility shall assure that all certifications and information provided to the Director, incident to the process of obtaining and retaining authorized provider status, is accurate and that it has no material errors or omissions. In the case of any misrepresentations, whether by inaccurate information being provided or material facts withheld, authorized provider status will be denied or terminated, and the facility will be ineligible for consideration for authorized provider status for a two year period.

(xv) Home health agencies (HHAs). HHAs must be Medicare approved and meet all Medicare conditions of participation under sections 1861(o) and 1891 of the Social Security Act (42 U.S.C. 1395x(o) and 1395bbb) and 42 CFR part 484 in relation to TRICARE beneficiaries in order to receive payment under the TRICARE program. An HHA may be found to be out of compliance with a particular Medicare condition of participation and still participate in the TRICARE program as long as the HHA is allowed continued participation in Medicare while the condition of noncompliance is being corrected. An HHA is a public or private organization, or a subdivision of such an agency or organization, that meets the following requirements:

(A) Engaged in providing skilled nursing services and other therapeutic services, such as physical therapy, speech-language pathology services, or occupational therapy, medical services, and home health aide services.

(1) Makes available part-time or intermittent skilled nursing services and at least one other therapeutic service on a visiting basis in place of residence used as a patient's home.

(2) Furnishes at least one of the qualifying services directly through agency employees, but may furnish the second qualifying service and additional services under arrangement with another HHA or organization.

(B) Policies established by a professional group associated with the agency or organization (including at least one physician and one registered nurse) to govern the services and provides for supervision of such services by a physician or a registered nurse.

(C) Maintains clinical records for all patients.

(D) Licensed in accordance with State and local law or is approved by the State or local licensing agency as meeting the licensing standards, where applicable.

(E) Enters into an agreement with TRICARE in order to participate and to be eligible for payment under the program. In this agreement the HHA and TRICARE agree that the HHA

will:

(1) Not charge the beneficiary or any other person for items or services for which the beneficiary is entitled to have payment under the TRICARE HHA prospective payment system.

(2) Be allowed to charge the beneficiary for items or services requested by the beneficiary in addition to those that are covered under the TRICARE HHA prospective payment system.

(F) Abide by the following consolidated billing requirements:

(1) The HHA must submit all TRICARE claims for all home health services, excluding durable medical equipment (DME), while the beneficiary is under the home health plan without regard to whether or not the item or service was furnished by the HHA, by others under arrangement with the HHA, or under any other contracting or consulting arrangement.

(2) Separate payment will be made for DME items and services provided under the home health benefit which are under the DME fee schedule. DME is excluded from the consolidated billing requirements.

(3) Home health services included in consolidated billing are:

(i) Part-time or intermittent skilled nursing;

(ii) Part-time or intermittent home health aide services;

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

(iv) Medical social services;

(v) Routine and non-routine medical supplies;

(vi) A covered osteoporosis drug (not paid under PPS rate) but excluding other drugs and biologicals;

(vii) Medical services provided by an intern 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;

(viii) Services at hospitals, SNFs or rehabilitation centers when they involve equipment too cumbersome to bring home.

(G) Meet such other requirements as the Secretary of Health and Human Services and/or Secretary of Defense may find necessary in the interest of the health and safety of the individuals who are provided care and services by such agency or organization.

(xvi) CAHs. CAHs must meet all conditions of participation under 42 CFR 485.601 through 485.645 in relation to TRICARE beneficiaries in order to receive payment under the TRICARE program. If a CAH provides inpatient psychiatric services or inpatient rehabilitation services

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in a distinct part unit, these distinct part units must meet the conditions of participation in 42 CFR 485.647, with the exception of being paid under the inpatient prospective payment system for psychiatric facilities as specified in 42 CFR 412.1(a)(2) or the inpatient prospective payment system for rehabilitation hospitals or rehabilitation units as specified in 42 CFR 412(a)(3).

(xvii) Sole community hospitals (SCHs). SCHs must meet all the criteria for classification as an SCH under 42 CFR 412.92, in order to be considered an SCH under the TRICARE program.

(xviii) Intensive outpatient programs. This paragraph (b)(4)(xviii) establishes standards and requirements for intensive outpatient treatment programs for psychiatric and substance use disorder.

(A) Organization and administration--(1) Definition. Intensive outpatient treatment (IOP) programs are defined in Sec. 199.2. IOP services consist of a comprehensive and complimentary schedule of recognized treatment approaches that may include day, evening, night, and weekend services consisting of individual and group counseling or therapy, and family counseling or therapy as clinically indicated for children and adolescents, or adults aged 18 and over, and may include case management to link patients and their families with community based support systems.

(2) Eligibility. (i) In order to qualify as a TRICARE authorized provider, every intensive outpatient program must meet the minimum basic standards set forth in paragraphs (b)(4)(xviii)(A) through (C) of this section, as well as additional elaborative criteria and standards as the Director determines are necessary to implement the basic standards. Each intensive outpatient program must be either a distinct part of an otherwise-authorized institutional provider or a free-standing psychiatric or substance use disorder intensive outpatient program. Approval of a hospital by TRICARE is sufficient for its IOP to be an authorized TRICARE provider. Such hospital-based intensive outpatient programs are not required to be separately authorized by TRICARE.

(ii) To qualify as a TRICARE authorized provider, the IOP is required to be licensed and operate in substantial compliance with state and federal regulations.

(iii) The IOP is currently accredited by an accrediting organization approved by the Director. Each IOP authorized to treat substance use disorder must be accredited to provide the level of required treatment by an accreditation body approved by the Director.

(iv) The facility has a written participation agreement with TRICARE. The IOP is not considered a TRICARE authorized provider and TRICARE benefits are not paid for services provided until the date upon which a participation agreement is signed by the Director.

(B) Participation agreement requirements. In addition to other requirements set forth in paragraph (b)(4)(xii) of this section, in order for the services of an IOP to be authorized, the IOP shall have entered into a Participation Agreement with TRICARE. A single consolidated participation agreement is acceptable for all units of the TRICARE authorized facility granted that all programs meet the requirements of this part. The period of a Participation Agreement shall be specified in the agreement, and will generally be for not more than five years. In addition to review of a facility's application and supporting documentation, an on-site

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inspection by DHA authorized personnel may be required prior to signing a participation agreement. The Participation Agreement shall include at least the following requirements:

- (1) Render intensive outpatient program services to eligible TRICARE beneficiaries in need of such services, in accordance with the participation agreement and TRICARE regulation.
- (2) Accept payment for its services based upon the methodology provided in Sec. 199.14, or such other method as determined by the Director;
- (3) Collect from the TRICARE beneficiary or the family of the TRICARE beneficiary only those amounts that represent the beneficiary's liability, as defined in Sec. 199.4, and charges for services and supplies that are not a benefit of TRICARE;
- (4) Make all reasonable efforts acceptable to the Director to collect those amounts, which represent the beneficiary's liability, as defined in Sec. 199.4;
- (5) Comply with the provisions of Sec. 199.8, and submit claims first to all health insurance coverage to which the beneficiary is entitled that is primary to TRICARE;
- (6) Submit claims for services provided to TRICARE beneficiaries at least every 30 days (except to the extent a delay is necessitated by efforts to first collect from other health insurance). If claims are not submitted at least every 30 days, the IOP agrees not to bill the beneficiary or the beneficiary's family for any amounts disallowed by TRICARE;
- (7) Free-standing intensive outpatient programs shall certify that:
  - (i) It is and will remain in compliance with the provisions of paragraph (b)(4)(xii) of this section establishing standards for psychiatric and SUD IOPs;
  - (ii) It has conducted a self-assessment of the facility's compliance with the CHAMPUS Standards for Intensive Outpatient Programs, as issued by the Director, and notified the Director of any matter regarding which the facility is not in compliance with such standards; and
  - (iii) It will maintain compliance with the TRICARE standards for IOPs, as issued by the Director, except for any such standards regarding which the facility notifies the Director, or a designee that it is not in compliance.
- (8) Designate an individual who will act as liaison for TRICARE inquiries. The IOP shall inform TRICARE, or a designee in writing of the designated individual;
- (9) Furnish OCHAMPUS with cost data, as requested by OCHAMPUS, certified by an independent accounting firm or other agency as authorized by the Director.
- (10) Comply with all requirements of this section applicable to institutional providers generally concerning accreditation requirements, preauthorization, concurrent care review, claims processing, beneficiary liability, double coverage, utilization and quality review, and other matters;
- (11) Grant the Director, or designee, the right to conduct quality assurance audits or

accounting audits with full access to patients and records (including records relating to patients who are not CHAMPUS beneficiaries) to determine the quality and cost effectiveness of care rendered. The audits may be conducted on a scheduled or unscheduled (unannounced) basis. This right to audit/review included, but is not limited to:

(i) Examination of fiscal and all other records of the center which would confirm compliance with the participation agreement and designation as an authorized TRICARE provider;

(ii) Conducting such audits of center records including clinical, financial, and census records, as may be necessary to determine the nature of the services being provided, and the basis for charges and claims against the United States for services provided CHAMPUS beneficiaries;

(iii) Examining reports of evaluations and inspection conducted by federal, state and local government, and private agencies and organizations;

(iv) Conducting on-site inspections of the facilities of the IOP and interviewing employees, members of the staff, contractors, board members, volunteers, and patients, as required.

(v) Audits conducted by the United States Government Accountability Office.

(C) Other requirements applicable to Intensive Outpatient Programs (IOP). (1) Even though an IOP may qualify as a TRICARE authorized provider and may have entered into a participation agreement with CHAMPUS, payment by CHAMPUS for particular services provided is contingent upon the IOP also meeting all conditions set forth in Sec. 199.4.

(2) The IOP may not discriminate against CHAMPUS beneficiaries in any manner, including admission practices, placement in special or separate wings or rooms, or provisions of special or limited treatment.

(3) The IOP shall assure that all certifications and information provided to the Director incident to the process of obtaining and retaining authorized provider status is accurate and that it has no material errors or omissions. In the case of any misrepresentations, whether by inaccurate information being provided or material facts withheld, authorized provider status will be denied or terminated, and the IOP will be ineligible for consideration for authorized provider status for a two year period.

(xix) Opioid Treatment Programs (OTPs). This paragraph (b)(4)(xix) establishes standards and requirements for Opioid Treatment Programs.

(A) Organization and administration. (1) Definition. Opioid Treatment Programs (OTPs) are defined in Sec. 199.2. Opioid Treatment Programs (OTPs) are organized, ambulatory, addiction treatment services for patients with an opioid use disorder. OTPs have the capacity to provide daily direct administration of medications without the prescribing of medications. Medication supplies for patients to take outside of OTPs originate from within OTPs. OTPs offer medication assisted treatment, patient-centered, recovery-oriented individualized treatment through addiction counseling, mental health therapy, case management, and health education.

(2) Eligibility. (i) Every free-standing Opioid Treatment Program must be accredited by an accrediting organization recognized by Director, under the current standards of an accrediting organization, as well as meet additional elaborative criteria and standards as the Director determines are necessary to implement the basic standards. OTPs adhere to requirements of the Department of Health and Human Services' 42 CFR part 8, the Substance Abuse and Mental Health Services Administration's Center for Substance Abuse Treatment, and the Drug Enforcement Agency. OTPs must be either a distinct part of an otherwise authorized institutional provider or a free-standing program. Approval of hospitals by TRICARE is sufficient for their OTPs to be authorized TRICARE providers. Such hospital-based OTPs, if certified under 42 CFR 8, are not required to be separately authorized by TRICARE.

(ii) To qualify as a TRICARE authorized provider, OTPs are required to be licensed and fully operational for a period of at least six months and operate in substantial compliance with state and federal regulations.

(iii) OTPs have a written participation agreement with OCHAMPUS. OTPs are not considered a TRICARE authorized provider, and CHAMPUS benefits are not paid for services provided until the date upon which a participation agreement is signed by the Director.

(B) Participation agreement requirements. In addition to other requirements set forth in this paragraph (b)(4)(xix), in order for the services of OTPs to be authorized, OTPs shall have entered into a Participation Agreement with TRICARE. A single consolidated participation agreement is acceptable for all units of a TRICARE authorized facility. The period of a Participation Agreement shall be specified in the agreement, and will generally be for not more than five years. In addition to review of a facility's application and supporting documentation, an on-site inspection by DHA authorized personnel may be required prior to signing a participation agreement. The Participation Agreement shall include at least the following requirements:

(1) Render services from OTPs to eligible TRICARE beneficiaries in need of such services, in accordance with the participation agreement and TRICARE regulation.

(2) Accept payment for its services based upon the methodology provided in Sec. 199.14, or such other method as determined by the Director;

(3) Collect from the TRICARE beneficiary or the family of the TRICARE beneficiary only those amounts that represent the beneficiary's liability, as defined in Sec. 199.4, and charges for services and supplies that are not a benefit of TRICARE;

(4) Make all reasonable efforts acceptable to the Director to collect those amounts, which represent the beneficiary's liability, as defined in Sec. 199.4;

(5) Comply with the provisions of Sec. 199.8, and submit claims first to all health insurance coverage to which the beneficiary is entitled that is primary to TRICARE;

(6) Submit claims for services provided to TRICARE beneficiaries at least every 30 days (except to the extent a delay is necessitated by efforts to first collect from other health insurance). If claims are not submitted at least every 30 days, OTPs agree not to bill the

beneficiary or the beneficiary's family for any amounts disallowed by TRICARE;

(7) Free-standing opioid treatment programs shall certify that:

(i) It is and will remain in compliance with the provisions of paragraph (b)(4)(xii) of this section establishing standards for opioid treatment programs;

(ii) It will maintain compliance with the TRICARE standards for OTPs, as issued by the Director, except for any such standards regarding which the facility notifies the Director, or a designee, that it is not in compliance.

(8) Designate an individual who will act as liaison for TRICARE inquiries. OTPs shall inform TRICARE, or a designee, in writing of the designated individual;

(9) Furnish TRICARE, or a designee, with cost data, as requested by TRICARE, certified by an independent accounting firm or other agency as authorized by the Director;

(10) Comply with all requirements of this section applicable to institutional providers generally concerning accreditation requirements, claims processing, beneficiary liability, double coverage, utilization and quality review, and other matters;

(11) Grant the Director, or designee, the right to conduct quality assurance audits or accounting audits with full access to patients and records (including records relating to patients who are not TRICARE beneficiaries) to determine the quality and cost effectiveness of care rendered. The audits may be conducted on a scheduled or unscheduled (unannounced) basis. This right to audit/review includes, but is not limited to:

(i) Examination of fiscal and all other records of OTPs which would confirm compliance with the participation agreement and designation as an authorized TRICARE provider;

(ii) Conducting such audits of OTPs' records including clinical, financial, and census records, as may be necessary to determine the nature of the services being provided, and the basis for charges and claims against the United States for services provided TRICARE beneficiaries;

(iii) Examining reports of evaluations and inspections conducted by federal, state and local government, and private agencies and organizations.

(C) Other requirements applicable to OTPs. (1) Even though OTPs may qualify as a TRICARE authorized provider and may have entered into a participation agreement with CHAMPUS, payment by CHAMPUS for particular services provided is contingent upon OTPs also meeting all conditions set forth in Sec. 199.4.

(2) OTPs may not discriminate against CHAMPUS beneficiaries in any manner, including admission practices or provisions of special or limited treatment.

(3) OTPs shall assure that all certifications and information provided to the Director incident to the process of obtaining and retaining authorized provider status is accurate and that it has no material errors or omissions. In the case of any misrepresentations, whether by inaccurate information being provided or material facts withheld, authorized provider status

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will be denied or terminated, and OTPs will be ineligible for consideration for authorized provider status for a two year period.

**(c) Individual professional providers of care—**(1) General—(i) Purpose. This individual professional provider class is established to accommodate individuals who are recognized by 10 U.S.C. 1079(a) as authorized to assess or diagnose illness, injury, or bodily malfunction as a prerequisite for CHAMPUS cost-share of otherwise allowable related preventive or treatment services or supplies, and to accommodate such other qualified individuals who the Director, OCHAMPUS, or designee, may authorize to render otherwise allowable services essential to the efficient implementation of a plan-of-care established and managed by a 10 U.S.C. 1079(a) authorized professional.

(ii) Professional corporation affiliation or association membership permitted. Paragraph (c) of this section applies to those individual health care professionals who have formed a professional corporation or association pursuant to applicable state laws. Such a professional corporation or association may file claims on behalf of a CHAMPUS-authorized individual professional provider and be the payee for any payment resulting from such claims when the CHAMPUS-authorized individual certifies to the Director, OCHAMPUS, or designee, in writing that the professional corporation or association is acting on the authorized individual's behalf.

(iii) Scope of practice limitation. For CHAMPUS cost-sharing to be authorized, otherwise allowable services provided by a CHAMPUS-authorized individual professional provider shall be within the scope of the individual's license as regulated by the applicable state practice act of the state where the individual rendered the service to the CHAMPUS beneficiary or shall be within the scope of the test which was the basis for the individual's qualifying certification.

(iv) Employee status exclusion. An individual employed directly, or indirectly by contract, by an individual or entity to render professional services otherwise allowable by this part is excluded from provider status as established by this paragraph (c) for the duration of each employment.

(v) Training status exclusion. Individual health care professionals who are allowed to render health care services only under direct and ongoing supervision as training to be credited towards earning a clinical academic degree or other clinical credential required for the individual to practice independently are excluded from provider status as established by this paragraph (c) for the duration of such training.

(2) Conditions of authorization—(i) Professional license requirement. The individual must be currently licensed to render professional health care services in each state in which the individual renders services to CHAMPUS beneficiaries. Such license is required when a specific state provides, but does not require, license for a specific category of individual professional provider. The license must be at full clinical practice level to meet this requirement. A temporary license at the full clinical practice level is acceptable.

(ii) Professional certification requirement. When a state does not license a specific category of individual professional, certification by a Qualified Accreditation Organization, as defined in Sec. 199.2, is required. Certification must be at full clinical practice level. A temporary certification at the full clinical practice level is acceptable.

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(iii) Education, training and experience requirement. The Director, OCHAMPUS, or designee, may establish for each category or type of provider allowed by this paragraph (c) specific education, training, and experience requirements as necessary to promote the delivery of services by fully qualified individuals.

(iv) Physician referral and supervision. When physician referral and supervision is a prerequisite for CHAMPUS cost-sharing of the services of a provider authorized under this paragraph (c), such referral and supervision means that the physicians must actually see the patient to evaluate and diagnose the condition to be treated prior to referring the beneficiary to another provider and that the referring physician provides ongoing oversight of the course of referral related treatment throughout the period during which the beneficiary is being treated in response to the referral. Written contemporaneous documentation of the referring physician's basis for referral and ongoing communication between the referring and treating provider regarding the oversight of the treatment rendered as a result of the referral must meet all requirements for medical records established by this part. Referring physician supervision does not require physical location on the premises of the treating provider or at the site of treatment.

(v) Subject to section 1079(a) of title 10, U.S.C., chapter 55, a physician or other health care practitioner who is eligible to receive reimbursement for services provided under Medicare (as defined in section 1086(d)(3)(C) of title 10 U.S.C., chapter 55) shall be considered approved to provide medical care authorized under section 1079 and section 1086 of title 10, U.S.C., chapter 55 unless the administering Secretaries have information indicating Medicare, TRICARE, or other Federal health care program integrity violations by the physician or other health care practitioner. Approval is limited to those classes of provider currently considered TRICARE authorized providers as outlined in 32 CFR 199.6. Services and supplies rendered by those providers who are not currently considered authorized providers shall be denied.

(3) Types of providers. Subject to the standards of participation provisions of this part, the following individual professional providers of medical care are authorized to provide services to CHAMPUS beneficiaries:

(i) Physicians. (A) Doctors of Medicine (M.D.).

(B) Doctors of Osteopathy (D.O.).

(ii) Dentists. Except for covered oral surgery as specified in Sec. 199.4(e) of this part, all otherwise covered services rendered by dentists require preauthorization.

(A) Doctors of Dental Medicine (D.M.D.).

(B) Doctors of Dental Surgery (D.D.S.).

(iii) Other allied health professionals. The services of the following individual professional providers of care are coverable on a fee-for-service basis provided such services are otherwise authorized in this or other sections of this part.

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- (A) Clinical psychologist. For purposes of CHAMPUS, a clinical psychologist is an individual who is licensed or certified by the state for the independent practice of psychology and:
- (1) Possesses a doctoral degree in psychology from a regionally accredited university; and
  - (2) Has has 2 years of supervised clinical experience in psychological health services of which at least 1 year is post-doctoral and 1 year (may be the post-doctoral year) is in an organized psychological health service training program; or
  - (3) As an alternative to paragraphs (c)(3)(iii)(A)(1) and (2) of this section is listed in the National Register of Health Service Providers in Psychology.
- (B) Doctors of Optometry.
- (C) Doctors of Podiatry or Surgical Chiropody.
- (D) Certified nurse midwives. (1) A certified nurse midwife may provide covered care independent of physician referral and supervision, provided the nurse midwife is:
- (i) Licensed, when required, by the local licensing agency for the jurisdiction in which the care is provided; and
  - (ii) Certified by the American College of Nurse Midwives. To receive certification, a candidate must be a registered nurse who has completed successfully an educational program approved by the American College of Nurse Midwives, and passed the American College of Nurse Midwives National Certification Examination.
- (2) The services of a registered nurse who is not a certified nurse midwife may be authorized only when the patient has been referred for care by a licensed physician and a licensed physician provides continuing supervision of the course of care. A lay midwife who is neither a certified nurse midwife nor a registered nurse is not a CHAMPUS-authorized provider, regardless of whether the services rendered may otherwise be covered.
- (E) Certified nurse practitioner. Within the scope of applicable licensure or certification requirements, a certified nurse practitioner may provide covered care independent of physician referral and supervision, provided the nurse practitioner is:
- (1) A licensed, registered nurse; and
  - (2) Specifically licensed or certified as a nurse practitioner by the state in which the care was provided, if the state offers such specific licensure or certification; or
  - (3) Certified as a nurse practitioner (certified nurse) by a professional organization offering certification in the speciality of practice, if the state does not offer specific licensure or certification for nurse practitioners.

(F) Certified Clinical Social Worker. A clinical social worker may provide covered services independent of physician referral and supervision, provided the clinical social worker:

(1) Is licensed or certified as a clinical social worker by the jurisdiction where practicing; or, if the jurisdiction does not provide for licensure or certification of clinical social workers, is certified by a national professional organization offering certification of clinical social workers; and

(2) Has at least a master's degree in social work from a graduate school of social work accredited by the Council on Social Work Education; and

(3) Has had a minimum of 2 years or 3,000 hours of post-master's degree supervised clinical social work practice under the supervision of a master's level social worker in an appropriate clinical setting, as determined by the Director, OCHAMPUS, or a designee.

NOTE: Patients' organic medical problems must receive appropriate concurrent management by a physician.

(G) Certified psychiatric nurse specialist. A certified psychiatric nurse specialist may provide covered care independent of physician referral and supervision. For purposes of CHAMPUS, a certified psychiatric nurse specialist is an individual who:

(1) Is a licensed, registered nurse; and

(2) Has at least a master's degree in nursing from a regionally accredited institution with a specialization in psychiatric and mental health nursing; and

(3) Has had at least 2 years of post-master's degree practice in the field of psychiatric and mental health nursing, including an average of 8 hours of direct patient contact per week; or

(4) Is listed in a CHAMPUS-recognized, professionally sanctioned listing of clinical specialists in psychiatric and mental health nursing.

(H) Certified physician assistant. A physician assistant may provide care under general supervision of a physician (see Sec. 199.14(j)(1)(ix) of this part for limitations on reimbursement). For purposes of CHAMPUS, a physician assistant must meet the applicable state requirements governing the qualifications of physician assistants and at least one of the following conditions:

(1) Is currently certified by the National Commission on Certification of Physician Assistants to assist primary care physicians, or

(2) Has satisfactorily completed a program for preparing physician assistants that:

(i) Was at least 1 academic year in length;

(ii) Consisted of supervised clinical practice and at least 4 months (in the aggregate) of classroom instruction directed toward preparing students to deliver health care; and

(iii) Was accredited by the American Medical Association's Committee on Allied Health Education and Accreditation; or

(3) Has satisfactorily completed a formal educational program for preparing program physician assistants that does not meet the requirement of paragraph (c)(3)(iii)(H)(2) of this section and had been assisting primary care physicians for a minimum of 12 months during the 18-month period immediately preceding January 1, 1987.

(l) Anesthesiologist Assistant. An anesthesiologist assistant may provide covered anesthesia services, if the anesthesiologist assistant:

(1) Works under the direct supervision of an anesthesiologist who bills for the services and for each patient;

(i) The anesthesiologist performs a pre-anesthetic examination and evaluation;

(ii) The anesthesiologist prescribes the anesthesia plan;

(iii) The anesthesiologist personally participates in the most demanding aspects of the anesthesia plan including, if applicable, induction and emergence;

(iv) The anesthesiologist ensures that any procedures in the anesthesia plan that he or she does not perform are performed by a qualified anesthesiologist assistant;

(v) The anesthesiologist monitors the course of anesthesia administration at frequent intervals;

(vi) The anesthesiologist remains physically present and available for immediate personal diagnosis and treatment of emergencies;

(vii) The anesthesiologist provides indicated post-anesthesia care; and

(viii) The anesthesiologist performs no other services while he or she supervises no more than four anesthesiologist assistants concurrently or a lesser number if so limited by the state in which the procedure is performed.

(2) Is in compliance with all applicable requirements of state law, including any licensure requirements the state imposes on nonphysician anesthetists; and

(3) Is a graduate of a Master's level anesthesiologist assistant educational program that is established under the auspices of an accredited medical school and that:

(i) Is accredited by the Committee on Allied Health Education and Accreditation, or its successor organization; and

(ii) Includes approximately two years of specialized basic science and clinical education in anesthesia at a level that builds on a premedical undergraduate science background.

(4) The Director, TMA, or a designee, shall issue TRICARE policies, instructions, procedures, guidelines, standards, and criteria as may be necessary to implement the intent

of this section.

(J) Certified Registered Nurse Anesthetist (CRNA). A certified registered nurse anesthetist may provide covered care independent of physician referral and supervision as specified by state licensure. For purposes of CHAMPUS, a certified registered nurse anesthetist is an individual who:

- (1) Is a licensed, registered nurse; and
- (2) Is certified by the Council on Certification of Nurse Anesthetists, or its successor organization.

(K) Other individual paramedical providers. (1) The services of the following individual professional providers of care to be considered for benefits on a fee-for-service basis may be provided only if the beneficiary is referred by a physician for the treatment of a medically diagnosed condition and a physician must also provide continuing and ongoing oversight and supervision of the program or episode of treatment provided by these individual paramedical providers.

(i) Licensed registered nurses.

(ii) Audiologists.

(2) The services of the following individual professional providers of care to be considered for benefits on a fee-for-service basis may be provided only if the beneficiary is referred by a physician, a certified physician assistant or certified nurse practitioner and a physician, a certified physician assistant, or certified nurse practitioner must also provide continuing and ongoing oversight and supervision of the program or episode of treatment provided by these individual paramedical providers.

(i) Licensed registered physical therapist and occupational therapist.

(ii) Licensed registered speech therapists (speech pathologists).

(L) Nutritionist. A nutritionist may provide DSMT via an accredited DSMT program. The nutritionist must be licensed by the State in which the care is provided, and must be under the supervision of a physician who is overseeing the DSMT program.

(M) Registered Dietitian. A dietitian may provide DSMT via an accredited DSMT program. The dietitian must be licensed by the State in which the care is provided, and must be under the supervision of a physician who is overseeing the DSMT program.

(N) TRICARE certified mental health counselor. For the purposes of CHAMPUS, a TRICARE certified mental health counselor (TCMHC) must be licensed for independent practice in mental health counseling by the jurisdiction where practicing. In jurisdictions with two or more licenses allowing for differing scopes of independent practice, the licensed mental health counselor may only practice within the scope of the license he or she possesses. In addition, a TCMHC must meet the requirements of either paragraph (c)(3)(iii)(N)(1) or the requirements of paragraph (c)(3)(iii)(N)(2) of this section.

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- (1) The requirements of this paragraph are that the TCMHC:
  - (i) Must have passed the National Clinical Mental Health Counselor Examination (NCMHCE) or its successor as determined by the Director, TMA; and
  - (ii) Must possess a master's or higher-level degree from a mental health counseling program of education and training accredited by the Council for Accreditation of Counseling and Related Educational Programs (CACREP); and
  - (iii) Must have a minimum of two (2) years of post-master's degree supervised mental health counseling practice which includes a minimum of 3,000 hours of supervised clinical practice and 100 hours of face-to-face supervision. Supervision must be provided by mental health counselors at the highest level of state licensure, psychiatrists, clinical psychologists, certified clinical social workers, or certified psychiatric nurse specialists who are licensed for independent practice in the jurisdiction where practicing and who are practicing within the scope of their licenses. Supervised clinical practice must be received in a manner that is consistent with the guidelines regarding knowledge, skills, and practice standards for supervision of the American Mental Health Counselors Association; and
  - (iv) Is licensed or certified for independent practice in mental health counseling by the jurisdiction where practicing (see paragraph (c)(2)(ii) of this section for more specific information).
- (2) The requirements of this paragraph are that the TCMHC, prior to January 1, 2017:
  - (i) Possess a master's or higher-level degree from a mental health counseling program of education and training accredited by CACREP and must have passed the National Counselor Examination (NCE); or
  - (ii) Possess a master's or higher-level degree from a mental health counseling program of education and training from either a CACREP or regionally accredited institution and have passed the NCMHCE; and
  - (iii) Must have a minimum of two (2) years of post-master's degree supervised mental health counseling practice which includes a minimum of 3,000 hours of supervised clinical practice and 100 hours of face-to-face supervision. Supervision must be provided by mental health counselors at the highest level of state licensure, psychiatrists, clinical psychologists, certified clinical social workers, or certified psychiatric nurse specialists who are licensed for independent practice in the jurisdiction where practicing and who are practicing within the scope of their licenses. Supervised clinical practice must be received in a manner that is consistent with the guidelines regarding knowledge, skills, and practice standards for supervision of the American Mental Health Counselors Association; and
  - (iv) Is licensed or certified for independent practice in mental health counseling by the jurisdiction where practicing (see paragraph (c)(2)(ii) of this section for more specific information).
- (3) The Director, TRICARE Management Activity may amend or modify existing or specify additional certification requirements as needed to accommodate future practice and licensing standards and to ensure that all TCMHCs continue to meet educational, licensing, and

clinical training requirements considered appropriate.

(iv) Extramedical individual providers. Extramedical individual providers are those who do counseling or nonmedical therapy and whose training and therapeutic concepts are outside the medical field. The services of extramedical individual professionals are coverable following the CHAMPUS determined allowable charge methodology provided such services are otherwise authorized in this or other sections of the regulation.

(A) Certified marriage and family therapists. For the purposes of CHAMPUS, a certified marriage and family therapist is an individual who meets the following requirements:

(1) Recognized graduate professional education with the minimum of an earned master's degree from a regionally accredited educational institution in an appropriate behavioral science field, mental health discipline; and

(2) The following experience:

(i) Either 200 hours of approved supervision in the practice of marriage and family counseling, ordinarily to be completed in a 2- to 3-year period, of which at least 100 hours must be in individual supervision. This supervision will occur preferably with more than one supervisor and should include a continuous process of supervision with at least three cases; and

(ii) 1,000 hours of clinical experience in the practice of marriage and family counseling under approved supervision, involving at least 50 different cases; or

(iii) 150 hours of approved supervision in the practice of psychotherapy, ordinarily to be completed in a 2- to 3-year period, of which at least 50 hours must be individual supervision; plus at least 50 hours of approved individual supervision in the practice of marriage and family counseling, ordinarily to be completed within a period of not less than 1 nor more than 2 years; and

(iv) 750 hours of clinical experience in the practice of psychotherapy under approved supervision involving at least 30 cases; plus at least 250 hours of clinical practice in marriage and family counseling under approved supervision, involving at least 20 cases; and

(3) Is licensed or certified to practice as a marriage and family therapist by the jurisdiction where practicing (see paragraph (c)(3)(iv)(D) of this section for more specific information regarding licensure); and

(4) Agrees that a patients' organic medical problems must receive appropriate concurrent management by a physician.

(5) Agrees to accept the CHAMPUS determined allowable charge as payment in full, except for applicable deductibles and cost-shares, and hold CHAMPUS beneficiaries harmless for noncovered care (i.e., may not bill a beneficiary for noncovered care, and may not balance bill a beneficiary for amounts above the allowable charge). The certified marriage and family therapist must enter into a participation agreement with the Office of CHAMPUS within which the certified marriage and family therapist agrees to all provisions specified

above.

(6) As of the effective date of termination, the certified marriage and family therapist will no longer be recognized as an authorized provider under CHAMPUS. Subsequent to termination, the certified marriage and family therapist may only be reinstated as an authorized CHAMPUS extramedical provider by entering into a new participation agreement as a certified marriage and family therapist.

(B) Pastoral counselors. For the purposes of CHAMPUS, a pastoral counselor is an individual who meets the following requirements:

(1) Recognized graduate professional education with the minimum of an earned master's degree from a regionally accredited educational institution in an appropriate behavioral science field, mental health discipline; and

(2) The following experience:

(i) Either 200 hours of approved supervision in the practice of pastoral counseling, ordinarily to be completed in a 2- to 3-year period, of which at least 100 hours must be in individual supervision. This supervision will occur preferably with more than one supervisor and should include a continuous process of supervision with at least three cases; and

(ii) 1,000 hours of clinical experience in the practice of pastoral counseling under approved supervision, involving at least 50 different cases; or

(iii) 150 hours of approved supervision in the practice of psychotherapy, ordinarily to be completed in a 2- to 3-year period, of which at least 50 hours must be individual supervision; plus at least 50 hours of approved individual supervision in the practice of pastoral counseling, ordinarily to be completed within a period of not less than 1 nor more than 2 years; and

(iv) 750 hours of clinical experience in the practice of psychotherapy under approved supervision involving at least 30 cases; plus at least 250 hours of clinical practice in pastoral counseling under approved supervision, involving at least 20 cases; and

(3) Is licensed or certified to practice as a pastoral counselor by the jurisdiction where practicing (see paragraph (c)(3)(iv)(D) of this section for more specific information regarding licensure); and

(4) The services of a pastoral counselor meeting the above requirements are coverable following the CHAMPUS determined allowable charge methodology, under the following specified conditions:

(i) The CHAMPUS beneficiary must be referred for therapy by a physician; and

(ii) A physician is providing ongoing oversight and supervision of the therapy being provided; and

(iii) The pastoral counselor must certify on each claim for reimbursement that a written

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communication has been made or will be made to the referring physician of the results of the treatment. Such communication will be made at the end of the treatment, or more frequently, as required by the referring physician (refer to Sec. 199.7).

(5) Because of the similarity of the requirements for licensure, certification, experience, and education, a pastoral counselor may elect to be authorized under CHAMPUS as a certified marriage and family therapist, and as such, be subject to all previously defined criteria for the certified marriage and family therapist category, to include acceptance of the CHAMPUS determined allowable charge as payment in full, except for applicable deductibles and cost-shares (i.e., balance billing of a beneficiary above the allowable charge is prohibited; may not bill beneficiary for noncovered care). The pastoral counselor must also agree to enter into the same participation agreement as a certified marriage and family therapist with the Office of CHAMPUS within which the pastoral counselor agrees to all provisions including licensure, national association membership and conditions upon termination, outlined above for certified marriage and family therapist.

NOTE: No dual status will be recognized by the Office of CHAMPUS. Pastoral counselors must elect to become one of the categories of extramedical CHAMPUS provides specified above. Once authorized as either a pastoral counselor, or a certified marriage and family therapist, claims review and reimbursement will be in accordance with the criteria established for the elected provider category.

(C) Supervised mental health counselor. For the purposes of TRICARE, a supervised mental health counselor is an individual who does not meet the requirements of a TRICARE certified mental health counselor in paragraph (c)(3)(iii)(N) of this section, but meets all of the following requirements and conditions of practice:

(1) Minimum of a master's degree in mental health counseling or allied mental health field from a regionally accredited institution; and

(2) Two years of post-masters experience which includes 3,000 hours of clinical work and 100 hours of face-to-face supervision; and

(3) Is licensed or certified to practice as a mental health counselor by the jurisdiction where practicing (see paragraph (c)(3)(iv)(D) of this section for more specific information); and

(4) May only be reimbursed when:

(i) The TRICARE beneficiary is referred for therapy by a physician; and

(ii) A physician is providing ongoing oversight and supervision of the therapy being provided; and

(iii) The mental health counselor certifies on each claim for reimbursement that a written communication has been made or will be made to the referring physician of the results of the treatment. Such communication will be made at the end of the treatment, or more frequently, as required by the referring physician (refer to Sec. 199.7).

(D) The following additional information applies to each of the above categories of extramedical individual providers:

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(1) These providers must also be licensed or certified to practice as a certified marriage and family therapist, pastoral counselor or mental health counselor by the jurisdiction where practicing. In jurisdictions that do not provide for licensure or certification, the provider must be certified by or eligible for full clinical membership in the appropriate national professional association that sets standards for the specific profession.

(2) Grace period for therapists or counselors in states where licensure/certification is optional. CHAMPUS is providing a grace period for those therapists or counselors who did not obtain optional licensure/certification in their jurisdiction, not realizing it was a CHAMPUS requirement for authorization. The exemption by state law for pastoral counselors may have misled this group into thinking licensure was not required. The same situation may have occurred with the other therapist or counselor categories where licensure was either not mandated by the state or was provided under a more general category such as "professional counselors." This grace period pertains only to the licensure/certification requirement, applies only to therapists or counselors who are already approved as of October 29, 1990, and only in those areas where the licensure/certification is optional. Any therapist or counselor who is not licensed/certified in the state in which he/she is practicing by August 1, 1991, will be terminated under the provisions of Sec. 199.9. This grace period does not change any of the other existing requirements which remain in effect. During this grace period, membership or proof of eligibility for full clinical membership in a recognized professional association is required for those therapists or counselors who are not licensed or certified by the state. The following organizations are recognized for therapists or counselors at the level indicated: Full clinical member of the American Association of Marriage and Family Therapy; membership at the fellow or diplomate level of the American Association of Pastoral Counselors; and membership in the National Academy of Certified Clinical Mental Health Counselors. Acceptable proof of eligibility for membership is a letter from the appropriate certifying organization. This opportunity for delayed certification/licensure is limited to the counselor or therapist category only as the language in all of the other provider categories has been consistent and unmodified from the time each of the other provider categories were added. The grace period does not apply in those states where licensure is mandatory.

(E) Christian Science practitioners and Christian Science nurses. CHAMPUS cost-shares the services of Christian Science practitioners and nurses. In order to bill as such, practitioners or nurses must be listed or be eligible for listing in the Christian Science Journal<sup>2</sup> at the time the service is provided.

**(d) Other providers.** Certain medical supplies and services of an ancillary or supplemental nature are coverable by CHAMPUS, subject to certain controls. This category of provider includes the following:

(1) Independent laboratory. Laboratory services of independent laboratories may be cost-shared if the laboratory is approved for participation under Medicare and certified by the Medicare Bureau, Health Care Financing Administration.

<sup>2</sup> Copies of this journal can be obtained through the Christian Science Publishing Company, 1 Norway Street, Boston, MA 02115-3122 or the Christian Science Publishing Society, P.O. Box 11369, Des Moines, IA 50340.

(2) Suppliers of portable x-ray services. Such suppliers must meet the conditions of coverage of the Medicare program, set forth in the Medicare regulations, or the Medicaid program in that state in which the covered service is provided.

(3) Pharmacies. Pharmacies must meet the applicable requirements of state law in the state in which the pharmacy is located. In addition to being subject to the policies and procedures for authorized providers established by this section, additional policies and procedures may be established for authorized pharmacies under Sec. 199.21 of this part implementing the Pharmacy Benefits Program.

(4) Ambulance companies. Such companies must meet the requirements of state and local laws in the jurisdiction in which the ambulance firm is licensed.

(5) Medical equipment firms, medical supply firms, and Durable Medical Equipment, Prosthetic, Orthotic, Supplies providers/suppliers. Any firm, supplier, or provider that is an authorized provider under Medicare or is otherwise designated an authorized provider by the Director, TRICARE Management Activity.

(6) Mammography suppliers. Mammography services may be cost-shared only if the supplier is certified by Medicare for participation as a mammography supplier, or is certified by the American College of Radiology as having met its mammography supplier standards.

**(e) Extended Care Health Option Providers.—**(1) General. (i) Services and items cost-shared through Sec. 199.5 must be rendered by a CHAMPUS-authorized provider.

(ii) A Program for Persons with Disabilities (PPPWD) provider with TRICARE-authorized status on the effective date for the Extended Care Health Option (ECHO) Program shall be deemed to be a TRICARE-authorized provider until the expiration of all outstanding PFPWD benefit authorizations for services or items being rendered by the provider.

(2) ECHO provider categories--(i) ECHO inpatient care provider. A provider of residential institutional care, which is otherwise an ECHO benefit, shall be:

(A) A not-for-profit entity or a public facility; and

(B) Located within a state; and

(C) Be certified as eligible for Medicaid payment in accordance with a state plan for medical assistance under Title XIX of the Social Security Act (Medicaid) as a Medicaid Nursing Facility, or Intermediate Care Facility for the Mentally Retarded, or be a TRICARE-authorized institutional provider as defined in paragraph (b) of this section, or be approved by a state educational agency as a training institution.

(ii) ECHO outpatient care provider. A provider of ECHO outpatient, ambulatory, or in-home services shall be:

(A) A TRICARE-authorized provider of services as defined in this section; or

(B) An individual, corporation, foundation, or public entity that predominantly renders services of a type uniquely allowable as an ECHO benefit and not otherwise allowable as a

benefit of Sec. 199.4, that meets all applicable licensing or other regulatory requirements of the state, county, municipality, or other political jurisdiction in which the ECHO service is rendered, or in the absence of such licensing or regulatory requirements, as determined by the Director, TRICARE Management Activity or designee.

(iii) ECHO vendor. A provider of an allowable ECHO item, such as supplies or equipment, shall be deemed to be a TRICARE-authorized vendor for the provision of the specific item, supply or equipment when the vendor supplies such information as the Director, TRICARE Management Activity or designee determines necessary to adjudicate a specific claim.

(3) ECHO provider exclusion or suspension. A provider of ECHO services or items may be excluded or suspended for a pattern of discrimination on the basis of disability. Such exclusion or suspension shall be accomplished according to the provisions of Sec. 199.9.

**(f) Corporate services providers—**(1) General. (i) This corporate services provider class is established to accommodate individuals who would meet the criteria for status as a CHAMPUS authorized individual professional provider as established by paragraph (c) of this section but for the fact that they are employed directly or contractually by a corporation or foundation that provides principally professional services which are within the scope of the CHAMPUS benefit.

(ii) Payment for otherwise allowable services may be made to a CHAMPUS-authorized corporate services provider subject to the applicable requirements, exclusions and limitations of this part.

(iii) The Director, OCHAMPUS, or designee, may create discrete types within any allowable category of provider established by this paragraph (f) to improve the efficiency of CHAMPUS management.

(iv) The Director, OCHAMPUS, or designee, may require, as a condition of authorization, that a specific category or type of provider established by this paragraph (f):

(A) Maintain certain accreditation in addition to or in lieu of the requirement of paragraph (f)(2)(v) of this section;

(B) Cooperate fully with a designated utilization and clinical quality management organization which has a contract with the Department of Defense for the geographic area in which the provider does business;

(C) Render services for which direct or indirect payment is expected to be made by CHAMPUS only after obtaining CHAMPUS written authorization; and

(D) Maintain Medicare approval for payment when the Director, OCHAMPUS, or designee, determines that a category, or type, of provider established by this paragraph (f) is substantially comparable to a provider or supplier for which Medicare has regulatory conditions of participation or conditions of coverage.

(v) Otherwise allowable services may be rendered at the authorized corporate services provider's place of business, or in the beneficiary's home under such circumstances as the Director, OCHAMPUS, or designee, determines to be necessary for the efficient delivery of

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such in-home services.

(vi) The Director, OCHAMPUS, or designee, may limit the term of a participation agreement for any category or type of provider established by this paragraph (f).

(vii) Corporate services providers shall be assigned to only one of the following allowable categories based upon the predominate type of procedure rendered by the organization;

- (A) Medical treatment procedures;
- (B) Surgical treatment procedures;
- (C) Maternity management procedures;
- (D) Rehabilitation and/or habilitation procedures; or
- (E) Diagnostic technical procedures.

(viii) The Director, OCHAMPUS, or designee, shall determine the appropriate procedural category of a qualified organization and may change the category based upon the provider's CHAMPUS claim characteristics. The category determination of the Director, OCHAMPUS, designee, is conclusive and may not be appealed.

(2) Conditions of authorization. An applicant must meet the following conditions to be eligible for authorization as a CHAMPUS corporate services provider:

- (i) Be a corporation or a foundation, but not a professional corporation or professional association; and
- (ii) Be institution-affiliated or freestanding as defined in Sec. 199.2; and
- (iii) Provide:
  - (A) Services and related supplies of a type rendered by CHAMPUS individual professional providers or diagnostic technical services and related supplies of a type which requires direct patient contact and a technologist who is licensed by the state in which the procedure is rendered or who is certified by a Qualified Accreditation Organization as defined in Sec. 199.2; and
  - (B) A level of care which does not necessitate that the beneficiary be provided with on-site sleeping accommodations and food in conjunction with the delivery of services; and
- (iv) Complies with all applicable organizational and individual licensing or certification requirements that are extant in the state, county, municipality, or other political jurisdiction in which the provider renders services; and
- (v) Be approved for Medicare payment when determined to be substantially comparable under the provisions of paragraph (f)(1)(iv)(D) of this section or, when Medicare approved status is not required, be accredited by a qualified accreditation organization, as defined in Sec. 199.2; and

(vi) Has entered into a participation agreement approved by the Director, OCHAMPUS, or designee, which at least complies with the minimum participation agreement requirements of this section.

(3) Transfer of participation agreement. In order to provide continuity of care for beneficiaries when there is a change of provider ownership, the provider agreement is automatically assigned to the new owner, subject to all the terms and conditions under which the original agreement was made.

(i) The merger of the provider corporation or foundation into another corporation or foundation, or the consolidation of two or more corporations or foundations resulting in the creation of a new corporation or foundation, constitutes a change of ownership.

(ii) Transfer of corporate stock or the merger of another corporation or foundation into the provider corporation or foundation does not constitute change of ownership.

(iii) The surviving corporation or foundation shall notify the Director, OCHAMPUS, or designee, in writing of the change of ownership promptly after the effective date of the transfer or change in ownership.

(4) Pricing and payment methodology: The pricing and payment of procedures rendered by a provider authorized under this paragraph (f) shall be limited to those methods for pricing and payment allowed by this part which the Director, OCHAMPUS, or designee, determines contribute to the efficient management of CHAMPUS.

(5) Termination of participation agreement. A provider may terminate a participation agreement upon 45 days written notice to the Director, OCHAMPUS, or designee, and to the public.

[51 FR 24008, Jul 1, 1986; 67 FR 40602, Jun 13, 2002; 67 FR 42720, Jun 25, 2002; 68 FR 65174, Nov 19, 2003; 69 FR 29229, May 21, 2004; 69 FR 44591, Jul 28, 2004; 69 FR 51568, Aug 20, 2004; 69 FR 55359, Sep 14, 2004; 70 FR 61378, Oct 24, 2005; 72 FR 63988, Nov 14, 2007; 74 FR 44755, Aug 31, 2009; 74 FR 55777, Oct 29, 2009; 74 FR 65438, Dec 10, 2009; 75 FR 47460, Aug 6, 2010; 75 FR 50882, Aug 18, 2010; 76 FR 41065, Jul 13, 2011; 76 FR 80743, Dec 27, 2011; 78 FR 48309, Aug 8, 2013; 79 FR 41641, Jul 17, 2014; 81 FR 61091, Sep 2, 2016]

**EDITORIAL NOTE:** For Federal Register citations affecting Sec. 199.6, see the List of Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

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CHAMPUS beneficiary or sponsor that could result from a retroactive denial, the following additional claims filing procedures are recommended or required.

(1) Continuing care. Except for claims subject to the CHAMPUS DRG-based payment system, whenever medical services and supplies are being rendered on a continuing basis, an appropriate claim or claims should be submitted every 30 days (monthly) whether submitted directly by the beneficiary or sponsor or by the provider on behalf of the beneficiary. Such claims may be submitted more frequently if the beneficiary or provider so elects. The Director, OCHAMPUS, or a designee, also may require more frequent claims submission based on dollars. Examples of care that may be rendered on a continuing basis are outpatient physical therapy, private duty (special) nursing, or inpatient stays. For claims subject to the CHAMPUS DRG-based payment system, claims may be submitted only after the beneficiary has been discharged or transferred from the hospital.

(2) (Reserved)

(3) Claims involving the services of marriage and family counselors, pastoral counselors, and supervised mental health counselors. CHAMPUS requires that marriage and family counselors, pastoral counselors, and supervised mental health counselors make a written report to the referring physician concerning the CHAMPUS beneficiary's progress. Therefore, each claim for reimbursement for services of marriage and family counselors, pastoral counselors, and supervised mental health counselors must include certification to the effect that a written communication has been made or will be made to the referring physician at the end of treatment, or more frequently, as required by the referring physician.

**(f) Preauthorization.** When specifically required in other sections of this part, preauthorization requires the following:

(1) Preauthorization must be granted before benefits can be extended. In those situations requiring preauthorization, the request for such preauthorization shall be submitted and approved before benefits may be extended, except as provided in Sec. 199.4(a)(11). If a claim for services or supplies is submitted without the required preauthorization, no benefits shall be paid, unless the Director, OCHAMPUS, or a designee, has granted an exception to the requirement for preauthorization.

(i) Specifically preauthorized services. An approved preauthorization specifies the exact services or supplies for which authorization is being given. In a preauthorization situation, benefits cannot be extended for services or supplies provided beyond the specific authorization.

(ii) Time limit on preauthorization. Approved preauthorizations are valid for specific periods of time, appropriate for the circumstances presented and specified at the time the preauthorization is approved. In general, preauthorizations are valid for 30 days. If the preauthorized service or supplies are not obtained or commenced within the specified time limit, a new preauthorization is required before benefits may be extended. For organ and stem cell transplants, the preauthorization shall remain in effect as long as the beneficiary continues to meet the specific transplant criteria set forth in the TRICARE/CHAMPUS Policy Manual, or until the approved transplant occurs.

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(2) Treatment plan. Each preauthorization request shall be accompanied by a proposed medical treatment plan (for inpatient stays under the Basic Program) which shall include generally a diagnosis; a detailed summary of complete history and physical; a detailed statement of the problem; the proposed treatment modality, including anticipated length of time the proposed modality will be required; any available test results; consultant's reports; and the prognosis. When the preauthorization request involves transfer from a hospital to another inpatient facility, medical records related to the inpatient stay also must be provided.

(3) Claims for services and supplies that have been preauthorized. Whenever a claim is submitted for benefits under CHAMPUS involving preauthorized services and supplies, the date of the approved preauthorization must be indicated on the claim form and a copy of the written preauthorization must be attached to the appropriate CHAMPUS claim.

(4) Advance payment prohibited. No CHAMPUS payment shall be made for otherwise authorized services or items not yet rendered or delivered to the beneficiary.

**(g) Claims review.** It is the responsibility of the CHAMPUS fiscal intermediary (or OCHAMPUS, including OCHAMPUSEUR) to review each CHAMPUS claim submitted for benefit consideration to ensure compliance with all applicable definitions, conditions, limitations, or exclusions specified or enumerated in this part. It is also required that before any CHAMPUS benefits may be extended, claims for medical services and supplies will be subject to utilization review and quality assurance standards, norms, and criteria issued by the Director, OCHAMPUS, or a designee (see paragraph (a)(1)(v) of Sec. 199.14 for review standards for claims subject to the CHAMPUS DRG-based payment system).

**(h) Benefit payments.** CHAMPUS benefit payments are made either directly to the beneficiary or sponsor or to the provider, depending on the manner in which the CHAMPUS claim is submitted.

(1) Benefit payments made to beneficiary or sponsor. When the CHAMPUS beneficiary or sponsor signs and submits a specific claim form directly to the appropriate CHAMPUS fiscal intermediary (or OCHAMPUS, including OCHAMPUSEUR), any CHAMPUS benefit payments due as a result of that specific claim submission will be made in the name of, and mailed to, the beneficiary or sponsor. In such circumstances, the beneficiary or sponsor is responsible to the provider for any amounts billed.

(2) Benefit payments made to participating provider. When the authorized provider elects to participate by signing a CHAMPUS claim form, indicating participation in the appropriate space on the claim form, and submitting a specific claim on behalf of the beneficiary to the appropriate CHAMPUS fiscal intermediary, any CHAMPUS benefit payments due as a result of that claim submission will be made in the name of and mailed to the participating provider. Thus, by signing the claim form, the authorized provider agrees to abide by the CHAMPUS-determined allowable charge or cost, whether or not lower than the amount billed. Therefore, the beneficiary or sponsor is responsible only for any required deductible amount and any cost-sharing portion of the CHAMPUS-determined allowable charge or cost as may be required under the terms and conditions set forth in Secs. 199.4 and 199.5 of this part.

(3) CEOB.(i) When a CHAMPUS claim is adjudicated, a CEOB is sent to the beneficiary or sponsor. A copy of the CEOB also is sent to the provider if the claim was submitted on a

participating basis. The CEOB form provides, at a minimum, the following information: (i) Name and address of beneficiary.

- (ii) Name and address of provider.
- (iii) Services or supplies covered by claim for which CEOB applies.
- (iv) Dates services or supplies provided.
- (v) Amount billed; CHAMPUS-determined allowable charge or cost; and amount of CHAMPUS payment.
- (vi) To whom payment, if any, was made.
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- (viii) Recourse available to beneficiary for review of claim decision (refer to Sec. 199.10 of this part).

NOTE: The Director, OCHAMPUS, or a designee, may authorize a CHAMPUS fiscal intermediary to waive a CEOB to protect the privacy of a CHAMPUS beneficiary.

(4) Benefit under \$1. If the CHAMPUS benefit is determined to be under \$1, payment is waived.

**(i) Extension of the Active Duty Dependents Dental Plan to areas outside the United States.** The Assistant Secretary of Defense (Health Affairs) (ASD(HA)) may, under the authority of 10 U.S.C. 1076a(h), extend the Active Duty Dependents Dental Plan to areas other than those areas specified in paragraph (a)(2)(i) of this section for the eligible beneficiaries of members of the Uniformed Services. In extending the program outside the Continental United States, the ASD(HA), or designee, is authorized to establish program elements, methods of administration and payment rates and procedures to providers that are different from those in effect under this section in the Continental United States to the extent the ASD(HA), or designee, determines necessary for the effective and efficient operation of the plan outside the Continental United States. This includes provisions for preauthorization of care if the needed services are not available in a Uniformed Service overseas dental treatment facility and payment by the Department of certain cost-shares and other portions of a provider's billed charges. Other differences may occur based on limitations in the availability and capabilities of the Uniformed Services overseas dental treatment facility and a particular nation's civilian sector providers in certain areas. Otherwise, rules pertaining to services covered under the plan and quality of care standards for providers shall be comparable to those in effect under this section in the Continental United States and available military guidelines. In addition, all provisions of 10 U.S.C. 1076a shall remain in effect.

**(j) General assignment of benefits not recognized.** CHAMPUS does not recognize any general assignment of CHAMPUS benefits to another person. All CHAMPUS benefits are payable as described in this and other Sections of this part.

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[51 FR 24008, Jul 1, 1986, as amended at 52 FR 33007, Sep 1, 1987; 53 FR 5373, Feb 24, 1988; 54 FR 25246, Jun 14, 1989; 56 FR 28487, Jun 21, 1991; 56 FR 59878, Nov 26, 1991; 58 FR 35408, Jul 1, 1993; 58 FR 51238, Oct 1, 1993; 58 FR 58961, Nov 5, 1993; 62 FR 35097, Jun 30, 1997; 63 FR 48446, Sep 10, 1998; 64 FR 38576, Jul 19, 1999; 67 FR 42721, Jun 25, 2002; 68 FR 44881, Jul 31, 2003; 69 FR 44952, Jul 28, 2004; 69 FR 51569, Aug 20, 2004; 70 FR 19265, Apr 13, 2005; 79 FR 41642, Jul 17, 2014; **81 FR 61097, Sep 2, 2016**]

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(D) Annual cost pass-through for direct medical education. In addition to payments made to lower volume hospitals under paragraph (a)(2)(iii) of this section, CHAMPUS shall annually reimburse hospitals for actual direct medical education costs associated with services to CHAMPUS beneficiaries. This reimbursement shall be done pursuant to the same procedures as are applicable to the CHAMPUS DRG-based payment system (see paragraph (a)(1)(iii)(G) of this section).

(iv) Base period and update factors. (A) Base period. The base period for calculating the hospital-specific and regional per diems, as described in paragraphs (a)(2)(ii) and (a)(2)(iii) of this section, is Federal fiscal year 1988. Base period calculations shall be based on actual claims paid during the period July 1, 1987 through May 31, 1988, trended forward to represent the 12-month period ending September 30, 1988 on the basis of the Medicare inpatient hospital market basket rate.

(B) Alternative hospital-specific data base. Upon application of a higher volume hospital or unit to the Director, OCHAMPUS, or a designee, the hospital or unit may have its hospital-specific base period calculations based on claims with a date of discharge (rather than date of payment) between July 1, 1987 through May 31, 1988 if it has generally experienced unusual delays in claims payments and if the use of such an alternative data base would result in a difference in the per diem amount of at least \$5.00. For this purpose, the unusual delays means that the hospital's or unit's average time period between date of discharge and date of payment is more than two standard deviations longer than the national average.

(C) Update factors--(1) The hospital-specific per diems and the regional per diems calculated for the base period pursuant to paragraphs (a)(2)(ii) of this section shall remain in effect for federal fiscal year 1989; there will be no additional update for fiscal year 1989.

(2) Except as provided in paragraph (a)(2)(iv)(C)(3) of this section, for subsequent federal fiscal years, each per diem shall be updated by the Medicare Inpatient Prospective Payment System update factor.

(3) As an exception to the update required by paragraph (a)(2)(iv)(C)(2) of this section, all per diems in effect at the end of fiscal year 1995 shall remain in effect, with no additional update, throughout fiscal years 1996 and 1997. For fiscal year 1998 and thereafter, the per diems in effect at the end of fiscal year 1997 will be updated in accordance with paragraph (a)(2)(iv)(C)(2).

(4) Hospitals and units with hospital-specific rates will be notified of their respective rates prior to the beginning of each Federal fiscal year. New hospitals shall be notified at such time as the hospital rate is determined. The actual amount of each regional per diem that will apply in any Federal fiscal year shall be posted to the Agency's official Web site at the start of that fiscal year.

(v) Higher volume hospitals. This paragraph describes the classification of and other provisions pertinent to hospitals with a higher volume of CHAMPUS patients.

(A) In general. Any hospital or unit that had an annual rate of 25 or more CHAMPUS discharges of CHAMPUS patients during the period July 1, 1987 through May 31, 1988 shall be considered a higher volume hospital has 25 or more CHAMPUS discharges, that hospital

shall be considered to be a higher volume hospital during Federal fiscal year 1989 and all subsequent fiscal years. All other hospitals and units covered by the CHAMPUS mental health per diem payment system shall be considered lower volume hospitals.

(B) Hospitals that subsequently become higher volume hospitals. In any Federal fiscal year in which a hospital, including a new hospital (see paragraph (a)(2)(v)(C) of this section), not previously classified as a higher volume hospital has 25 or more CHAMPUS discharges, that hospital shall be considered to be a higher volume hospital during the next Federal fiscal year and all subsequent fiscal years. The hospital specific per diem amount shall be calculated in accordance with the provisions of paragraph (a)(2)(ii) of this section, except that the base period average daily charge shall be deemed to be the hospital's average daily charge in the year in which the hospital had 25 or more discharges, adjusted by the percentage change in average daily charges for all higher volume hospitals and units between the year in which the hospital had 25 or more CHAMPUS discharges and the base period. The base period amount, however, may not exceed the cap described in paragraph (a)(2)(ii)(B) of this section.

(C) Special retrospective payment provision for new hospitals. For purposes of this paragraph, a new hospital is a hospital that qualifies for the Medicare exemption from the rate of increase ceiling applicable to new hospitals which are PPS-exempt psychiatric hospitals. Any new hospital that becomes a higher volume hospital, in addition to qualifying prospectively as a higher volume hospital for purposes of paragraph (a)(2)(v)(B) of this section, may additionally, upon application to the Director, OCHAMPUS, receive a retrospective adjustment. The retrospective adjustment shall be calculated so that the hospital receives the same government share payments it would have received had it been designated a higher volume hospital for the federal fiscal year in which it first had 25 or more CHAMPUS discharges and the preceding fiscal year (if it had any CHAMPUS patients during the preceding fiscal year). Such new hospitals must agree not to bill CHAMPUS beneficiaries for any additional costs beyond that determined initially.

(D) Review of classification. Any hospital or unit which OCHAMPUS erroneously fails to classify as a higher volume hospital may apply to the Director, OCHAMPUS, or a designee, for such a classification. The hospital shall have the burden of proof.

(vi) Payment for hospital based professional services. Lower volume hospitals and units may not bill separately for hospital based professional mental health services; payment for those services is included in the per diems. Higher volume hospitals and units, whether they billed CHAMPUS separately for hospital based professional mental health services or included those services in the hospital's billing to CHAMPUS, shall continue the practice in effect during the period July 1, 1987 to May 31, 1988 (or other data base period used for calculating the hospital's or unit's per diem), except that any such hospital or unit may change its prior practice (and obtain an appropriate revision in its per diem) by providing to OCHAMPUS notice in accordance with procedures established by the Director, OCHAMPUS, or a designee.

(vii) Leave days. CHAMPUS shall not pay for days where the patient is absent on leave from the specialty psychiatric hospital or unit. The hospital must identify these days when claiming reimbursement. CHAMPUS shall not count a patient's leave of absence as a discharge in determining whether a facility should be classified as a higher volume hospital pursuant to paragraph (a)(2)(v) of this section.

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(viii) Exemptions from the CHAMPUS mental health per diem payment system. The following providers and procedures are exempt from the CHAMPUS mental health per diem payment system.

(A) Non-specialty providers. Providers of inpatient care which are not either psychiatric hospitals or psychiatric specialty units as described in paragraph (a)(2)(i)(A) of this section are exempt from the CHAMPUS mental health per diem payment system. Such providers should refer to paragraph (a)(1) of this section for provisions pertinent to the CHAMPUS DRG-based payment system.

(B) DRG 424. Admissions for operating room procedures involving a principal diagnosis of mental illness (services which group into DRG 424) are exempt from the per diem payment system. They will be reimbursed pursuant to the provisions of paragraph (a)(3) of this section.

(C) Non-mental health services. Admissions for non-mental health procedures in specialty psychiatric hospitals and units are exempt from the per diem payment system. They will be reimbursed pursuant to the provisions of paragraph (a)(3) of this section.

(D) Sole community hospitals (SCHs). Prior to implementation of the SCH reimbursement method described in paragraph (a)(7) of this section, any hospital that has qualified for special treatment under the Medicare prospective payment system as an SCH and has not given up that classification is exempt.

(E) Hospitals outside the U.S. A hospital is exempt if it is not located in one of the 50 states, the District of Columbia or Puerto Rico.

(ix) Payment for psychiatric and substance use disorder rehabilitation partial hospitalization services, intensive outpatient psychiatric and substance use disorder services and opioid treatment services--(A) Per diem payments. Psychiatric and substance use disorder partial hospitalization services, intensive outpatient psychiatric and substance use disorder services and opioid treatment services authorized by Sec. 199.4(b)(9), (b)(10), and (b)(11), respectively, and provided by institutional providers authorized under Sec. 199.6(b)(4)(xii), (b)(4)(xviii) and (b)(4)(xix), respectively, are reimbursed on the basis of prospectively determined, all-inclusive per diem rates pursuant to the provisions of paragraphs (a)(2)(ix)(A)(1) through (3) of this section, with the exception of hospital-based psychiatric and substance use disorder and opioid services which are reimbursed in accordance with provisions of paragraph (a)(6)(ii) of this section and freestanding opioid treatment programs when reimbursed on a fee-for-service basis as specified in paragraph (a)(2)(ix)(A)(3)(ii) of this section. The per diem payment amount must be accepted as payment in full, subject to the outpatient cost-sharing provisions under Sec. 199.4(f), for institutional services provided, including board, routine nursing services, group therapy, ancillary services (e.g., music, dance, and occupational and other such therapies), psychological testing and assessment, overhead and any other services for which the customary practice among similar providers is included in the institutional charges, except for those services which may be billed separately under paragraph (a)(2)(ix)(B) of this section. Per diem payment will not be allowed for leave days during which treatment is not provided.

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(1) Partial hospitalization programs. For any full-day partial hospitalization program (minimum of 6 hours), the maximum per diem payment amount is 40 percent of the average inpatient per diem amount per case established under the TRICARE mental health per diem reimbursement system during the fiscal year for both high and low volume psychiatric hospitals and units [as defined in paragraph (a)(2) of this section]. Intensive outpatient services provided in a PHP setting lasting less than 6 hours, with a minimum of 2 hours, will be paid as provided in paragraph (a)(2)(ix)(A)(2) of this section. PHP per diem rates will be updated annually by the Medicare update factor used for their Inpatient Prospective Payment System.

(2) Intensive outpatient programs. For intensive outpatient programs (IOPs) (minimum of 2 hours), the maximum per diem amount is 75 percent of the rate for a full-day partial hospitalization program as established in paragraph (a)(2)(ix)(A)(1) of this section. IOP per diem rates will be updated annually by the Medicare update factor used for their Inpatient Prospective Payment System.

(3) Opioid treatment programs. Opioid treatment programs (OTPs) authorized by Sec. 199.4(b)(11) and provided by providers authorized under Sec. 199.6(b)(4)(xix) will be reimbursed based on the variability in the dosage and frequency of the drug being administered and in related supportive services.

(i) Weekly all-inclusive per diem rate. Methadone OTPs will be reimbursed the lower of the billed charge or the weekly all-inclusive per diem rate (the weekly national all-inclusive rate adjusted for locality), including the cost of the drug and related services (i.e., the costs related to the initial intake/assessment, drug dispensing and screening and integrated psychosocial and medical treatment and support services). The bundled weekly per diem payments will be accepted as payment in full, subject to the outpatient cost-sharing provisions under Sec. 199.4(f). The methadone per diem rate for OTPs will be updated annually by the Medicare update factor used for their Inpatient Prospective Payment System.

(ii) Exceptions to per diem reimbursement. When providing other medications which are more likely to be prescribed and administered in an office-based opioid treatment setting, but which are still available for treatment of substance use disorders in an outpatient treatment program setting, OTPs will be reimbursed on a fee-for-service basis (i.e., separate payments will be allowed for both the medication and accompanying support services), subject to the outpatient cost-sharing provisions under Sec. 199.4(f). OTPs' rates will be updated annually by the Medicare update factor used for their Inpatient Prospective Payment System.

(iii) Discretionary authority. The Director, TRICARE, will have discretionary authority in establishing the reimbursement methodologies for new drugs and biologicals that may become available for the treatment of substance use disorders in OTPs. The type of reimbursement (e.g., fee-for-service versus bundled per diem payments) will be dependent on the variability of the dosage and frequency of the medication being administered, as well as the support services.

(B) Services which may be billed separately. Psychotherapy sessions and non-mental health related medical services not normally included in the evaluation and assessment of PHP, IOP or OTPs, provided by authorized independent professional providers who are not employed by, or under contract with, PHP, IOP or OTPs for the purposes of providing clinical

patient care are not included in the per diem rate and may be billed separately. This includes ambulance services when medically necessary for emergency transport.

(3) Reimbursement for inpatient services provided by a CAH. (i) For admissions on or after December 1, 2009, inpatient services provided by a CAH, other than services provided in psychiatric and rehabilitation distinct part units, shall be reimbursed at allowable cost (i.e., 101 percent of reasonable cost) under procedures, guidelines and instructions issued by the TMA Director, or designee. This does not include any costs of physician services or other professional services provided to CAH inpatients. Inpatient services provided in psychiatric distinct part units would be subject to the CHAMPUS mental health payment system. Inpatient services provided in rehabilitation distinct part units would be subject to billed charges.

(ii) The percentage amount stated in paragraph (a)(3)(i) of this section is subject to possible upward adjustment based on a inpatient GTMCPA for TRICARE network hospitals deemed essential for military readiness and support during contingency operations under paragraph (a)(8) of this section.

(4) Billed charges and set rates. The allowable costs for authorized care in all hospitals not subject to the CHAMPUS DRG-based payment system, the CHAMPUS mental health per-diem system, the reasonable cost method for CAHs, or the reimbursement rules for SCHs shall be determined on the basis of billed charges or set rates.

(i) The actual charge for such service made to the general public; or

(ii) The allowed charge applicable to the policyholders or subscribers of the CHAMPUS fiscal intermediary for comparable services under comparable circumstances, when extended to CHAMPUS beneficiaries by consent or agreement; or

(iii) The allowed charge applicable to the citizens of the community or state as established by local or state regulatory authority, excluding title XIX of the Social Security Act or other welfare program, when extended to CHAMPUS beneficiaries by consent or agreement.

(5) CHAMPUS discount rates. The CHAMPUS-determined allowable cost for authorized care in any hospital may be based on discount rates established under paragraph (l) of this section.

(6) Hospital outpatient services. This paragraph (a)(6) identifies and clarifies payment methods for certain outpatient services, including emergency services, provided by hospitals.

(i) Outpatient Services Not Subject to Hospital Outpatient Prospective Payment System (OPPS). The following are payment methods for outpatient services that are either provided in an OPPS exempt hospital or paid outside the OPPS payment methodology under existing fee schedules or other prospectively determined rates in a hospital subject to OPPS reimbursement.

(A) Laboratory services. TRICARE payments for hospital outpatient laboratory services including clinical laboratory services are based on the allowable charge method under paragraph (j)(1) of the section. In the case of laboratory services for which the CMAC rates

are established under that paragraph, a payment rate for the technical component of the laboratory services is provided. Hospital charges for an outpatient laboratory service are reimbursed using the CMAC technical component rate.

(B) Rehabilitation therapy services. Rehabilitation therapy services provided on an outpatient basis by hospitals are paid on the same basis as rehabilitation therapy services covered by the allowable charge method under paragraph (j)(1) of this section.

(C) Venipuncture. Routine venipuncture services provided on an outpatient basis by hospitals are paid on the same basis as such services covered by the allowable charge method under paragraph (j)(1) of this section. Routine venipuncture services provided on an outpatient basis by institutional providers other than hospitals are also paid on this basis.

(D) Radiology services. TRICARE payments for hospital outpatient radiology services are based on the allowable charge method under paragraph (j)(1) of the section. In the case of radiology services for which the CMAC rates are established under that paragraph, a payment rate for the technical component of the radiology services is provided. Hospital charges for an outpatient radiology service are reimbursed using the CMAC technical component rate.

(E) Diagnostic services. TRICARE payments for hospital outpatient diagnostic services are based on the allowable charge method under paragraph (j)(1) of the section. In the case of diagnostic services for which the CMAC rates are established under that paragraph, a payment rate for the technical component of the diagnostic services is provided. Hospital charges for an outpatient diagnostic service are reimbursed using the CMAC technical component rate.

(F) Ambulance services. Ambulance services provided on an outpatient basis by hospitals are paid on the same basis as ambulance services covered by the allowable charge method under paragraph (j)(1) of this section.

(G) Durable medical equipment (DME) and supplies. Durable medical equipment and supplies provided on an outpatient basis by hospitals are paid on the same basis as durable medical equipment and supplies covered by the allowable charge method under paragraph (j)(1) of this section.

(H) Oxygen and related supplies. Oxygen and related supplies provided on an outpatient basis by hospitals are paid on the same basis as oxygen and related supplies covered by the allowable charge method under paragraph (j)(1) of this section.

(I) Drugs administered other than oral method. Drugs administered other than oral method provided on an outpatient basis by hospitals are paid on the same basis as drugs administered other than oral method covered by the allowable charge method under paragraph (j)(1) of this section. The allowable charge for drugs administered other than oral method is established from a schedule of allowable charges based on a formulary of the average wholesale price.

(J) Professional provider services. TRICARE payments for hospital outpatient professional provider services rendered in an emergency room, clinic, or hospital outpatient department, etc., are based on the allowable charge method under paragraph (j)(1) of the

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section. In the case of professional services for which the CMAC rates are established under that paragraph, a payment rate for the professional component of the services is provided. Hospital charges for an outpatient professional service are reimbursed using the CMAC professional component rate. If the professional outpatient hospital services are billed by a professional provider group, not by the hospital, no payment shall be made to the hospital for these services.

(K) Facility charges. TRICARE payments for hospital outpatient facility charges that would include the overhead costs of providing the outpatient service would be paid as billed. For the definition of facility charge, see Sec. 199.2(b).

(L) Ambulatory surgery services. Hospital outpatient ambulatory surgery services shall be paid in accordance with Sec. 199.14(d).

(ii) Outpatient Services Subject to OPSS. Outpatient services provided in hospitals subject to Medicare OPSS as specified in 42 CFR 413.65 and 42 CFR Sec. 419.20 will be paid in accordance with the provisions outlined in sections 1833(t) of the Social Security Act and its implementing Medicare regulation (42 CFR Part 419) subject to exceptions as authorized by Sec. 199.14(a)(5)(ii). Under the above governing provisions, CHAMPUS will recognize to the extent practicable, in accordance with 10 U.S.C. 1079(j)(2), Medicare's OPSS reimbursement methodology to include specific coding requirements, ambulatory payment classifications (APCs), nationally established APC amounts and associated adjustments (e.g., discounting for multiple surgery procedures, wage adjustments for variations in labor-related costs across geographical regions and outlier calculations). While CHAMPUS intends to remain as true as possible to Medicare's basic OPSS methodology, there will be some deviations required to accommodate CHAMPUS' unique benefit structure and beneficiary population as authorized under the provisions of 10 U.S.C. 1079(j)(2). Temporary transitional payment adjustments (TTPAs) will be in place for all hospitals, both network and non-network in order to buffer the initial decline in payments upon implementation of TRICARE's OPSS. For network hospitals, the temporary transitional payment adjustments (TTPAs) will cover a four-year period. The four-year transition will set higher payment percentages for the ten Ambulatory Payment Classification (APC) codes 604-609 and 613-616, with reductions in each of the transition years. For non-network hospitals, the adjustments will cover a three year period, with reductions in each of the transition years. For network hospitals, under the TTPAs, the APC payment level for the five clinic visit APCs would be set at 175 percent of the Medicare APC level, while the five ER visit APCs would be increased by 200 percent in the first year of OPSS implementation. In the second year, the APC payment levels would be set at 150 percent of the Medicare APC level for clinic visits and 175 percent for ER APCs. In the third year, the APC visit amounts would be set at 130 percent of the Medicare APC level for clinic visits and 150 percent for ER APCs. In the fourth year, the APC visit amounts would be set at 115 percent of the Medicare APC level for clinic visits and 130 per cent for ER APCs. In the fifth year, the TRICARE and Medicare payment levels for the 10 APC visit codes would be identical.

For non-network hospitals, under the TTPAs, the APC payment level for the five clinic and ER visit APCs would be set at 140 percent of the Medicare APC level in the first year of OPSS implementation. In the second year, the APC payment levels would be set at 125 percent of the Medicare APC level for clinic and ER visits. In the third year, the APC visit amounts would be set at 110 percent of the Medicare APC level for clinic and ER visits. In the fourth

year, the TRICARE and Medicare payment levels for the 10 APC visit codes would be identical.

An additional temporary military contingency payment adjustment (TMCPA) will also be available at the discretion of the Director, TMA, or a designee, at any time after implementation to adopt, modify and/or extend temporary adjustments to OPSS payments for TRICARE network hospitals deemed essential for military readiness and deployment in time of contingency operations. Any TMCPAs to OPSS payments shall be made only on the basis of a determination that it is impracticable to support military readiness or contingency operations by making OPSS payments in accordance with the same reimbursement rules implemented by Medicare. The criteria for adopting, modifying, and/or extending deviations and/or adjustments to OPSS payments shall be issued through CHAMPUS policies, instructions, procedures and guidelines as deemed appropriate by the Director, TMA, or a designee. TMCPAs may also be extended to non-network hospitals on a case-by-case basis for specific procedures where it is determined that the procedures cannot be obtained timely enough from a network hospital. For such case-by-case extensions, "Temporary" might be less than three years at the discretion of the TMA Director, or designee.

(iii) Outpatient Services Subject to CAH Reasonable Cost Method. For services on or after December 1, 2009, outpatient services provided by a CAH, shall be reimbursed at 101 percent of reasonable cost. This does not include any costs of physician services or other professional services provided to CAH outpatients.

(iv) CAH Ambulance Services. Effective for services provided on or after December 1, 2009, payment for ambulance services furnished by a CAH or an entity that is owned and operated by a CAH is the reasonable costs of the CAH or the entity in furnishing those services, but only if the CAH or the entity is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH or the entity as specified under 42 CFR part 413.70(b)(5)(ii).

(7) Reimbursement for inpatient services provided by an SCH. (i) In accordance with 10 U.S.C. 1079(j)(2), TRICARE payment methods for institutional care shall be determined, to the extent practicable, in accordance with the same reimbursement rules as those that apply to payments to providers of services of the same type under Medicare. TRICARE's SCH reimbursements approximate Medicare's for SCHs. Inpatient services provided by an SCH, other than services provided in psychiatric and rehabilitation distinct part units, shall be reimbursed through a two-step process.

(ii) The first step referred to in paragraph (a)(7)(i) of this section will be to calculate the TRICARE allowable cost by multiplying the applicable TRICARE percentage by the billed charge amount on each institutional inpatient claim. The applicable TRICARE percentage is the greater of: the SCH's most recently available cost-to-charge ratio (CCR) from the Centers for Medicare and Medicaid Services' (CMS') inpatient Provider Specific File (after the ratio has been converted to a percentage), or the TRICARE allowed-to-billed ratio, defined as the ratio of the TRICARE allowed amounts (including discounts) to the amount of billed charges for TRICARE inpatient admissions at the SCH in FY 2012 (after it has been converted to a percentage). The TRICARE allowed-to-billed ratio in FY 2012 shall be reduced as follows (after the ratio has been converted to a percentage):

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- (A) In the first year of implementation, 10 percentage points for network SCHs and 15 percentage points for non-network SCHs.
- (B) In the second year of implementation, 20 percentage points for network SCHs and 30 percentage points for non-network SCHs.
- (C) In the third year of implementation, 30 percentage points for network SCHs and 45 percentage points for non-network SCHs.
- (D) In the fourth year of implementation, 40 percentage points for network SCHs and 60 percentage points for non-network SCHs.
- (E) In the fifth year of implementation, 50 percentage points for network SCHs and 75 percentage points for non-network SCHs.
- (F) In the sixth year of implementation, 60 percentage points for network SCHs and 90 percentage points for non-network SCHs.
- (G) In the seventh year of implementation, 70 percentage points for network SCHs and 100 percentage points for non-network SCHs.
- (H) In the eighth year of implementation, 80 percentage points for network SCHs and 100 percentage points for non-network SCHs.
- (I) In the ninth year of implementation, 90 percentage points for network SCHs and 100 percentage points for non-network SCHs.
- (J) In the tenth year of implementation, 100 percentage points for network SCHs and 100 percentage points for non-network SCHs.
- (iii) The second step referred to in paragraph (a)(7)(i) of this section is a year-end adjustment. The year-end adjustment will compare the aggregate allowable costs over a 12-month period under paragraph (a)(7)(ii) of this section to the aggregate amount that would have been allowed for the same care using the TRICARE DRG-method (under paragraph (a)(1) of this section). In the event that the DRG method amount is the greater, the year-end adjustment will be the amount by which it exceeds the aggregate allowable costs. In addition, the year-end adjustment also may incorporate a possible upward adjustment for inpatient services based on a GTMCPA for TRICARE network hospitals under paragraph (a)(8) of this section.
- (iv) At the end of an SCH's transition period, when the SCH reaches its Medicare CCR, a special allowable cost shall be applicable for discharges that group to inpatient nursery and labor/delivery DRGs. For these discharges, instead of using the percentage of the SCH's Medicare cost-to-charge ratio (as described in paragraph (a)(7)(ii) of this section), the percentage will be 130 percent of the Medicare CCR.
- (v) The SCH reimbursement provisions of paragraphs (a)(7)(i) through (iv) of this section do not apply to any costs of physician services or other professional services provided to SCH inpatients (which are subject to individual provider payment provisions of this section), inpatient services provided in psychiatric distinct part units (which are subject to the

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CHAMPUS mental health per-diem payment system), or inpatient services provided in rehabilitation distinct part units (which are reimbursed on the basis of billed charges or set rates).

(vi) The SCH payment system under this paragraph (a)(7) applies to hospitals classified by CMS as Essential Access Community Hospitals (EACHs).

(vii) The SCH payment system under this paragraph (a)(7) does not apply to hospitals in States that are paid by Medicare and TRICARE under a cost containment waiver.

(8) General temporary military contingency payment adjustment for SCHs and CAHs. (i) Payments under paragraph (a) of this section for inpatient services provided by SCHs and CAHs may be supplemented by a GTMCPA. This is a year-end discretionary, temporary adjustment that the TMA Director may approve based on all the following criteria:

(A) The hospital serves a disproportionate share of ADSMs and ADDs;

(B) The hospital is a TRICARE network hospital;

(C) The hospital's actual costs for inpatient services exceed TRICARE payments or other extraordinary economic circumstance exists; and,

(D) Without the GTMCPA, DoD's ability to meet military contingency mission requirements will be significantly compromised.

(ii) Policy and procedural instructions implementing the GTMCPA will be issued as deemed appropriate by the Director, TMA, or a designee. As with other discretionary authority under this Part, a decision to allow or deny a GTMCPA to a hospital is not subject to the appeal and hearing procedures of § 199.10.

**(b) Skilled nursing facilities (SNFs).** (1) Use of Medicare prospective payment system and rates. TRICARE payments to SNFs are determined using the same methods and rates used under the Medicare prospective payment system for SNFs under 42 CFR part 413, subpart J, except for children under age ten. SNFs receive a per diem payment of a predetermined Federal payment rate appropriate for the case based on patient classification (using the RUG classification system), urban or rural location of the facility, and area wage index.

(2) Payment in full. The SNF payment rates represent payment in full (subject to any applicable beneficiary cost shares) for all costs (routine, ancillary, and capital-related) associated with furnishing inpatient SNF services to TRICARE beneficiaries other than costs associated with operating approved educational activities.

(3) Education costs. Costs for approved educational activities shall be subject to separate payment under procedures established by the Director, TRICARE Management Activity. Such procedures shall be similar to procedures for payments for direct medical education costs of hospitals under paragraph (a)(1)(iii)(G)(2) of this section.

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(4) Resident assessment data. SNFs are required to submit the same resident assessment data as is required under the Medicare program. (The residential assessment is addressed in the Medicare regulations at 42 CFR 483.20.) SNFs must submit assessments according to an assessment schedule. This schedule must include performance of patient assessments on the 5th, 14th, and 30th days of SNF care and at each successive 30 day interval of SNF admissions that are longer than 30 days. It must also include such other assessments that are necessary to account for changes in patient care needs. TRICARE pays a default rate for the days of a patient's care for which the SNF has failed to comply with the assessment schedule.

**(c) Reimbursement for Other Than Hospitals and SNFs.** The Director, OCHAMPUS, or a designee, shall establish such other methods of determining allowable cost or charge reimbursement for those institutions, other than hospitals and SNFs, as may be required.

**(d) Payment of institutional facility costs for ambulatory surgery.** (1) In general. CHAMPUS pays institutional facility costs for ambulatory surgery on the basis of prospectively determined amounts, as provided in this paragraph, with the exception of ambulatory surgery procedures performed in hospital outpatient departments or in CAHs, which are to be reimbursed in accordance with the provisions of paragraph (a)(6)(ii) or (a)(6)(iii) respectively, of this section.

(2) Payment in full. The payment provided for under this paragraph is the payment in full for services covered by this paragraph. Facilities may not charge beneficiaries for amounts, if any, in excess of the payment amounts determined pursuant to this paragraph.

(3) Calculation of standard payment rates. Standard payment rates are calculated for groups of procedures under the following steps:

(i) Step 1: Calculate a median standardized cost for each procedure. For each ambulatory surgery procedure, a median standardized cost will be calculated on the basis of all ambulatory surgery charges nationally under CHAMPUS during a recent one-year base period. The steps in this calculation include standardizing for local labor costs by reference to the same wage index and labor/non-labor-related cost ratio as applies to the facility under Medicare, applying a cost-to-charge ratio, calculating a median cost for each procedure, and updating to the year for which the payment rates will be in effect by the Consumer Price Index-Urban. In applying a cost-to-charge ratio, the Medicare cost-to-charge ratio for freestanding ambulatory surgery centers (FASCs) will be used for all charges from FASCs, and the Medicare cost-to-charge ratio for hospital outpatient settings will be used for all charges from hospitals.

(ii) Step 2: Grouping procedures. Procedures will then be placed into one of ten groups by their median per procedure cost, starting with \$0 to \$299 for group 1 and ending with \$1000 to \$1299 for group 9 and \$1300 and above for group 10, with groups 2 through 8 set on the basis of \$100 fixed intervals.

(iii) Step 3: Adjustments to groups. The Director, OCHAMPUS may make adjustments to the groupings resulting from step 2 to account for any ambulatory surgery procedures for which there were insufficient data to allow a grouping or to correct for any anomalies resulting from data or statistical factors or other special factors that fairness requires be specially recognized. In making any such adjustments, the Director may take into

consideration the placing of particular procedures in the ambulatory surgery groups under Medicare.

(iv) Step 4: Standard payment amount per group. The standard payment amount per group will be the volume weighted median per procedure cost for the procedures in that group. For cases in which the standard payment amount per group exceeds the CHAMPUS-determined inpatient allowable amount, the Director, TSO or his designee, may make adjustments.

(v) Step 5: Actual payments. Actual payment for a procedure will be the standard payment amount for the group which covers that procedure, adjusted for local labor costs by reference to the same labor/non-labor-related cost ratio and hospital wage index as used for ambulatory surgery centers by Medicare.

(4) Multiple procedures. In cases in which authorized multiple procedures are performed during the same operative session, payment shall be based on 100 percent of the payment amount for the procedure with the highest ambulatory surgery payment amount, plus, for each other procedure performed during the session, 50 percent of its payment amount.

(5) Annual updates. The standard payment amounts will be updated annually by the same update factor as is used in the Medicare annual updates for ambulatory surgery center payments.

(6) Recalculation of rates. The Director, OCHAMPUS may periodically recalculate standard payment rates for ambulatory surgery using the steps set forth in paragraph (d)(3) of this section.

**(e) Reimbursement of Birthing Centers.** (1) Reimbursement for maternity care and childbirth services furnished by an authorized birthing center shall be limited to the lower of the CHAMPUS established all-inclusive rate or the center's most-favored all-inclusive rate. The all-inclusive rate shall include the following to the extent that they are usually associated with a normal pregnancy and childbirth: Laboratory studies, prenatal management, labor management, delivery, post-partum management, newborn care, birth assistant, certified nurse-midwife professional services, physician professional services, and the use of the facility.

(2) The CHAMPUS established all-inclusive rate is equal to the sum of the CHAMPUS area prevailing professional charge for total obstetrical care for a normal pregnancy and delivery and the sum of the average CHAMPUS allowable institutional charges for supplies, laboratory, and delivery room for a hospital inpatient normal delivery. The CHAMPUS established all-inclusive rate areas will coincide with those established for prevailing professional charges and will be updated concurrently with the CHAMPUS area prevailing professional charge database.

(3) Extraordinary maternity care services, when otherwise authorized, may be reimbursed at the lesser of the billed charge or the CHAMPUS allowable charge.

(4) Reimbursement for an incomplete course of care will be limited to claims for professional services and tests where the beneficiary has been screened but rejected for

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admission into the birthing center program, or where the woman has been admitted but is discharged from the birthing center program prior to delivery, adjudicated as individual professional services and items.

(5) The beneficiary's share of the total reimbursement to a birthing center is limited to the cost-share amount plus the amount billed for non-covered services and supplies.

**(f) Reimbursement of Residential Treatment Centers.** The CHAMPUS rate is the per diem rate that CHAMPUS will authorize for all mental health services rendered to a patient and the patient's family as part of the total treatment plan submitted by a CHAMPUS-approved RTC, and approved by the Director, OCHAMPUS, or designee.

(1) The all-inclusive per diem rate for RTCs operating or participating in CHAMPUS during the base period of July 1, 1987, through June 30, 1988, will be the lowest of the following conditions:

(i) The CHAMPUS rate paid to the RTC for all-inclusive services as of June 30, 1988, adjusted by the Consumer Price Index--Urban (CPI-U) for medical care as determined applicable by the Director, OCHAMPUS, or designee; or

(ii) The per diem rate accepted by the RTC from any other agency or organization (public or private) that is high enough to cover one-third of the total patient days during the 12-month period ending June 30, 1988, adjusted by the CPI-U; or

NOTE: The per diem rate accepted by the RTC from any other agency or organization includes the rates accepted from entities such as Government contractors in CHAMPUS demonstration projects.

(iii) An OCHAMPUS determined capped per diem amount not to exceed the 80th percentile of all established CHAMPUS RTC rates nationally, weighted by total CHAMPUS days provided at each rate during the base period discussed in paragraph (f)(1) of this section.

(2) The all-inclusive per diem rates for RTCs which began operation after June 30, 1988, or began operation before July 1, 1988, but had less than 6 months of operation by June 30, 1988, will be calculated based on the lower of the per diem rate accepted by the RTC that is high enough to cover one-third of the total patient days during its first 6 to 12 consecutive months of operation, or the CHAMPUS determined capped amount. Rates for RTCs beginning operation prior to July 1, 1988, will be adjusted by an appropriate CPI-U inflation factor for the period ending June 30, 1988. A period of less than 12 months will be used only when the RTC has been in operation for less than 12 months. Once a full 12 months is available, the rate will be recalculated.

(3) For care on or after April 6, 1995, the per diem amount may not exceed a cap of the 70th percentile of all established Federal fiscal year 1994 RTC rates nationally, weighted by total CHAMPUS days provided at each rate during the first half of Federal fiscal year 1994, and updated to FY95. For Federal fiscal years 1996 and 1997, the cap shall remain unchanged. For Federal fiscal years after fiscal year 1997, the cap shall be adjusted by the Medicare update factor for hospitals and units exempt from the Medicare prospective payment system.

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- (4) All educational costs, whether they include routine education or special education costs, are excluded from reimbursement except when appropriate education is not available from, or not payable by, a cognizant public entity.
  - (i) The RTC shall exclude educational costs from its daily costs.
  - (ii) The RTC's accounting system must be adequate to assure CHAMPUS is not billed for educational costs.
  - (iii) The RTC may request payment of educational costs on an individual case basis from the Director, OCHAMPUS, or designee, when appropriate education is not available from, or not payable by, a cognizant public entity. To qualify for reimbursement of educational costs in individual cases, the RTC shall comply with the application procedures established by the Director, OCHAMPUS, or designee, including, but not limited to, the following:
    - (A) As part of its admission procedures, the RTC must counsel and assist the beneficiary and the beneficiary's family in the necessary procedures for assuring their rights to a free and appropriate public education.
    - (B) The RTC must document any reasons why an individual beneficiary cannot attend public educational facilities and, in such a case, why alternative educational arrangements have not been provided by the cognizant public entity.
    - (C) If reimbursement of educational costs is approved for an individual beneficiary by the Director, OCHAMPUS, or designee, such educational costs shall be shown separately from the RTC's daily costs on the CHAMPUS claim. The amount paid shall not exceed the RTC's most-favorable rate to any other patient, agency, or organization for special or general educational services whichever is appropriate.
    - (D) If the RTC fails to request CHAMPUS approval of the educational costs on an individual case, the RTC agrees not to bill the beneficiary or the beneficiary's family for any amounts disallowed by CHAMPUS. Requests for payment of educational costs must be referred to the Director, OCHAMPUS, or designee for review and a determination of the applicability of CHAMPUS benefits.
- (5) Subject to the applicable RTC cap, adjustments to the RTC rates may be made annually.
  - (i) For Federal fiscal years through 1995, the adjustment shall be based on the Consumer Price Index-Urban (CPI-U) for medical care as determined applicable by the Director, OCHAMPUS.
  - (ii) For purposes of rates for Federal fiscal years 1996 and 1997:
    - (A) For any RTC whose 1995 rate was at or above the thirtieth percentile of all established Federal fiscal year 1995 RTC rates normally, weighted by total CHAMPUS days provided at each rate during the first half of Federal fiscal year 1994, that rate shall remain in effect, with no additional update, throughout fiscal years 1996 and 1997; and
    - (B) For any RTC whose 1995 rate was below the 30th percentile level determined under paragraph (f)(5)(ii)(A) of this section, the rate shall be adjusted by the lesser of: the CPI-U for

medical care, or the amount that brings the rate up to that 30th percentile level.

(iii) For subsequent Federal fiscal years after fiscal year 1997, RTC rates shall be updated by the Medicare update factor for hospitals and units exempt from the Medicare prospective payment system.

(6) For care provided on or after July 1, 1995, CHAMPUS will not pay for days in which the patient is absent on leave from the RTC. The RTC must identify these days when claiming reimbursement.

**(g) Reimbursement of hospice programs.** Hospice care will be reimbursed at one of four predetermined national CHAMPUS rates based on the type and intensity of services furnished to the beneficiary. A single rate is applicable for each day of care except for continuous home care where payment is based on the number of hours of care furnished during a 24-hour period. These rates will be adjusted for regional differences in wages using wage indices for hospice care.

(1) National hospice rates. CHAMPUS will use the national hospice rates for reimbursement of each of the following levels of care provided by or under arrangement with a CHAMPUS approved hospice program:

(i) Routine home care. The hospice will be paid the routine home care rate for each day the patient is at home, under the care of the hospice, and not receiving continuous home care. This rate is paid without regard to the volume or intensity of routine home care services provided on any given day.

(ii) Continuous home care. The hospice will be paid the continuous home care rate when continuous home care is provided. The continuous home care rate is divided by 24 hours in order to arrive at an hourly rate.

(A) A minimum of 8 hours of care must be provided within a 24-hour day starting and ending at midnight.

(B) More than half of the total actual hours being billed for each 24-hour period must be provided by either a registered or licensed practical nurse.

(C) Homemaker and home health aide services may be provided to supplement the nursing care to enable the beneficiary to remain at home.

(D) For every hour or part of an hour of continuous care furnished, the hourly rate will be reimbursed to the hospice up to 24 hours a day.

(iii) Inpatient respite care. The hospice will be paid at the inpatient respite care rate for each day on which the beneficiary is in an approved inpatient facility and is receiving respite care.

(A) Payment for respite care may be made for a maximum of 5 days at a time, including the date of admission but not counting the date of discharge. The necessity and frequency of respite care will be determined by the hospice interdisciplinary group with input from the patient's attending physician and the hospice's medical director.

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- (B) Payment for the sixth and any subsequent days is to be made at the routine home care rate.
- (iv) General inpatient care. Payment at the inpatient rate will be made when general inpatient care is provided for pain control or acute or chronic symptom management which cannot be managed in other settings. None of the other fixed payment rates (i.e., routine home care) will be applicable for a day on which the patient receives general inpatient care except on the date of discharge.
- (v) Date of discharge. For the day of discharge from an inpatient unit, the appropriate home care rate is to be paid unless the patient dies as an inpatient. When the patient is discharged deceased, the inpatient rate (general or respite) is to be paid for the discharge date.
- (2) Use of Medicare rates. CHAMPUS will use the most current Medicare rates to reimburse hospice programs for services provided to CHAMPUS beneficiaries. It is CHAMPUS' intent to adopt changes in the Medicare reimbursement methodology as they occur; e.g., Medicare's adoption of an updated, more accurate wage index.
- (3) Physician reimbursement. Payment is dependent on the physician's relationship with both the beneficiary and the hospice program.
  - (i) Physicians employed by, or contracted with, the hospice. (A) Administrative and supervisory activities (i.e., establishment, review and updating of plans of care, supervising care and services, and establishing governing policies) are included in the adjusted national payment rate.
  - (B) Direct patient care services are paid in addition to the adjusted national payment rate.
    - (1) Physician services will be reimbursed an amount equivalent to 100 percent of the CHAMPUS' allowable charge; i.e., there will be no cost-sharing and/or deductibles for hospice physician services.
    - (2) Physician payments will be counted toward the hospice cap limitation.
      - (ii) Independent attending physician. Patient care services rendered by an independent attending physician (a physician who is not considered employed by or under contract with the hospice) are not part of the hospice benefit.
        - (A) Attending physician may bill in his/her own right.
        - (B) Services will be subject to the appropriate allowable charge methodology.
        - (C) Reimbursement is not counted toward the hospice cap limitation.
        - (D) Services provided by an independent attending physician must be coordinated with any direct care services provided by hospice physicians.
        - (E) The hospice must notify the CHAMPUS contractor of the name of the physician whenever the attending physician is not a hospice employee.

(iii) Voluntary physician services. No payment will be allowed for physician services furnished voluntarily (both physicians employed by, and under contract with, the hospice and independent attending physicians). Physicians may not discriminate against CHAMPUS beneficiaries; e.g., designate all services rendered to non-CHAMPUS patients as volunteer and at the same time bill for CHAMPUS patients.

(4) Unrelated medical treatment. Any covered CHAMPUS services not related to the treatment of the terminal condition for which hospice care was elected will be paid in accordance with standard reimbursement methodologies; i.e., payment for these services will be subject to standard deductible and cost-sharing provisions under the CHAMPUS. A determination must be made whether or not services provided are related to the individual's terminal illness. Many illnesses may occur when an individual is terminally ill which are brought on by the underlying condition of the ill patient. For example, it is not unusual for a terminally ill patient to develop pneumonia or some other illness as a result of his or her weakened condition. Similarly, the setting of bones after fractures occur in a bone cancer patient would be treatment of a related condition. Thus, if the treatment or control of an upper respiratory tract infection is due to the weakened state of the terminal patient, it will be considered a related condition, and as such, will be included in the hospice daily rates.

(5) Cap amount. Each CHAMPUS-approved hospice program will be subject to a cap on aggregate CHAMPUS payments from November 1 through October 31 of each year, hereafter known as "the cap period."

(i) The cap amount will be adjusted annually by the percent of increase or decrease in the medical expenditure category of the Consumer Price Index for all urban consumers (CPI-U).

(ii) The aggregate cap amount (i.e., the statutory cap amount times the number of CHAMPUS beneficiaries electing hospice care during the cap period) will be compared with total actual CHAMPUS payments made during the same cap period.

(iii) Payments in excess of the cap amount must be refunded by the hospice program. The adjusted cap amount will be obtained from the Health Care Financing Administration (HCFA) prior to the end of each cap period.

(iv) Calculation of the cap amount for a hospice which has not participated in the program for an entire cap year (November 1 through October 31) will be based on a period of at least 12 months but no more than 23 months. For example, the first cap period for a hospice entering the program on October 1, 1994, would run from October 1, 1994 through October 31, 1995. Similarly, the first cap period for hospice providers entering the program after November 1, 1993 but before November 1, 1994 would end October 31, 1995.

(6) Inpatient limitation. During the 12-month period beginning November 1 of each year and ending October 31, the aggregate number of inpatient days, both for general inpatient care and respite care, may not exceed 20 percent of the aggregate total number of days of hospice care provided to all CHAMPUS beneficiaries during the same period.

(i) If the number of days of inpatient care furnished to CHAMPUS beneficiaries exceeds 20 percent of the total days of hospice care to CHAMPUS beneficiaries, the total payment for

inpatient care is determined follows:

(A) Calculate the ratio of the maximum number of allowable inpatient days of the actual number of inpatient care days furnished by the hospice to Medicare patients.

(B) Multiply this ratio by the total reimbursement for inpatient care made by the CHAMPUS contractor.

(C) Multiply the number of actual inpatient days in excess of the limitation by the routine home care rate.

(D) Add the amounts calculated in paragraphs (g)(6)(i)(B) and (C) of this section.

(ii) Compare the total payment for inpatient care calculated in paragraph (g)(6)(i)(D) of this section to actual payments made to the hospice for inpatient care during the cap period.

(iii) Payments in excess of the inpatient limitation must be refunded by the hospice program.

(7) Hospice reporting responsibilities. The hospice is responsible for reporting the following data within 30 days after the end of the cap period:

(i) Total reimbursement received and receivable for services furnished CHAMPUS beneficiaries during the cap period, including physician's services not of an administrative or general supervisory nature.

(ii) Total reimbursement received and receivable for general inpatient care and inpatient respite care furnished to CHAMPUS beneficiaries during the cap period.

(iii) Total number of inpatient days furnished to CHAMPUS hospice patients (both general inpatient and inpatient respite days) during the cap period.

(iv) Total number of CHAMPUS hospice days (both inpatient and home care) during the cap period.

(v) Total number of beneficiaries electing hospice care. The following rules must be adhered to by the hospice in determining the number of CHAMPUS beneficiaries who have elected hospice care during the period:

(A) The beneficiary must not have been counted previously in either another hospice's cap or another reporting year.

(B) The beneficiary must file an initial election statement during the period beginning September 28 of the previous cap year through September 27 of the current cap year in order to be counted as an electing CHAMPUS beneficiary during the current cap year.

(C) Once a beneficiary has been included in the calculation of a hospice cap amount, he or she may not be included in the cap for that hospice again, even if the number of covered days in a subsequent reporting period exceeds that of the period where the beneficiary was included.

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(D) There will be proportional application of the cap amount when a beneficiary elects to receive hospice benefits from two or more different CHAMPUS-certified hospices. A calculation must be made to determine the percentage of the patient's length of stay in each hospice relative to the total length of hospice stay.

(8) Reconsideration of cap amount and inpatient limit. A hospice dissatisfied with the contractor's calculation and application of its cap amount and/or inpatient limitation may request and obtain a contractor review if the amount of program reimbursement in controversy--with respect to matters which the hospice has a right to review--is at least \$1000. The administrative review by the contractor of the calculation and application of the cap amount and inpatient limitation is the only administrative review available. These calculations are not subject to the appeal procedures set forth in Sec. 199.10. The methods and standards for calculation of the hospice payment rates established by CHAMPUS, as well as questions as to the validity of the applicable law, regulations or CHAMPUS decisions, are not subject to administrative review, including the appeal procedures of Sec. 199.10.

(9) Beneficiary cost-sharing. There are no deductibles under the CHAMPUS hospice benefit. CHAMPUS pays the full cost of all covered services for the terminal illness, except for small cost-share amounts which may be collected by the individual hospice for outpatient drugs and biologicals and inpatient respite care.

(i) The patient is responsible for 5 percent of the cost of outpatient drugs or \$5 toward each prescription, whichever is less. Additionally, the cost of prescription drugs (drugs or biologicals) may not exceed that which a prudent buyer would pay in similar circumstances; that is, a buyer who refuses to pay more than the going price for an item or service and also seeks to economize by minimizing costs.

(ii) For inpatient respite care, the cost-share for each respite care day is equal to 5 percent of the amount CHAMPUS has estimated to be the cost of respite care, after adjusting the national rate for local wage differences.

(iii) The amount of the individual cost-share liability for respite care during a hospice cost-share period may not exceed the Medicare inpatient hospital deductible applicable for the year in which the hospice cost-share period began. The individual hospice cost-share period begins on the first day an election is in effect for the beneficiary and ends with the close of the first period of 14 consecutive days on each of which an election is not in effect for the beneficiary.

**(h) Reimbursement of Home Health Agencies (HHAs).** HHAs will be reimbursed using the same methods and rates as used under the Medicare HHA prospective payment system under Section 1895 of the Social Security Act (42 U.S.C. 1395fff) and 42 CFR Part 484, Subpart E except as otherwise necessary to recognize distinct characteristics of TRICARE beneficiaries and as described in instructions issued by the Director, TMA. Under this methodology, an HHA will receive a fixed case-mix and wage-adjusted national 60-day episode payment amount as payment in full for all costs associated with furnishing home health services to TRICARE-eligible beneficiaries with the exception of osteoporosis drugs

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and DME. The full case-mix and wage-adjusted 60-day episode amount will be payment in full subject to the following adjustments and additional payments:

(1) Split percentage payments. The initial percentage payment for initial episodes is paid to an HHA at 60 percent of the case-mix and wage adjusted 60-day episode rate. The residual final payment for initial episodes is paid at 40 percent of the case-mix and wage adjusted 60-day episode rate subject to appropriate adjustments. The initial percentage payment for subsequent episodes is paid at 50 percent of the case-mix and wage-adjusted 60-day episode rate. The residual final payment for subsequent episodes is paid at 50 percent of the case-mix and wage-adjusted 60-day episode rate subject to appropriate adjustments.

(2) Low-utilization payment. A low utilization payment is applied when a HHA furnishes four or fewer visits to a beneficiary during the 60-day episode. The visits are paid at the national per-visit amount by discipline updated annually by the applicable market basket for each visit type.

(3) Partial episode payment (PEP). A PEP adjustment is used for payment of an episode of less than 60 days resulting from a beneficiary's elected transfer to another HHA prior to the end of the 60-day episode or discharge and readmission of a beneficiary to the same HHA before the end of the 60-day episode. The PEP payment is calculated by multiplying the proportion of the 60-day episode during which the beneficiary remained under the care of the original HHA by the beneficiary's assigned 60-day episode payment.

(4) Significant change in condition (SCIC). The full-episode payment amount is adjusted if a beneficiary experiences a significant change in condition during the 60-day episode that was not envisioned in the initial treatment plan. The total significant change in condition payment adjustment is a proportional payment adjustment reflecting the time both prior to and after the patient experienced a significant change in condition during the 60-day episode. The initial percentage payment provided at the start of the 60-day episode will be adjusted at the end of the episode to reflect the first and second parts of the total SCIC adjustment determined at the end of the 60-day episode. The SCIC payment adjustment is calculated in two parts:

(i) The first part of the SCIC payment adjustment reflects the adjustment to the level of payment prior to the significant change in the patient's condition during the 60-day episode.

(ii) The second part of the SCIC payment adjustment reflects the adjustment to the level of payment after the significant change in the patient's condition occurs during the 60-day episode.

(5) Outlier payment. Outlier payments are allowed in addition to regular 60-day episode payments for beneficiaries generating excessively high treatment costs. The following methodology is used for calculation of the outlier payment:

(i) TRICARE makes an outlier payment for an episode whose estimated cost exceeds a threshold amount for each case-mix group.

(ii) The outlier threshold for each case-mix group is the episode payment amount for that group, the PEP adjustment amount for the episode or the total significant change in condition adjustment amount for the episode plus a fixed dollar loss amount that is the same

for all case-mix groups.

(iii) The outlier payment is a proportion of the amount of estimated cost beyond the threshold.

(iv) TRICARE imputes the cost for each episode by multiplying the national per-visit amount of each discipline by the number of visits in the discipline and computing the total imputed cost for all disciplines.

(v) The fixed dollar loss amount and the loss sharing proportion are chosen so that the estimated total outlier payment is no more than the predetermined percentage of total payment under the home health PPS as set by the Centers for Medicare & Medicaid Services (CMS).

(6) Services paid outside the HHA prospective payment system. The following are services that receive a separate payment amount in addition to the prospective payment amount for home health services:

(i) Durable medical equipment (DME). Reimbursement of DME is based on the same amounts established under the Medicare Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) fee schedule under 42 CFR part 414, subpart D.

(ii) Osteoporosis drugs. Although osteoporosis drugs are subject to home health consolidated billing, they continue to be paid on a cost basis, in addition to episode payments.

(7) Accelerated payments. Upon request, an accelerated payment may be made to an HHA that is receiving payment under the home health prospective payment system if the HHA is experiencing financial difficulties because there is a delay by the contractor in making payment to the HHA. The following are criteria for making accelerated payments:

(i) Approval of payment. An HHA's request for an accelerated payment must be approved by the contractor and TRICARE Management Activity (TMA).

(ii) Amount of payment. The amount of the accelerated payment is computed as a percentage of the net payment for unbilled or unpaid covered services.

(iii) Recovery of payment. Recovery of the accelerated payment is made by recoupment as HHA bills are processed or by direct payment by the HHA.

(8) Assessment data. Beneficiary assessment data, incorporating the use of the current version of the OASIS items, must be submitted to the contractor for payment under the HHA prospective payment system.

(9) Administrative review. An HHA is not entitled to judicial or administrative review with regard to:

(i) Establishment of the payment unit, including the national 60-day prospective episode payment rate, adjustments and outlier payment.

- (ii) Establishment of transition period, definition and application of the unit of payment.
- (iii) Computation of the initial standard prospective payment amounts.
- (iv) Establishment of case-mix and area wage adjustment factors.

**(i) Changes in Federal Law affecting Medicare.** With regard to paragraph (b) and (h) of this section, the Department of Defense must, within the time frame specified in law and to the extent it is practicable, bring the TRICARE program into compliance with any changes in Federal Law affecting the Medicare program that occur after the effective date of the DoD rule to implement the prospective payment systems for skilled nursing facilities and home health agencies.

**(j) Reimbursement of individual health care professionals and other non-institutional, non-professional providers.** The CHAMPUS-determined reasonable charge (the amount allowed by CHAMPUS) for the service of an individual health care professional or other non-institutional, non-professional provider (even if employed by or under contract to an institutional provider) shall be determined by one of the following methodologies, that is, whichever is in effect in the specific geographic location at the time covered services and supplies are provided to a CHAMPUS beneficiary.

(1) Allowable charge method--(i) Introduction--(A) In general. The allowable charge method is the preferred and primary method for reimbursement of individual health care professionals and other non-institutional health care providers (covered by 10 U.S.C. 1079(h)(1)). The allowable charge for authorized care shall be the lower of the billed charge or the local CHAMPUS Maximum Allowable Charge (CMAC).

(B) CHAMPUS Maximum Allowable Charge. Beginning in calendar year 1992, prevailing charge levels and appropriate charge levels will be calculated on a national level. There will then be calculated a national CHAMPUS Maximum Allowable Charge (CMAC) level for each procedure, which shall be the lesser of the national prevailing charge level or the national appropriate charge level. The national CMAC will then be adjusted for localities in accordance with paragraph (j)(1)(iv) of this section.

(C) Limits on balance billing by nonparticipating providers. Nonparticipating providers may not balance bill a beneficiary an amount which exceeds the applicable balance billing limit. The balance billing limit shall be the same percentage as the Medicare limiting charge percentage for nonparticipating physicians. The balance billing limit may be waived by the Director, OCHAMPUS on a case-by-case basis if requested by the CHAMPUS beneficiary (or sponsor) involved. A decision by the Director to waive or not waive the limit in any particular case is not subject to the appeal and hearing procedures of Sec. 199.10.

(D) Special rule for TRICARE Prime Enrollees. In the case of a TRICARE Prime enrollee (see section 199.17) who receives authorized care from a non-participating provider, the CHAMPUS determined reasonable charge will be the CMAC level as established in paragraph (j)(1)(i)(B) of this section plus any balance billing amount up to the balance billing limit as referred to in paragraph (j)(1)(i)(C) of this section. The authorization for such care shall be pursuant to the procedures established by the Director, OCHAMPUS (also referred to as the TRICARE Support Office).

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(E) Special rule for certain TRICARE Standard Beneficiaries. In the case of dependent spouse or child, as defined in paragraphs (b)(2)(ii)(A) through (F) and (b)(2)(ii)(H)(1), (2), and (4) of Sec. 199.3, of a Reserve Component member serving on active duty pursuant to a call or order to active duty for a period of more than 30 days in support of a contingency operation under a provision of law referred to in section 101(a)(13)(B) of title 10, United States Code, the Director, TRICARE Management Activity, may authorize non-participating providers the allowable charge to be the CMAC level as established in paragraph (j)(1)(i)(B) of this section plus any balance billing amount up to the balance billing limit as referred to in paragraph (j)(1)(i)(C) of this section.

(ii) Prevailing charge level. (A) Beginning in calendar year 1992, the prevailing charge level shall be calculated on a national basis.

(B) The national prevailing charge level referred to in paragraph (j)(1)(ii)(A) of this section is the level that does not exceed the amount equivalent to the 80th percentile of billed charges made for similar services during the base period. The 80th percentile of charges shall be determined on the basis of statistical data and methodology acceptable to the Director, OCHAMPUS (or a designee).

(C) For purposes of paragraph (j)(1)(ii)(B) of this section, the base period shall be a period of 12 calendar months and shall be adjusted once a year, unless the Director, OCHAMPUS, determines that a different period for adjustment is appropriate and publishes a notice to that effect in the Federal Register.

(iii) Appropriate charge level. Beginning in calendar year 1992, the appropriate charge level shall be calculated on a national basis. The appropriate charge level for each procedure is the product of the two-step process set forth in paragraphs (j)(1)(iii)(A) and (B) of this section. This process involves comparing the prior year's CMAC with the fully phased in Medicare fee. For years after the Medicare fee has been fully phased in, the comparison shall be to the current year Medicare fee. For any particular procedure for which comparable Medicare fee and CHAMPUS data are unavailable, but for which alternative data are available that the Director, OCHAMPUS (or designee) determines provide a reasonable approximation of relative value or price, the comparison may be based on such alternative data.

(A) Step 1: Procedures classified. All procedures are classified into one of three categories, as follows:

(1) Overpriced procedures. These are the procedures for which the prior year's national CMAC exceeds the Medicare fee.

(2) Other procedures. These are procedures subject to the allowable charge method that are not included in either the overpriced procedures group or the underpriced procedures group.

(3) Underpriced procedures. These are the procedures for which the prior year's national CMAC is less than the Medicare fee.

(B) Step 2: Calculating appropriate charge levels. For each year, appropriate charge levels will be calculated by adjusting the prior year's CMAC as follows:

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(1) For overpriced procedures, the appropriate charge level for each procedure shall be the prior year's CMAC, reduced by the lesser of: the percentage by which it exceeds the Medicare fee or fifteen percent.

(2) For other procedures, the appropriate charge level for each procedure shall be the same as the prior year's CMAC.

(3) For underpriced procedures, the appropriate charge level for each procedure shall be the prior year's CMAC, increased by the lesser of: the percentage by which it is exceeded by the Medicare fee or the Medicare Economic Index.

(C) Special rule for cases in which the CHAMPUS appropriate charge was prematurely reduced. In any case in which a recalculation of the Medicare fee results in a Medicare rate higher than the CHAMPUS appropriate charge for a procedure that had been considered an overpriced procedure, the reduction in the CHAMPUS appropriate charge shall be restored up to the level of the recalculated Medicare rate.

(D) Special rule for cases in which the national CMAC is less than the Medicare rate.

NOTE: This paragraph will be implemented when CMAC rates are published.

In any case in which the national CMAC calculated in accordance with paragraphs (j)(1)(i) through (iii) of this section is less than the Medicare rate, the Director, TSO, may determine that the use of the Medicare Economic Index under paragraph (j)(1)(iii)(B) of this section will result in a CMAC rate below the level necessary to assure that beneficiaries will retain adequate access to health care services. Upon making such a determination, the Director, TSO, may increase the national CMAC to a level not greater than the Medicare rate.

(iv) Calculating CHAMPUS Maximum Allowable Charge levels for localities. (A) In general. The national CHAMPUS Maximum Allowable Charge level for each procedure will be adjusted for localities using the same (or similar) geographical areas and the same geographic adjustment factors as are used for determining allowable charges under Medicare.

(B) Special locality-based phase-in provision. (1) In general. Beginning with the recalculation of CMACS for calendar year 1993, the CMAC in a locality will not be less than 72.25 percent of the maximum charge level in effect for that locality on December 31, 1991. For recalculations of CMACs for calendar years after 1993, the CMAC in a locality will not be less than 85 percent of the CMAC in effect for that locality at the end of the prior calendar year.

(2) Exception. The special locality-based phase-in provision established by paragraph (j)(1)(iv)(B)(1) of this section shall not be applicable in the case of any procedure code for which there were not CHAMPUS claims in the locality accounting for at least 50 services.

(C) Special locality-based waivers of reductions to assure adequate access to care. Beginning with the recalculation of CMACs for calendar year 1993, in the case of any procedure classified as an overpriced procedure pursuant to paragraph (j)(1)(iii)(A)(1) of this section, a reduction in the CMAC in a locality below the level in effect at the end of the

previous calendar year that would otherwise occur pursuant to paragraphs (j)(1)(iii) and (j)(1)(iv) of this section may be waived pursuant to paragraph (j)(1)(iii)(C) of this section.

(1) Waiver based on balanced billing rates. Except as provided in paragraph (j)(1)(iv)(C)(2) of this section such a reduction will be waived if there has been excessive balance billing in the locality for the procedure involved. For this purpose, the extent of balance billing will be determined based on a review of all services under the procedure code involved in the prior year (or most recent period for which data are available). If the number of services for which balance billing was not required was less than 60 percent of all services provided, the Director will determine that there was excessive balance billing with respect to that procedure in that locality and will waive the reduction in the CMAC that would otherwise occur. A decision by the Director to waive or not waive the reduction is not subject to the appeal and hearing procedures of Sec. 199.10.

(2) Exception. As an exception to the paragraph (j)(1)(iv)(C)(1) of this section, the waiver required by that paragraph shall not be applicable in the case of any procedure code for which there were not CHAMPUS claims in the locality accounting for at least 50 services. A waiver may, however, be granted in such cases pursuant to paragraph (j)(1)(iv)(C)(3) of this section.

(3) Waiver based on other evidence that adequate access to care would be impaired. The Director, OCHAMPUS may waive a reduction that would otherwise occur (or restore a reduction that was already taken) if the Director determines that available evidence shows that the reduction would impair adequate access. For this purpose, such evidence may include consideration of the number of providers in the locality who provide the affected services, the number of such providers who are CHAMPUS Participating Providers, the number of CHAMPUS beneficiaries in the area, and other relevant factors. Providers or beneficiaries in a locality may submit to the Director, OCHAMPUS a petition, together with appropriate documentation regarding relevant factors, for a determination that adequate access would be impaired. The Director, OCHAMPUS will consider and respond to all such petitions. Petitions may be filed at any time. Any petition received by the date which is 120 days prior to the implementation of a recalculation of CMACs will be assured of consideration prior to that implementation. The Director, OCHAMPUS may establish procedures for handling petitions. A decision by the Director to waive or not waive a reduction is not subject to the appeal and hearing procedures of Sec. 199.10.

(D) Special locality-based exception to applicable CMACs to assure adequate beneficiary access to care. In addition to the authority to waive reductions under paragraph (j)(1)(iv)(C) of this section, the Director may authorize establishment of higher payment rates for specific services than would otherwise be allowable, under paragraph (j)(1) of this section, if the Director determines that available evidence shows that access to health care services is severely impaired. For this purpose, such evidence may include consideration of the number of providers in the locality who provide the affected services, the number of providers who are CHAMPUS participating providers, the number of CHAMPUS beneficiaries in the locality, the availability of military providers in the location or nearby, and any other factors the Director determines relevant.

(1) Procedure. Providers or beneficiaries in a locality may submit to the Director, a petition, together with appropriate documentation regarding relevant factors, for a determination that adequate access to health care services is severely impaired. The Director,

will consider and respond to all petitions. A decision to authorize a higher payment amount is subject to review and determination or modification by the Director at any time if circumstances change so that adequate access to health care services would no longer be severely impaired. A decision by the Director, to authorize, not authorize, terminate, or modify authorization of higher payment amounts is not subject to the appeal and hearing procedures of Sec. 199.10 of the part.

(2) Establishing the higher payment rate(s). When the Director, determines that beneficiary access to health care services in a locality is severely impaired, the Director may establish the higher payment rate(s) as he or she deems appropriate and cost-effective through one of the following methodologies to assure adequate access:

(i) A percent factor may be added to the otherwise applicable payment amount allowable under paragraph (j)(1) of this section;

(ii) A prevailing charge may be calculated, by applying the prevailing charge methodology of paragraph (j)(1)(ii) of this section to a specific locality (which need not be the same as the localities used for purposes of paragraph (j)(1)(iv)(A) of this section; or another government payment rate may be adopted, for example, an applicable state Medicaid rate).

(3) Application of higher payment rates. Higher payment rates defined under paragraph (j)(1)(iv)(D) of this section may be applied to all similar services performed in a locality, or, if circumstances warrant, a new locality may be defined for application of the higher payments. Establishment of a new locality may be undertaken where access impairment is localized and not pervasive across the existing locality. Generally, establishment of a new, more specific locality will occur when the area is remote so that geographical characteristics and other factors significantly impair transportation through normal means to health care services routinely available within the existing locality.

(E) Special locality-based exception to applicable CMACs to ensure an adequate TRICARE Prime preferred network. The Director, may authorize reimbursements to health care providers participating in a TRICARE preferred provider network under Sec. 199.17(p) of this part at rates higher than would otherwise be allowable under paragraph (j)(1) of this section, if the Director, determines that application of the higher rates is necessary to ensure the availability of an adequate number and mix of qualified health care providers in a network in a specific locality. This authority may only be used to ensure adequate networks in those localities designated by the Director, as requiring TRICARE preferred provider networks, not in localities in which preferred provider networks have been suggested or established but are not determined by the Director to be necessary. Appropriate evidence for determining that higher rates are necessary may include consideration of the number of available primary care and specialist providers in the network locality, availability (including reassignment) of military providers in the location or nearby, the appropriate mix of primary care and specialists needed to satisfy demand and meet appropriate patient access standards (appointment/waiting time, travel distance, etc.), the efforts that have been made to create an adequate network, other cost-effective alternatives, and other relevant factors. The Director, may establish procedures by which exceptions to applicable CMACs are requested and approved or denied under paragraph (j)(1)(iv)(E) of this section. A decision by the Director, to authorize or deny an exception is not subject to the appeal and hearing procedures of Sec. 199.10. When the Director, determines that it is necessary and cost-effective to approve a higher rate or rates in order to ensure the availability of an adequate number of qualified

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health care providers in a network in a specific locality, the higher rate may not exceed the lesser of the following:

(1) The amount equal to the local fee for service charge for the service in the service area in which the service is provided as determined by the Director, based on one or more of the following payment rates:

- (i) Usual, customary, and reasonable;
- (ii) The Health Care Financing Administration's Resource Based Relative Value Scale;
- (iii) Negotiated fee schedules;
- (iv) Global fees; or
- (v) Sliding scale individual fee allowances.

(2) The amount equal to 115 percent of the otherwise allowable charge under paragraph (j)(1) of the section for the service.

(v) Special rules for 1991. (A) Appropriate charge levels for care provided on or after January 1, 1991, and before the 1992 appropriate levels take effect shall be the same as those in effect on December 31, 1990, except that appropriate charge levels for care provided on or after October 7, 1991, shall be those established pursuant to this paragraph (j)(1)(v) of this section.

(B) Appropriate charge levels will be established for each locality for which a appropriate charge level was in effect immediately prior to October 7, 1991. For each procedure, the appropriate charge level shall be the prevailing charge level in effect immediately prior to October 7, 1991, adjusted as provided in (j)(1)(v)(B)(1) through (3) of this section.

(1) For each overpriced procedure, the level shall be reduced by fifteen percent. For this purpose, overpriced procedures are the procedures determined by the Physician Payment Review Commission to be overvalued pursuant to the process established under the Medicare program, other procedures considered overvalued in the Medicare program (for which Congress directed reductions in Medicare allowable levels for 1991), radiology procedures and pathology procedures.

(2) For each other procedure, the level shall remain unchanged. For this purpose, other procedures are procedures which are not overpriced procedures or primary care procedures.

(3) For each primary care procedure, the level shall be adjusted by the MEI, as the MEI is applied to Medicare prevailing charge levels. For this purpose, primary care procedures include maternity care and delivery services and well baby care services.

(C) For purposes of this paragraph (j)(i)(v), "appropriate charge levels" in effect at any time prior to October 7, 1991 shall mean the lesser of:

- (1) The prevailing charge levels then in effect, or

(2) The fiscal year 1988 prevailing charge levels adjusted by the Medicare Economic Index (MEI), as the MEI was applied beginning in the fiscal year 1989.

(vi) Special transition rule for 1992. (A) For purposes of calculating the national appropriate charge levels for 1992, the prior year's appropriate charge level for each service will be considered to be the level that does not exceed the amount equivalent to the 80th percentile of billed charges made for similar services during the base period of July 1, 1986 to June 30, 1987 (determined as under paragraph (j)(1)(ii)(B) of this section), adjusted to calendar year 1991 based on the adjustments made for maximum CHAMPUS allowable charge levels through 1990 and the application of paragraph (j)(1)(v) of this section for 1991.

(B) The adjustment to calendar year 1991 of the product of paragraph (j)(1)(vi)(A) of this section shall be as follows:

(1) For procedures other than those described in paragraph (j)(1)(vi)(B)(2) of this section, the adjustment to 1991 shall be on the same basis as that provided under paragraph (j)(1)(v) of this section.

(2) For any procedure that was considered an overpriced procedure for purposes of the 1991 appropriate charge levels under paragraph (j)(1)(v) of this section for which the resulting 1991 appropriate charge level was less than 150 percent of the Medicare converted relative value unit, the adjustment to 1991 for purposes of the special transition rule for 1992 shall be as if the procedure had been treated under paragraph (j)(1)(v)(B)(2) of this section for purposes of the 1991 appropriate charge level.

(vii) Adjustments and procedural rules. (A) The Director, OCHAMPUS may make adjustments to the appropriate charge levels calculated pursuant to paragraphs (j)(1)(iii) and (j)(1)(v) of this section to correct any anomalies resulting from data or statistical factors, significant differences between Medicare-relevant information and CHAMPUS-relevant considerations or other special factors that fairness requires be specially recognized. However, no such adjustment may result in reducing an appropriate charge level.

(B) The Director, OCHAMPUS will issue procedural instructions for administration of the allowable charge method.

(viii) Clinical laboratory services. The allowable charge for clinical diagnostic laboratory test services shall be calculated in the same manner as allowable charges for other individual health care providers are calculated pursuant to paragraphs (j)(1)(i) through (j)(1)(iv) of this section, with the following exceptions and clarifications.

(A) The calculation of national prevailing charge levels, national appropriate charge levels and national CMACs for laboratory service shall begin in calendar year 1993. For purposes of the 1993 calculation, the prior year's national appropriate charge level or national prevailing charge level shall be the level that does not exceed the amount equivalent to the 80th percentile of billed charges made for similar services during the period July 1, 1991, through June 30, 1992 (referred to in this paragraph (j)(1)(viii) of this section as the "base period").

(B) For purposes of comparison to Medicare allowable payment amounts pursuant to paragraph (j)(1)(iii) of this section, the Medicare national laboratory payment limitation amounts shall be used.

(C) For purposes of establishing laboratory service local CMACs pursuant to paragraph (j)(1)(iv) of this section, the adjustment factor shall equal the ratio of the local average charge (standardized for the distribution of clinical laboratory services) to the national average charge for all clinical laboratory services during the base period.

(D) For purposes of a special locality-based phase-in provision similar to that established by paragraph (j)(1)(iv)(B) of this section, the CMAC in a locality will not be less than 85 percent of the maximum charge level in effect for that locality during the base period.

(ix) The allowable charge for physician assistant services other than assistant-at-surgery shall be at the same percentage, used by Medicare, of the allowable charge for a comparable service rendered by a physician performing the service in a similar location. For cases in which the physician assistant and the physician perform component services of a procedure other than assistant-at-surgery (e.g., home, office, or hospital visit), the combined allowable charge for the procedure may not exceed the allowable charge for the procedure rendered by a physician alone. The allowable charge for physician assistant services performed as an assistant-at-surgery shall be at the same percentage, used by Medicare, of the allowable charge for a physician serving as an assistant surgeon when authorized as CHAMPUS benefits in accordance with the provisions of Sec. 199.4(c)(3)(iii). Physician assistant services must be billed through the employing physician who must be an authorized CHAMPUS provider.

(x) A charge that exceeds the CHAMPUS Maximum Allowable Charge can be determined to be allowable only when unusual circumstances or medical complications justify the higher charge. The allowable charge may not exceed the billed charge under any circumstances.

(2) Bonus payments in medically underserved areas. A bonus payment, in addition to the amount normally paid under the allowable charge methodology, may be made to physicians in medically underserved areas. For purposes of this paragraph, medically underserved areas are the same as those determined by the Secretary of Health and Human Services for the Medicare program. Such bonus payments shall be equal to the bonus payments authorized by Medicare, except as necessary to recognize any unique or distinct characteristics or requirements of the TRICARE program, and as described in instructions issued by the Executive Director, TRICARE Management Activity. If the Department of Health and Human Services acts to amend or remove the provision for bonus payments under Medicare, TRICARE likewise may follow Medicare in amending or removing provision for such payments.

(3) All-inclusive rate. Claims from individual health-care professional providers for services rendered to CHAMPUS beneficiaries residing in an RTC that is either being reimbursed on an all-inclusive per diem rate, or is billing an all-inclusive per diem rate, shall be denied; with the exception of independent health-care professionals providing geographically distant family therapy to a family member residing a minimum of 250 miles from the RTC or covered medical services related to a nonmental health condition rendered outside the RTC. Reimbursement for individual professional services is included in the rate paid the institutional provider.

(4) Alternative method. The Director, OCHAMPUS, or a designee, may, subject to the approval of the ASD(HA), establish an alternative method of reimbursement designed to produce reasonable control over health care costs and to ensure a high level of acceptance of

the CHAMPUS-determined charge by the individual health-care professionals or other noninstitutional health-care providers furnishing services and supplies to CHAMPUS beneficiaries. Alternative methods may not result in reimbursement greater than the allowable charge method above.

**(k) Reimbursement of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS).** Reimbursement of DMEPOS may be based on the same amounts established under the Centers for Medicare and Medicaid Services (CMS) DMEPOS fee schedule under 42 CFR part 414, subpart D.

**(l) Reimbursement Under the Military-Civilian Health Services Partnership Program.** The Military-Civilian Health Services Partnership Program, as authorized by section 1096, chapter 55, title 10, provides for the sharing of staff, equipment, and resources between the civilian and military health care system in order to achieve more effective, efficient, or economical health care for authorized beneficiaries. Military treatment facility commanders, based upon the authority provided by their respective Surgeons General of the military departments, are responsible for entering into individual partnership agreements only when they have determined specifically that use of the Partnership Program is more economical overall to the Government than referring the need for health care services to the civilian community under the normal operation of the CHAMPUS Program. (See paragraph (p) of Sec. 199.1 for general requirements of the Partnership Program.)

(1) Reimbursement of institutional health care providers. Reimbursement of institutional health care providers under the Partnership Program shall be on the same basis as non-Partnership providers.

(2) Reimbursement of individual health-care professionals and other non-institutional health care providers. Reimbursement of individual health care professionals and other non-institutional health care providers shall be on the same basis as non-Partnership providers as detailed in paragraph (j) of this section.

**(m) Accommodation of Discounts Under Provider Reimbursement Methods.**

(1) General rule. The Director, OCHAMPUS (or designee) has authority to reimburse a provider at an amount below the amount usually paid pursuant to this section when, under a program approved by the Director, the provider has agreed to the lower amount.

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

(i) In the case of individual health care professionals and other non-institutional providers, if the discounted fee is below the provider's normal billed charge and the prevailing charge level (see paragraph (g) of this section), the discounted fee shall be the provider's actual billed charge and the CHAMPUS allowable charge.

(ii) In the case of institutional providers normally paid on the basis of a pre-set amount (such as DRG-based amount under paragraph (a)(1) of this section or per-diem amount under paragraph (a)(2) of this section), if the discount rate is lower than the pre-set rate, the discounted rate shall be the CHAMPUS-determined allowable cost. This is an exception to the usual rule that the pre-set rate is paid regardless of the institutional provider's billed charges or other factors.

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(3) Procedures. (i) This paragraph applies only when both the provider and the Director have agreed to the discounted payment rate. The Director's agreement may be in the context of approval of a program that allows for such discounts.

(ii) The Director of OCHAMPUS may establish uniform terms, conditions and limitations for this payment method in order to avoid administrative complexity.

**(n) Outside the United States.** The Director, OCHAMPUS, or a designee, shall determine the appropriate reimbursement method or methods to be used in the extension of CHAMPUS benefits for otherwise covered medical services or supplies provided by hospitals or other institutional providers, physicians or other individual professional providers, or other providers outside the United States.

**(o) Implementing Instructions.** The Director, OCHAMPUS, or a designee, shall issue CHAMPUS policies, instructions, procedures, and guidelines, as may be necessary to implement the intent of this section.

[55 FR 13266, Apr 10, 1990, as amended at 55 FR 31180, Aug 1, 1990; 55 FR 42562, Oct 22, 1990; 55 FR 43342, Oct 29, 1990; 56 FR 44006, Sep 6, 1991; 56 FR 50273, Oct 4, 1991; 58 FR 35408, Jul 1, 1993; 58 FR 51239, Oct 1, 1993; 58 FR 58961, Nov 5, 1993; 60 FR 6019, Feb 1, 1995; 60 FR 12437, Mar 7, 1995; 60 FR 52094, Oct 5, 1995; 63 FR 7287, Feb 13, 1998; 63 FR 48446, Sep 10, 1998; 63 FR 56082, Oct 21, 1998; 64 FR 60671, Nov 8, 1999; 65 FR 41003, Jul 3, 2000; 67 FR 45172, Aug 28, 2001; 67 FR 18115, Apr 15, 2002; 67 FR 40604, Jun 13, 2002; 69 FR 60555, Oct 12, 2004; 70 FR 61378, Oct 24, 2005; 72 FR 63988, Nov 14, 2007; 73 FR 46809, Aug 12, 2008; 73 FR 74965, Dec 10, 2008; 74 FR 44755, Aug 31, 2009; 77 FR 38175, Jun 27, 2012; 78 FR 48309, Aug 8, 2013; 79 FR 29087, May 21, 2014; **81 FR 61097, Sep 2, 2016**]

**EDITORIAL NOTE:** The following text, appearing at 63 FR 48445, Sept. 10, 1998, could not be incorporated into Sec. 199.14 because it was not mentioned in the amendatory instruction. For the convenience of the user, the text is set forth as follows: Sec. 199.14 Provider reimbursement methods.

(a) \* \* \*

(1) \* \* \*

\* \* \* \* \*

(iii) \* \* \*

(B) Empty and low-volume DRGs. For any DRG with less than ten (10) occurrences in the CHAMPUS database, the Director, TSO, or designee, has the authority to consider alternative methods for estimating CHAMPUS weights in these low-volume DRG categories.

\* \* \* \* \*

(D) \* \* \*

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(7) Differentiate large urban and other area charges. All charges in the database shall be sorted into large urban and other area groups (using the same definitions for these categories used in the Medicare program.

\* \* \* \* \*

(5) Preliminary base year standardized amount. A preliminary base year standardized amount shall be calculated by summing all costs in the database applicable to the large urban or other area group and dividing by the total number of discharges in the respective group.

\* \* \* \* \*

(E) \* \* \*

(7) \* \* \*

(i) \* \* \*

(A) Short-stay outliers. Any discharge with a length-of-stay (LOS) less than 1.94 standard deviations from the DRG's arithmetic LOS shall be classified as a short-stay outlier. Short-stay outliers shall be reimbursed at 200 percent of the per diem rate for the DRG for each covered day of the hospital stay, not to exceed the DRG amount. The per diem rate shall equal the DRG amount divided by the arithmetic mean length-of-stay for the DRG.

(B) Long-stay outliers. Any discharge (except for neonatal services and services in children's hospitals) which has a length-of-stay (LOS) exceeding a threshold established in accordance with the criteria used for the Medicare Prospective Payment System as contained in 42 CFR 412.82 shall be classified as a long-stay outlier. Any discharge for neonatal services or for services in a children's hospital which has a LOS exceeding the lesser of 1.94 standard deviations or 17 days from the DRG's arithmetic mean LOS also shall be classified as a long-stay outlier. Long-stay outliers shall be reimbursed the DRG-based amount plus a percentage (as established for the Medicare Prospective Payment System) of the per diem rate for the DRG for each covered day of care beyond the long-stay outlier threshold. The per diem rate shall equal the DRG amount divided by the arithmetic mean LOS for the DRG. For admissions on or after October 1, 1997, the long stay outlier has been eliminated for all cases except children's hospitals and neonates. For admissions on or after October 1, 1998, the long stay outlier has been eliminated for children's hospitals and neonates.

(i) \* \* \*

(A) Cost outliers except those in children's hospitals or for neonatal services. Any discharge which has standardized costs that exceed a threshold established in accordance with the criteria used for the Medicare Prospective Payment System as contained in 42 CFR 412.84 shall qualify as a cost outlier. The standardized costs shall be calculated by multiplying the total charges by the factor described in Sec. 199.14(a)(1)(iii)(D)(4) and adjusting this amount for indirect medical education costs. Cost outliers shall be reimbursed the DRG-based amount plus a percentage (as established for the Medicare Prospective Payment System) of all costs exceeding the threshold. Effective with admissions occurring on or after October 1, 1997, the standardized costs are no longer adjusted for indirect medical education costs.

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(B) Cost outliers in children's hospitals and for neonatal services. Any discharge for services in a children's hospital or for neonatal services which has standardized costs that exceed a threshold of the greater of two times the DRG-based amount or \$13,500 shall qualify as a cost outlier. The standardized costs shall be calculated by multiplying the total charges by the factor described in Sec. 199.14(a)(1)(iii)(D)(4) (adjusted to include average capital and direct medical education costs) and adjusting this amount for indirect medical education costs. Cost outliers for services in children's hospitals and for neonatal services shall be reimbursed the DRG-based amount plus a percentage (as established for the Medicare Prospective Payment System) of all costs exceeding the threshold. Effective with admissions occurring on or after October 1, 1998, standardized costs are no longer adjusted for indirect medical education costs. In addition, CHAMPUS will calculate the outlier payments that would have occurred at each of the 59 Children's hospitals under the FY99 outlier policy for all cases that would have been outliers under the FY94 policies using the most accurate data available in September 1998. A ratio will be calculated which equals the level of outlier payments that would have been made under the FY94 outlier policies and the outlier payments that would be made if the FY99 outlier policies had applied to each of these potential outlier cases for these hospitals. The ratio will be calculated across all outlier claims for the 59 hospitals and will not be hospital specific. The ratio will be used to increase cost outlier payments in FY 1999 and FY 2000, unless the hospital has a negotiated agreement with a managed care support contractor which would affect this payment. For hospitals with managed care support agreements which affect these payments, CHAMPUS will apply these payments if the increased payments would be consistent with the agreements. In FY 2000 the ratio of outlier payments (long stay and cost) that would have occurred under the FY 94 policy and actual cost outlier payments made under the FY 99 policy will be recalculated. If the ratio has changed significantly, the ratio will be revised for use in FY 2001 and thereafter. In FY 2002, the actual cost outlier cases in FY 2000 and 2001 will be reexamined. The ratio of outlier payments that would have occurred under the FY94 policy and the actual cost outlier payments made under the FY 2000 and FY 2001 policies. If the ratio has changed significantly, the ratio will be revised for use in FY 2003.

\* \* \* \* \*

(G) \* \* \*

(3) Information necessary for payment of capital and direct medical education costs. All hospitals subject to the CHAMPUS DRG-based payment system, except for children's hospitals, may be reimbursed for allowed capital and direct medical education costs by submitting a request to the CHAMPUS contractor. Beginning October 1, 1998, such request shall be filed with CHAMPUS on or before the last day of the twelfth month following the close of the hospitals' cost reporting period, and shall cover the one-year period corresponding to the hospital's Medicare cost-reporting period. The first such request may cover a period of less than a full year--from the effective date of the CHAMPUS DRG-based payment system to the end of the hospital's Medicare cost-reporting period. All costs reported to the CHAMPUS contractor must correspond to the costs reported on the hospital's Medicare cost report. An extension of the due date for filing the request may only be granted if an extension has been granted by HCFA due to a provider's operations being significantly adversely affected due to extraordinary circumstances over which the provider has no control, such as flood or fire. (If these costs change as a result of a subsequent audit by Medicare, the revised costs are to be reported to the hospital's CHAMPUS contractor within 30 days of the date the hospital is notified of the change.) The request must be signed by the

hospital official responsible for verifying the amounts and shall contain the following information.

\* \* \* \* \*

(d) \* \* \*

(3) \* \* \*

(iv) Step 4: standard payment amount per group. The standard payment amount per group will be the volume weighted median per procedure cost for the procedures in that group. For cases in which the standard payment amount per group exceeds the CHAMPUS-determined inpatient allowable amount, the Director, TSO or his designee, may make adjustments.

\* \* \* \* \*

(h) Reimbursement of individual health care professionals and other non-institutional, non-professional providers. The CHAMPUS-determined reasonable charge (the amount allowed by CHAMPUS) for the service of an individual health care professional or other non-institutional, non-professional provider (even if employed by or under contract to an institutional provider) shall be determined by one of the following methodologies, that is, whichever is in effect in the specific geographic location at the time covered services and supplies are provided to a CHAMPUS beneficiary.

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## PART 199.15 - QUALITY AND UTILIZATION REVIEW PEER REVIEW ORGANIZATION PROGRAM

(a) **General.** (1) Purpose. The purpose of this section is to establish rules and procedures for the CHAMPUS Quality and Utilization Review Peer Review Organization program.

(2) Applicability of program. All claims submitted for health services under CHAMPUS are subject to review for quality of care and appropriate utilization. The Director, OCHAMPUS shall establish generally accepted standards, norms and criteria as are necessary for this program of utilization and quality review. These standards, norms and criteria shall include, but not be limited to, need for inpatient admission or inpatient or outpatient service, length of inpatient stay, intensity of care, appropriateness of treatment, and level of institutional care required. The Director, OCHAMPUS may issue implementing instructions, procedures and guidelines for retrospective, concurrent and prospective review.

(3) Contractor implementation. The CHAMPUS Quality and Utilization Review Peer Review Organization program may be implemented through contracts administered by the Director, OCHAMPUS. These contractors may include contractors that have exclusive functions in the area of utilization and quality review, fiscal intermediary contractors (which perform these functions along with a broad range of administrative services), and managed care contractors (which perform a range of functions concerning management of the delivery and financing of health care services under CHAMPUS). Regardless of the contractors involved, utilization and quality review activities follow the same standards, rules and procedures set forth in this section, unless otherwise specifically provided in this section or elsewhere in this part.

(4) Medical issues affected. The CHAMPUS Quality and Utilization Review Peer Review Organization program is distinguishable in purpose and impact from other activities relating to the administration and management of CHAMPUS in that the Peer Review Organization program is concerned primarily with medical judgments regarding the quality and appropriateness of health care services. Issues regarding such matters as benefit limitations are similar, but, if not determined on the basis of medical judgments, are governed by CHAMPUS rules and procedures other than those provided in this section. (See, for example, Sec. 199.7 regarding claims submission, review and payment.) Based on this purpose, a major attribute of the Peer Review Organization program is that medical judgments are made by (directly or pursuant to guidelines and subject to direct review) reviewers who are peers of the health care providers providing the services under review.

(5) Provider responsibilities. Because of the dominance of medical judgments in the quality and utilization review program, principal responsibility for complying with program rules and procedures rests with health care providers. For this reason, there are limitations, set forth in this section and in Sec. 199.4(h), on the extent to which beneficiaries may be held financially liable for health care services not provided in conformity with rules and procedures of the quality and utilization review program concerning medical necessity of care.

(6) Medicare rules used as model. **The CHAMPUS Quality and Utilization Review Peer Review Organization program, based on specific statutory authority, follows many of the**

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quality and utilization review requirements and procedures in effect for the Medicare Peer Review Organization program, subject to adaptations appropriate for the CHAMPUS program. In recognition of the similarity of purpose and design between the Medicare and CHAMPUS PRO programs, and to avoid unnecessary duplication of effort, the CHAMPUS Quality and Utilization Review Peer Review Organization program will have special procedures applicable to supplies and services furnished to Medicare-eligible CHAMPUS beneficiaries. These procedures will enable CHAMPUS normally to rely upon Medicare determinations of medical necessity and appropriateness in the processing of CHAMPUS claims as a second payer to Medicare. As a general rule, only in cases involving Medicare-eligible CHAMPUS beneficiaries where Medicare payment for services and supplies is denied for reasons other than medical necessity and appropriateness will the CHAMPUS claim be subject to review for quality of care and appropriate utilization under the CHAMPUS PRO program. TRICARE will continue to perform a medical necessity and appropriateness review for quality of care and appropriate utilization under the CHAMPUS PRO program where required by statute.

**(b) Objectives and general requirements of review system--**(1) In general. Broadly, the program of quality and utilization review has as its objective to review the quality, completeness and adequacy of care provided, as well as its necessity, appropriateness and reasonableness.

(2) Payment exclusion for services provided contrary to utilization and quality standards. (i) In any case in which health care services are provided in a manner determined to be contrary to quality or necessity standards established under the quality and utilization review program, payment may be wholly or partially excluded.

(ii) In any case in which payment is excluded pursuant to paragraph (b)(2)(i) of this section, the patient (or the patient's family) may not be billed for the excluded services.

(iii) Limited exceptions and other special provisions pertaining to the requirements established in paragraphs (b)(2)(i) and (ii) of this section, are set forth in Sec. 199.4(h).

(3) Review of services covered by DRG-based payment system. Application of these objectives in the context of hospital services covered by the DRG-based payment system also includes a validation of diagnosis and procedural information that determines CHAMPUS reimbursement, and a review of the necessity and appropriateness of care for which payment is sought on an outlier basis.

(4) Preauthorization and other utilization review procedures--(i) In general. all health care services for which payment is sought under TRICARE are subject to review for appropriateness of utilization as determined by the Director, TRICARE Management Activity, or a designee.

(A) The procedures for this review may be prospective (before the care is provided), concurrent (while the care is in process), or retrospective (after the care has been provided). Regardless of the procedures of this utilization review, the same generally accepted standards, norms and criteria for evaluating the medical necessity, appropriateness and reasonableness of the care involved shall apply. The Director, TRICARE Management Activity, or a designee, shall establish procedures for conducting reviews, including types of health care services for which preauthorization or concurrent review shall be required.

Preauthorization or concurrent review may be required for categories of health care services. Except where required by law, the categories of health care services for which preauthorization or concurrent review is required may vary in different geographical locations or for different types of providers.

(B) For healthcare services provided under TRICARE contracts entered into by the Department of Defense after October 30, 2000, medical necessity preauthorization will not be required for referrals for specialty consultation appointment services requested by primary care providers or specialty providers when referring TRICARE Prime beneficiaries for specialty consultation appointment services within the TRICARE contractor's network. However, the lack of medical necessity preauthorization requirements for consultative appointment services does not mean that non-emergent admissions or invasive diagnostic or therapeutic procedures which in and of themselves constitute categories of health care services related to, but beyond the level of the consultation appointment service, are not subject to medical necessity prior authorization. In fact many such health care services may continue to require medical necessity prior authorization as determined by the Director, TRICARE Management Activity, or a designee. TRICARE Prime beneficiaries are also required to obtain preauthorization before seeking health care services from a non-network provider.

(ii) Preauthorization procedures. With respect to categories of health care (inpatient or outpatient) for which preauthorization is required, the following procedures shall apply:

(A) The requirement for preauthorization shall be widely publicized to beneficiaries and providers.

(B) All requests for preauthorization shall be responded to in writing. Notification of approval or denial shall be sent to the beneficiary. Approvals shall specify the health care services and supplies approved and identify any special limits or further requirements applicable to the particular case.

(C) An approved preauthorization shall state the number of days, appropriate for the type of care involved, for which it is valid. In general, preauthorizations will be valid for 30 days. If the services or supplies are not obtained within the number of days specified, a new preauthorization request is required. For organ and stem cell transplants, the preauthorization shall remain in effect as long as the beneficiary continues to meet the specific transplant criteria set forth in the TRICARE/CHAMPUS Policy Manual, or until the approved transplant occurs.

(D) For healthcare services provided under TRICARE contracts entered into by the Department of Defense after October 30, 2000, medical necessity preauthorization for specialty consultation appointment services within the TRICARE contractor's network will not be required. However, the Director, TRICARE Management Activity, or designee, may continue to require or waive medical necessity prior (or pre) authorization for other categories of other health care services based on best business practice.

(iii) Payment reduction for noncompliance with required utilization review procedures. (A) Paragraph (b)(4)(iii) of this section applies to any case in which:

(1) A provider was required to obtain preauthorization or continued stay (in connection

with required concurrent review procedures) approval.

- (2) The provider failed to obtain the necessary approval; and
- (3) The health care services have not been disallowed on the basis of necessity, appropriateness or reasonableness.

In such a case, reimbursement will be reduced, unless such reduction is waived based on special circumstances.

(B) In a case described in paragraph (b)(4)(iii)(A) of this section, reimbursement will be reduced, unless such reduction is waived based on special circumstances. The amount of this reduction shall be at least ten percent of the amount otherwise allowable for services for which preauthorization (including preauthorization for continued stays in connection with concurrent review requirements) approval should have been obtained, but was not obtained.

(C) The payment reduction set forth in paragraph (b)(4)(iii)(B) of this section may be waived by the Director, OCHAMPUS when the provider could not reasonably have been expected to know of the preauthorization requirement or some other special circumstance justifies the waiver.

(D) Services for which payment is disallowed under paragraph (b)(4)(iii) of this section may not be billed to the patient (or the patient's family).

**(c) Hospital cooperation.** All hospitals which participate in CHAMPUS and submit CHAMPUS claims are required to provide all information necessary for CHAMPUS to properly process the claims. In order for CHAMPUS to be assured that services for which claims are submitted meet quality of care standards, hospitals are required to provide the Peer Review Organization (PRO) responsible for quality review with all the information, within timeframes to be established by OCHAMPUS, necessary to perform the review functions required by this paragraph. Additionally, all participating hospitals shall provide CHAMPUS beneficiaries, upon admission, with information about the admission and quality review system including their appeal rights. A hospital which does not cooperate in this activity shall be subject to termination as a CHAMPUS-authorized provider.

(1) Documentation that the beneficiary has received the required information about the CHAMPUS PRO program must be maintained in the same manner as is the notice required for the Medicare program by 42 CFR 466.78(b).

(2) The physician acknowledgment required for Medicare under 42 CFR 412.46 is also required for CHAMPUS as a condition for payment and may be satisfied by the same statement as required for Medicare, with substitution or addition of "CHAMPUS" when the word "Medicare" is used.

(3) Participating hospitals must execute a memorandum of understanding with the PRO providing appropriate procedures for implementation of the PRO program.

(4) Participating hospitals may not charge a CHAMPUS beneficiary for inpatient hospital services excluded on the basis of Sec. 199.4(g)(1) (not medically necessary), Sec. 199.4(g)(3) (inappropriate level), or Sec. 199.4(g)(7) (custodial care) unless all of the conditions

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established by 42 CFR 412.42(c) with respect to Medicare beneficiaries have been met with respect to the CHAMPUS beneficiary. In such cases in which the patient requests a PRO review while the patient is still an inpatient in the hospital, the hospital shall provide to the PRO the records required for the review by the close of business of the day the patient requests review, if such request was made before noon. If the hospital fails to provide the records by the close of business, that day and any subsequent working day during which the hospital continues to fail to provide the records shall not be counted for purposes of the two-day period of 42 CFR 412.42(c)(3)(ii).

**(d) Areas of review--**(1) Admissions. The following areas shall be subject to review to determine whether inpatient care was medically appropriate and necessary, was delivered in the most appropriate setting and met acceptable standards of quality. This review may include preadmission or prepayment review when appropriate.

(i) Transfers of CHAMPUS beneficiaries from a hospital or hospital unit subject to the CHAMPUS DRG-based payment system to another hospital or hospital unit.

(ii) CHAMPUS admissions to a hospital or hospital unit subject to the CHAMPUS DRG-based payment system which occur within a certain period (specified by OCHAMPUS) of discharge from a hospital or hospital unit subject to the CHAMPUS DRG-based payment system.

(iii) A random sample of other CHAMPUS admissions for each hospital subject to the CHAMPUS DRG-based payment system.

(iv) CHAMPUS admissions in any DRGs which have been specifically identified by OCHAMPUS for review or which are under review for any other reason.

(2) DRG validation. The review organization responsible for quality of care reviews shall be responsible for ensuring that the diagnostic and procedural information reported by hospitals on CHAMPUS claims which is used by the fiscal intermediary to assign claims to DRGs is correct and matches the information contained in the medical records. In order to accomplish this, the following review activities shall be done.

(i) Perform DRG validation reviews of each case under review.

(ii) Review of claim adjustments submitted by hospitals which result in the assignment of a higher weighted DRG.

(iii) Review for physician's acknowledgement of annual receipt of the penalty statement as contained in the Medicare regulation at 42 CFR 412.46.

(iv) Review of a sample of claims for each hospital reimbursed under the CHAMPUS DRG-based payment system. Sample size shall be determined based upon the volume of claims submitted.

(3) Outlier review. Claims which qualify for additional payment as a long-stay outlier or as a cost-outlier shall be subject to review to ensure that the additional days or costs were medically necessary and appropriate and met all other requirements for CHAMPUS coverage. In addition, claims which qualify as short-stay outliers shall be reviewed to ensure

that the admission was medically necessary and appropriate and that the discharge was not premature.

(4) Procedure review. Claims for procedures identified by OCHAMPUS as subject to a pattern of abuse shall be the subject of intensified quality assurance review.

(5) Other review. Any other cases or types of cases identified by OCHAMPUS shall be subject to focused review.

**(e) Actions as a result of review--**(1) Findings related to individual claims. If it is determined, based upon information obtained during reviews, that a hospital has misrepresented admission, discharge, or billing information, or is found to have quality of care defects, or has taken an action that results in the unnecessary admissions of an individual entitled to benefits, unnecessary multiple admission of an individual, or other inappropriate medical or other practices with respect to beneficiaries or billing for services furnished to beneficiaries, the PRO, in conjunction with the fiscal intermediary, shall, as appropriate:

(i) Deny payment for or recoup (in whole or in part) any amount claimed or paid for the inpatient hospital and professional services related to such determination.

(ii) Require the hospital to take other corrective action necessary to prevent or correct the inappropriate practice.

(iii) Advise the provider and beneficiary of appeal rights, as required by Sec. 199.10 of this part.

(iv) Notify OCHAMPUS of all such actions.

(2) Findings related to a pattern of inappropriate practices. In all cases where a pattern of inappropriate admissions and billing practices that have the effect of circumventing the CHAMPUS DRG-based payment system is identified, OCHAMPUS shall be notified of the hospital and practice involved.

(3) Revision of coding relating to DRG validation. The following provisions apply in connection with the DRG validation process set forth in paragraph (d)(2) of this section.

(i) If the diagnostic and procedural information in the patient's medical record is found to be inconsistent with the hospital's coding or DRG assignment, the hospital's coding on the CHAMPUS claim will be appropriately changed and payments recalculated on the basis of the appropriate DRG assignment.

(ii) If the information stipulated under paragraph (d)(2) of this section is found not to be correct, the PRO will change the coding and assign the appropriate DRG on the basis of the changed coding.

**(f) Special procedures in connection with certain types of health care services or certain types of review activities--**(1) In general. Many provisions of this section are directed to the context of services covered by the CHAMPUS DRG-based payment system. This section, however, is also applicable to other services. In addition, many provisions of

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this section relate to the context of peer review activities performed by Peer Review Organizations whose sole functions for CHAMPUS relate to the Quality and Utilization Review Peer Review Organization program. However, it also applies to review activities conducted by contractors who have responsibilities broader than those related to the quality and utilization review program. Paragraph (f) of this section authorizes certain special procedures that will apply in connection with such services and such review activities.

(2) Services not covered by the DRG-based payment system. In implementing the quality and utilization review program in the context of services not covered by the DRG-based payment system, the Director, OCHAMPUS may establish procedures, appropriate to the types of services being reviewed, substantively comparable to services covered by the DRG-based payment system regarding obligations of providers to cooperate in the quality and utilization review program, authority to require appropriate corrective actions and other procedures. The Director, OCHAMPUS may also establish such special, substantively comparable procedures in connection with review of health care services which, although covered by the DRG-based payment method, are also affected by some other special circumstances concerning payment method, nature of care, or other potential utilization or quality issue.

(3) Peer review activities by contractors also performing other administration or management functions--(i) Sole-function PRO versus multi-function PRO. In all cases, peer review activities under the Quality and Utilization Review Peer Review Organization program are carried out by physicians and other qualified health care professionals, usually under contract with OCHAMPUS. In some cases, the Peer Review Organization contractor's only functions are pursuant to the quality and utilization review program. In paragraph (f)(3) of this section, this type of contractor is referred to as a "sole function PRO." In other cases, the Peer Review Organization contractor is also performing other functions in connection with the administration and management of CHAMPUS. In paragraph (f)(3) of this section, this type of contractor is referred to as a "multi-function PRO." As an example of the latter type, managed care contractors may perform a wide range of functions regarding management of the delivery and financing of health care services under CHAMPUS, including but not limited to functions under the Quality and Utilization Review Peer Review Organization program.

(ii) Special rules and procedures. With respect to multi-function PROs, the Director, OCHAMPUS may establish special procedures to assure the independence of the Quality and Utilization Review Peer Review Organization program and otherwise advance the objectives of the program. These special rules and procedures include, but are not limited to, the following:

(A) A reconsidered determination that would be final in cases involving sole-function PROs under paragraph (i)(2) of this section will not be final in connection with multi-function PROs. Rather, in such cases (other than any case which is appealable under paragraph (i)(3) of this section), an opportunity for a second reconsideration shall be provided. The second reconsideration will be provided by OCHAMPUS or another contractor independent of the multi-function PRO that performed the review. The second reconsideration may not be further appealed by the provider.

(B) Procedures established by paragraphs (g) through (m) of this section shall not apply to any action of a multi-function PRO (or employee or other person or entity affiliated with the

PRO) carried out in performance of functions other than functions under this section.

**(g) Procedures regarding initial determinations.** The CHAMPUS PROs shall establish and follow procedures for initial determinations that are substantively the same or comparable to the procedures applicable to Medicare under 42 CFR 466.83 to 466.104. In addition, these procedures shall provide that a PRO's determination that an admission is medically necessary is not a guarantee of payment by CHAMPUS; normal CHAMPUS benefit and procedural coverage requirements must also be applied.

**(h) Procedures regarding reconsiderations.** The CHAMPUS PROs shall establish and follow procedures for reconsiderations that are substantively the same or comparable to the procedures applicable to reconsiderations under Medicare pursuant to 42 CFR 473.15 to 473.34, except that the time limit for requesting reconsideration (see 42 CFR 473.20(a)(1)) shall be 90 days. A PRO reconsidered determination is final and binding upon all parties to the reconsideration except to the extent of any further appeal pursuant to paragraph (i) of this section.

**(i) Appeals and hearings.** (1) Beneficiaries may appeal a PRO reconsideration determination of OCHAMPUS and obtain a hearing on such appeal to the extent allowed and under the procedures set forth in Sec. 199.10(d).

(2) Except as provided in paragraph (i)(3), a PRO reconsidered determination may not be further appealed by a provider.

(3) A provider may appeal a PRO reconsideration determination to OCHAMPUS and obtain a hearing on such appeal to the extent allowed under the procedures set forth in Sec. 199.10(d) if it is a determination pursuant to Sec. 199.4(h) that the provider knew or could reasonably have been expected to know that the services were excludable.

(4) For purposes of the hearing process, a PRO reconsidered determination shall be considered as the procedural equivalent of a formal review determination under Sec. 199.10, unless revised at the initiative of the Director, OCHAMPUS prior to a hearing on the appeal, in which case the revised determination shall be considered as the procedural equivalent of a formal review determination under Sec. 199.10.

(5) The provisions of Sec. 199.10(e) concerning final action shall apply to hearings cases.

**(j) Acquisition, protection and disclosure of peer review information.** The provisions of 42 CFR part 476, except Sec. 476.108, shall be applicable to the CHAMPUS PRO program as they are to the Medicare PRO program.

**(k) Limited immunity from liability for participants in PRO program.** The provisions of section 1157 of the Social Security Act (42 U.S.C. 1320c-6) are applicable to the CHAMPUS PRO program in the same manner as they apply to the Medicare PRO program. Section 1102(g) of title 10, United States Code also applies to the CHAMPUS PRO program.

**(l) Additional provision regarding confidentiality of records--**(1) General rule. The provisions of 10 U.S.C. 1102 regarding the confidentiality of medical quality assurance records shall apply to the activities of the CHAMPUS PRO program as they do to the

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activities of the external civilian PRO program that reviews medical care provided in military hospitals.

(2) Specific applications. (i) Records concerning PRO deliberations are generally nondisclosable quality assurance records under 10 U.S.C. 1102.

(ii) Initial denial determinations by PROs pursuant to paragraph (g) of this section (concerning medical necessity determinations, DRG validation actions, etc.) and subsequent decisions regarding those determinations are not nondisclosable quality assurance records under 10 U.S.C. 1102.

(iii) Information the subject of mandatory PRO disclosure under 42 CFR part 476 is not a nondisclosable quality assurance record under 10 U.S.C. 1102.

**(m) Obligations, sanctions and procedures.** (1) The provisions of 42 CFR 1004.1-1004.80 shall apply to the CHAMPUS PRO program as they do the Medicare PRO program, except that the functions specified in those sections for the Office of Inspector General of the Department of Health and Human Services shall be the responsibility of OCHAMPUS.

(2) The provisions of 42 U.S.C. section 1395ww(f)(2) concerning circumvention by any hospital of the applicable payment methods for inpatient services shall apply to CHAMPUS payment methods as they do to Medicare payment methods.

(3) The Director, or a designee, of CHAMPUS shall determine whether to impose a sanction pursuant to paragraphs (m)(1) and (m)(2) of this section. Providers may appeal adverse sanctions decisions under the procedures set forth in Sec. 199.10(d).

**(n) Authority to integrate CHAMPUS PRO and military medical treatment facility utilization review activities.** (1) In the case of a military medical treatment facility (MTF) that has established utilization review requirements similar to those under the CHAMPUS PRO program, the contractor carrying out this function may, at the request of the MTF, utilize procedures comparable to the CHAMPUS PRO program procedures to render determinations or recommendations with respect to utilization review requirements.

(2) In any case in which such a contractor has comparable responsibility and authority regarding utilization review in both an MTF (or MTFs) and CHAMPUS, determinations as to medical necessity in connection with services from an MTF or CHAMPUS-authorized provider may be consolidated.

(3) In any case in which an MTF reserves authority to separate an MTF determination on medical necessity from a CHAMPUS PRO program determination on medical necessity, the MTF determination is not binding on CHAMPUS.

[55 FR 625, Jan. 8, 1990, as amended at 58 FR 58961, Nov. 5, 1993; 60 FR 52095, Oct. 5, 1995; 63 FR 48447, Sep. 10, 1998; 66 FR 40608, Aug. 3, 2001; 67 FR 42721, Jun. 25, 2002; 68 FR 23033, Apr. 30, 2003; 68 FR 32363, May 30, 2003; 68 FR 44881, Jul. 31, 2003; 70 FR 19266, Apr. 13, 2005; 81 FR 61098, Sep 2, 2016]



UNIFORM HMO BENEFIT

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## PART 199.18 - UNIFORM HMO BENEFIT

**(a) In general.** There is established a Uniform HMO Benefit. The purpose of the Uniform HMO benefit is to establish a health benefit option modeled on health maintenance organization plans. This benefit is intended to be uniform wherever offered throughout the United States and to be included in all managed care programs under the MHSS. Most care purchased from civilian health care providers (outside an MTF) will be under the rules of the Uniform HMO Benefit or the Basic CHAMPUS Program (see Sec. 199.4). The Uniform HMO Benefit shall apply only as specified in this section or other sections of this part, and shall be subject to any special applications indicated in such other sections.

**(b) Services covered under the uniform HMO benefit option.** (1) Except as specifically provided or authorized by this section, all CHAMPUS benefits provided, and benefit limitations established, pursuant to this part, shall apply to the Uniform HMO Benefit.

(2) Certain preventive care services not normally provided as part of basic program benefits under CHAMPUS are covered benefits when provided to Prime enrollees by providers in the civilian provider network. Standards for preventive care services shall be developed based on guidelines from the U.S. Department of Health and Human Services. Such standards shall establish a specific schedule, including frequency or age specifications for:

- (i) Laboratory and x-ray tests, including blood lead, rubella, cholesterol, fecal occult blood testing, and mammography;
- (ii) Pap smears;
- (iii) Eye exams;
- (iv) Immunizations;
- (v) Periodic health promotion and disease prevention exams;
- (vi) Blood pressure screening;
- (vii) Hearing exams;
- (viii) Sigmoidoscopy or colonoscopy;
- (ix) Serologic screening; and
- (x) Appropriate education and counseling services. The exact services offered shall be established under uniform standards established by the Assistant Secretary of Defense (Health Affairs).

(3) In addition to preventive care services provided pursuant to paragraph (b)(2) of this section, other benefit enhancements may be added and other benefit restrictions may be

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waived or relaxed in connection with health care services provided to include the Uniform HMO Benefit. Any such other enhancements or changes must be approved by the Assistant Secretary of Defense (Health Affairs) based on uniform standards.

**(c) Enrollment fee under the uniform HMO benefit.** (1) The CHAMPUS annual deductible amount (see Sec. 199.4(f)) is waived under the Uniform HMO Benefit during the period of enrollment. In lieu of a deductible amount, an annual enrollment fee is applicable. The specific enrollment fee requirements shall be published annually by the Assistant Secretary of Defense (Health Affairs), and shall be uniform within the following groups: dependents of active duty members in pay grades of E-4 and below; active duty dependents of sponsors in pay grades E-5 and above; and retirees and their dependents. **As an exception to the requirement for uniformity within the group of retirees and their dependents, the Assistant Secretary of Defense (Health Affairs) may exempt Survivors of Active Duty Deceased Sponsors and Medically Retired Uniformed Services Members and their Dependents from future increases in enrollment fees.**

(2) Amount of enrollment fees. In fiscal year 2001, the annual enrollment fee for retirees and their dependents is \$230 individual, \$460 family.

(3) Waiver of enrollment fee for certain beneficiaries. The Assistant Secretary of Defense (Health Affairs) may waive the enrollment fee requirements of this section for Medicare-eligible beneficiaries.

**(d) Outpatient cost sharing requirements under the uniform HMO benefit--**(1) In general. In lieu of usual CHAMPUS cost sharing requirements (see Sec. 199.4(f)), special reduced cost sharing percentages or per service specific dollar amounts are required. The specific requirements shall be uniform and shall be published periodically by the Assistant Secretary of Defense (Health Affairs). For care provided on or after April 1, 2001, no copayment shall be charged for care provided under TRICARE Prime to a dependent of an active duty member, except for the copayments charged under the Pharmacy Benefits Program (see Sec. 199.21) and under the point of service option of TRICARE Prime (see Sec. 199.17(n)(4)).

(2) Structure of outpatient cost sharing. The special cost sharing requirements for outpatient services include the following specific structural provisions:

(i) For most physician office visits and other routine services, there is a per visit fee for retirees and their dependents. This fee applies to primary care and specialty care visits, except as provided elsewhere in this paragraph (d)(2) of this section. It also applies to family health services, home health care visits, eye examinations, and immunizations. It does not apply to ancillary health services or to preventive health services described in paragraph (b)(2) of this section, or to maternity services under Sec. 199.4(e)(16).

**(ii) The per visit fee provided in paragraph (d)(2)(i) of this section shall also apply to partial hospitalization services, intensive outpatient treatment, and opioid treatment program services. The per visit fee shall be applied on a per day basis on days services are received, with the exception of opioid treatment program services reimbursed in accordance with Sec. 199.14(a)(2)(ix)(A)(3)(i) which per visit fee will apply on a weekly basis.**

**(iii) [Reserved]**

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- (iv) For emergency room services, there is a per visit fee for retirees and their dependents.
  - (v) For ambulatory surgery services, there is a per service fee for retirees and their dependents.
  - (vi) There is a copayment for prescription drugs per prescription, including medical supplies necessary for administration, for dependents of active duty members and for retirees and their dependents under the Pharmacy Benefits Program (see Sec. 199.17(m)(5)).
  - (vii) There is a copayment for ambulance services for retirees and their dependents.
- (3) Amount of outpatient cost sharing requirements. In fiscal year 2001, the outpatient cost sharing requirements are as follows:
- (i) For most physician office visits and other routine services, as described in paragraph (d)(2)(i) of this section, the per visit fee for retirees and their dependents is \$12.
  - (ii) For outpatient mental health visits, the per visit fee for retirees and their dependents is \$25. For group outpatient mental health visits, there is a lower per visit fee for retirees and their dependents of \$17.
  - (iii) The cost share for durable medical equipment, prosthetic devices, and other authorized supplies for retirees and their dependents is 20 percent of the negotiated fee.
  - (iv) For emergency room services, the per visit fee for retirees and their dependents is \$30.
  - (v) For primary surgeon services in ambulatory surgery, the per service fee for retirees and their dependents is \$25.
  - (vi) The copayments for prescription drugs are established under the Pharmacy Benefits Program (see Sec. 199.21).
  - (vii) The copayment for ambulance services for retirees and their dependents is \$20.

**(e) Inpatient cost sharing requirements under the uniform HMO benefit--**(1) In general. In lieu of usual CHAMPUS cost sharing requirements (see Sec. 199.4(f)), special cost sharing amounts are required. The specific requirements shall be uniform and shall be published periodically by the Assistant Secretary of Defense (Health Affairs). For services provided on or after April 1, 2001, no co-payment shall be charged for inpatient care provided under TRICARE Prime to a dependent of an active duty member except under the point of service option of TRICARE Prime (see Sec. 199.17(n)(4)). In addition, for services provided on or after April 1, 2001, no copayment shall be charged for inpatient care provided under TRICARE Prime to a dependent of an active duty member in military medical treatment facilities.

(2) **Structure of cost-sharing.** For inpatient admissions, there is a nominal copayment for retired members, dependents of retired members, and survivors. This nominal copayment shall apply to an inpatient admission to any hospital or other authorized institutional provider, including inpatient admission to a residential treatment center, substance use disorder rehabilitation facility residential treatment program, or skilled nursing facility.

(3) Amount of inpatient cost-sharing requirements. In fiscal year 2001, the inpatient cost-sharing requirements for retirees and their dependents for acute care admissions and other inpatient admissions is a per diem charge of \$11, with a minimum charge of \$25 per admission.

**(f) Limit on out-of-pocket costs under the uniform HMO benefit.** (1) Total out-of-pocket costs per family of dependents of active duty members under the Uniform HMO Benefit may not exceed \$1,000 during the one-year enrollment period. Total out-of-pocket costs per family of retired members, dependents of retired members and survivors under the Uniform HMO Benefit may not exceed \$3,000 during the one-year enrollment period. For this purpose, out-of-pocket costs means all payments required of beneficiaries under paragraphs (c), (d), and (e) of this section. In any case in which a family reaches this limit, all remaining payments that would have been required of the beneficiary under paragraphs (c), (d), and (e) of this section will be made by the program in which the Uniform HMO Benefit is in effect.

(2) The limits established by paragraph (f)(1) of this section do not apply to out-of-pocket costs incurred pursuant to paragraph (m)(1)(i) or (m)(2)(i) of Sec. 199.17 under the point-of-service option of TRICARE Prime.

**(g) Updates.** The enrollment fees for fiscal year 2001 set under paragraph (c) of this section and the per service specific dollar amounts for fiscal year 2001 set under paragraphs (d) and (e) of this section may be updated for subsequent years to the extent necessary to maintain compliance with statutory requirements pertaining to government costs. This updating does not apply to cost sharing that is expressed as a percentage of allowable charges; these percentages will remain unchanged.

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