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MANAGEMENT ACTIVITY

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

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

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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) Prescription drugs and medicines. Prescription drugs and medicines that by United States law require a physician's or other authorized individual professional provider's prescription (acting within the scope of their license) and that are ordered or prescribed by a physician or other authorized individual professional provider (except that insulin is covered for a known diabetic, even though a prescription may not be required for its purchase) in connection with an otherwise covered condition or treatment, including 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.

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(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 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.

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- (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) Treatment of substance use disorders. Emergency and inpatient hospital care for complications of alcohol and drug abuse or dependency and detoxification are covered as for any other medical condition. Specific coverage for the treatment of substance use disorders includes detoxification, rehabilitation, and outpatient care provided in authorized substance use disorder rehabilitation facilities.

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

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

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

services provided by the substance use disorder rehabilitation facility must be under general medical supervision.

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

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

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

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

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

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

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

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

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

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

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

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- (A) General. (1) Benefits may be allowed for medically necessary services and supplies related to an organ transplant for:
- (i) Evaluation of potential candidate's suitability for an organ transplant, whether or not the patient is ultimately accepted as a candidate for transplant.
 - (ii) Pre- and post-transplant inpatient hospital and outpatient services.
 - (iii) Pre- and post-operative services of the transplant team.
 - (iv) Blood and blood products.
 - (v) FDA approved immunosuppression drugs to include off-label uses when determined to be medically necessary for the treatment of the condition for which it is administered, according to accepted standards of medical practice.
 - (vi) Complications of the transplant procedure, including inpatient care, management of infection and rejection episodes.
 - (vii) Periodic evaluation and assessment of the successfully transplanted patient.
 - (viii) The donor acquisition team, including the costs of transportation to the location of the donor organ and transportation of the team and the donated organ to the location of the transplant center.
 - (ix) The maintenance of the viability of the donor organ after all existing legal requirements for excision of the donor organ have been met.
- (2) TRICARE benefits are payable for recipient costs when the recipient of the transplant is a CHAMPUS beneficiary, whether or not the donor is a CHAMPUS beneficiary.
- (3) Donor costs are payable when:
- (i) Both the donor and recipient are CHAMPUS beneficiaries.
 - (ii) The donor is a CHAMPUS beneficiary but the recipient is not.
 - (iii) The donor is the sponsor and the recipient is a CHAMPUS beneficiary. (In such an event, donor costs are paid as a part of the beneficiary and recipient costs.)
 - (iv) The donor is neither a CHAMPUS beneficiary nor a sponsor, if the recipient is a CHAMPUS beneficiary. (Again, in such an event, donor costs are paid as a part of the beneficiary and recipient costs.)
- (4) If the donor is not a CHAMPUS beneficiary, TRICARE benefits for donor costs are limited to those directly related to the transplant procedure itself and do not include any medical care costs related to other treatment of the donor, including complications.
- (5) TRICARE benefits will not be allowed for transportation of an organ donor.

(B) (Reserved)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(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.

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- (O) Electrolysis.
- (P) Any procedures related to transsexualism or such other conditions as gender dysphoria except as provided in paragraph (e)(7) of this section.
- (Q) Penile implant procedure for psychological impotency, transsexualism, or such other conditions as gender dysphoria.
- (R) Insertion of prosthetic testicles for transsexualism, or such other conditions as gender dysphoria.
- (9) Complications (unfortunate sequelae) resulting from noncovered initial surgery or treatment. Benefits are available for otherwise covered services and supplies required in the treatment of complications resulting from a noncovered incident of treatment (such as nonadjunctive dental care, transsexual surgery, and 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 procedures related to the complication that essentially is similar to the initial noncovered 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 or repair of a prolapsed vagina in a biological male who had undergone transsexual surgery.
- (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 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:

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

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

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

(vi) Anesthesia and institutional costs for dental care for children and certain other patients. Institutional benefits specified in paragraph (b) of this section may be extended for hospital and in-out surgery settings related to noncovered, nonadjunctive dental care when such outpatient care or inpatient stay is in conjunction with dental treatment for patients with developmental, mental, or physical disabilities or for pediatric patients age 5 or under. For these patients, anesthesia services will be limited to the administration of general anesthesia only. Patients with developmental, mental, or physical disabilities are those patients with conditions that prohibit dental treatment in a safe and effective manner. Therefore, it is medically or psychologically necessary for these patients to require general

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

(11) Drug abuse. Under the Basic Program, benefits may be extended for medically necessary prescription drugs required in the treatment of an illness or injury or in connection with maternity care (refer to paragraph (d) of this section). However, CHAMPUS 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.

(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) Drug maintenance programs excluded. Drug maintenance programs when one addictive drug is substituted for another on a maintenance basis (such as methadone substituted for heroin) are not covered. This exclusion applies even in areas outside the United States where addictive drugs are dispensed legally by physicians on a maintenance dosage level.

(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.

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

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

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

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

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

(12) (Reserved)

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

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

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

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

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

(ii) Benefits available in connection with a domiciliary care case. Should the beneficiary receive otherwise covered medical services or supplies while also being in a

domiciliary care situation, CHAMPUS benefits are payable for those medical services or supplies, or both, in the same manner as though the beneficiary resided in his or her own home. Such benefits would be cost-shared as though rendered to an outpatient.

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

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

- (A) The patient is referred for the diagnostic procedure by a physician.
 - (B) The CT scan procedure is consistent with the preliminary diagnosis or symptoms.
 - (C) Other noninvasive and less costly means of diagnosis have been attempted or are not appropriate.
 - (D) The CT scan equipment is licensed or registered by the appropriate state agency responsible for licensing or registering medical equipment that emits ionizing radiation.
 - (E) The CT scan equipment is operated under the general supervision and direction of a physician.
 - (F) The results of the CT scan diagnostic procedure are interpreted by a physician.
- (ii) Review guidelines and criteria. The Director, OCHAMPUS, or a designee, will issue specific guidelines and criteria for CHAMPUS coverage of medically necessary head and body part CT scans.

(15) Morbid obesity. The CHAMPUS morbid obesity benefit is limited to the gastric bypass, gastric stapling, or gastroplasty method.

- (i) Conditions for coverage. Payment may be extended for the gastric bypass, gastric stapling, or gastroplasty method only when one of the following conditions is met:
- (A) The patient is 100 pounds over the ideal weight for height and bone structure and has an associated severe medical condition. These associated medical conditions are diabetes mellitus, hypertension, cholecystitis, narcolepsy, pickwickian syndrome (and other severe respiratory disease), hypothalamic disorders, and severe arthritis of the weight-bearing joints.
 - (B) The patient is 200 percent or more of the ideal weight for height and bone structure. An associated medical condition is not required for this category.
 - (C) The patient has had an intestinal bypass or other surgery for obesity and, because of

complications, requires a second surgery (a takedown). The surgeon in many cases, will do a gastric bypass, gastric stapling, 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.

(ii) Exclusions.(A) CHAMPUS payment may not be made for nonsurgical treatment of obesity or morbid obesity, for dietary control, or weight reduction.

(B) CHAMPUS payment may not be made for surgical procedures other than the gastric bypass, gastric stapling, or gastroplasty, even if morbid obesity is present.

(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.

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

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

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

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

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

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

(A) Physician services.

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

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

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

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

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

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

(D) Counseling services provided to the terminally ill individual and the family member or other persons caring for the individual at home. Counseling, including dietary counseling, may be provided both for the purpose of training the individual's family or other care-giver to provide care, and for the purpose of helping the individual and those caring for him or her

to adjust to the individual's approaching death. Bereavement counseling, which consists of counseling services provided to the individual's family after the individual's death, is a required hospice service but it is not reimbursable.

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

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

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

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

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

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

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

(v) Periods of care. Hospice care is divided into distinct periods/episodes of care. The terminally ill beneficiary may elect to receive hospice benefits for an initial period of 90 days, a subsequent period of 90 days, a second subsequent period of 30 days, and a final period of unlimited duration.

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

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

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

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

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

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

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

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

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

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

(B) The terminally ill beneficiary must elect to receive hospice care for each specified period of time; i.e., the two 90-day periods, a subsequent 30-day period, and a final period of unlimited duration. If the individual is found to be mentally incompetent, his or her

representative may file the election statement. Representative means an individual who has been authorized under State law to terminate medical care or to elect or revoke the election of hospice care on behalf of a terminally ill individual who is found to be mentally incompetent.

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

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

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

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

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

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

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

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

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

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

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

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

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- (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

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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

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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.

(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 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.

(2) 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(5) Cost-Sharing under the Military-Civilian Health Services Partnership Program.

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

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

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

(6)–(7) [Reserved]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(A) Treatment that is not related to the unproven drug, device or medical treatment or procedure; e.g., medically necessary in the absence of the unproven treatment.

(B) Treatment which is necessary follow-up to the unproven drug, device or medical treatment or procedure but which might have been necessary in the absence of the unproven treatment.

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

drugs, devices or medical treatment or procedures, all of which are excluded from CHAMPUS benefits:

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

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

sciatic nerve during total hip replacement. Recording SEPs in unconscious head injured patients to assess the status of the somatosensory system. The use of SEPs to define conceptional or gestational age in preterm infants.

(RR) Autolymphocyte therapy (ALT) (immunotherapy used for treating metastatic kidney cancer patients).

(SS) Radioimmunoguided surgery in the detection of cancer.

(TT) Gait analysis (also known as a walk study or electrodynamogram)

(UU) Use of cerebellar stimulators/pacemakers for the treatment of neurologic disorders.

(VV) Signal-averaged ECG.

(WW) Peri-urethral Teflon injections to manage urinary incontinence.

(XX) Extraoperative electrocorticography for stimulation and recording

(YY) Quantitative computed tomography (QCT) for the detection and monitoring of osteoporosis.

(ZZ) [Reserved]

(AAA) Percutaneous transluminal angioplasty in the treatment of obstructive lesions of the carotoid, vertebral and cerebral arteries.

(BBB) Endoscopic third ventriculostomy.

(CCC) Holding therapy--Involves holding the patient in an attempt to achieve interpersonal contact, and to improve the patient's ability to concentrate on learning tasks.

(DDD) In utero fetal surgery.

(EEE) Light therapy for seasonal depression (also known as seasonal affective disorder (SAD)).

(FFF) Dorsal column and deep brain electrical stimulation of treatment of motor function disorder.

(GGG) Chelation therapy, except with products and for indications approved by the FDA.

(HHH) All organ transplants *except* heart, heart-lung, lung, kidney, some bone marrow, liver, liver-kidney, corneal, heart-valve, and kidney-pancreas transplants for Type I diabetics with chronic renal failure who require kidney transplants.

(III) Implantable infusion pumps, *except* for treatment of spasticity, chronic intractable pain, and hepatic artery perfusion chemotherapy for the treatment of primary liver cancer or metastatic colorectal liver cancer.

(JJJ) Services related to the candidiasis hypersensitivity syndrome, yeast syndrome, or gastrointestinal candidiasis (i.e., allergenic extracts of *Candida albicans* for immunotherapy and/or provocation/neutralization).

(KKK) Treatment of chronic fatigue syndrome.

(LLL) Extracorporeal immunoabsorption using protein A columns for conditions other than acute idiopathic thrombocytopenia purpura.

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

(NNN) Laparoscopic myomectomy.

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

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

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

(2) Ovarian cancer.

(3) Testicular cancer.

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

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

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

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

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

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

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

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

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

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

(26) Electrolysis.

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

(28) Obesity, weight reduction. Services and supplies related to obesity or weight reduction whether surgical or nonsurgical; wiring of the jaw or any procedure of similar purpose, regardless of the circumstances under which performed; except that benefits may be provided for the gastric bypass, gastric stapling, or gastroplasty procedures in connection with morbid obesity as provided in paragraph (e)(15) of this section.

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

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

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

(32) Dyslexia.

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

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

(35) Nonprescription contraceptives.

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

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

- (i) Well-child care.
- (ii) Immunizations for individuals age six and older, as recommended by the CDC.
- (iii) Rabies shots.
- (iv) Tetanus shot following an accidental injury.
- (v) Rh immune globulin.
- (vi) Genetic tests as specified in paragraph (e)(3)(ii) of this section.
- (vii) Immunizations and physical examinations provided when required in the case of dependents of active duty military personnel who are traveling outside the United States as a result of an active duty member's assignment and such travel is being performed under orders issued by a Uniformed Service.
- (viii) Screening mammography for asymptomatic women 40 years of age and older, and for high risk women 35 years of age and older, when provided under the terms and conditions contained in the guidelines adopted by the Deputy Assistant Secretary of Defense, Health Services Financing.
- (ix) Cancer screening Papanicolaou (PAP) test for women who are at risk for sexually transmissible diseases, women who have or have had multiple sexual partners (or if their partner has or has had multiple sexual partners), women who smoke cigarettes, and women 18 years of age and older when provided under the terms and conditions contained in the guidelines adopted by the Deputy Assistant Secretary of Defense, Health Services Financing.
- (x) Other cancer screenings authorized by 10 U.S.C. 1079.
- (xi) Health promotion and disease prevention visits (which may include all of the services provided pursuant to Sec. 199.18(b)(2)) may be provided in connection with immunizations and cancer screening examinations authorized by paragraphs (g)(37)(ii) of this section or (g)(37)(viii) through (x) of this section.

(xii) Physical examinations for beneficiaries ages 5 through 11 that are required in connection with school enrollment, and that are provided on or after October 30, 2000.

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

(39) **Counseling.** Counseling services that are not medically necessary in the treatment of a diagnosed medical condition: For example, educational counseling, vocational counseling, nutritional counseling, and counseling for socioeconomic purposes, stress management, lifestyle modification. Services provided by a certified marriage and family therapist, pastoral, or mental health counselor in the treatment of a mental disorder are covered only as specifically provided in Section 199.6. Services provided by alcoholism rehabilitation counselors are covered only when rendered in a CHAMPUS-authorized treatment setting and only when the cost of those services is included in the facility's CHAMPUS-determined allowable cost rate.

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

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

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

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

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

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

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

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

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

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

(43) Exercise/relaxation/comfort devices. Exercise equipment, spas, whirlpools, hot tubs, swimming pools, health club membership or other such charges or items.

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

(45) (Reserved).

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

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

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

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

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

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

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

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

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

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

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

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

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

(70)-(71) [Reserved]

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

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

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

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

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

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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**]

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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(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. 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.

(1) Licensed registered nurses.

(2) Licensed registered physical therapists and occupational therapists.

(3) Licensed registered physical therapists.

(4) Audiologists.

(5) 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.

(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

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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 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,

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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) Mental health counselor. For the purposes of CHAMPUS, a mental health counselor is an individual who meets the following requirements:

(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 3000 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 CHAMPUS 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:

(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

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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 Journal² 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.

(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.

² 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.

(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.

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(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 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.

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(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**]

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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