PART 199.4 - BASIC PROGRAM BENEFITS

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

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

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

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

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

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

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

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

(i) Disclosure of such information is authorized specifically by the beneficiary;

(ii) Disclosure is necessary to permit authorized governmental officials to investigate and prosecute criminal actions, or

(iii) Disclosure is authorized or required specifically under the terms of the Privacy Act or Freedom of Information Act (refer to Sec. 199.1(m) of this part).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(10) (Reserved)

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

(12) (Reserved)

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

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

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

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

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

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

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

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

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

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

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

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

(ii) General staff nursing services.

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

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

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

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

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

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

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

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

(x) Radiation therapy. Includes radioisotopes.

(xi) Physical therapy.

(xii) Oxygen. Includes equipment for its administration.

(xiii) Intravenous injections. Includes solution.

(xiv) Shock therapy.

(xv) Chemotherapy.

(xvi) Renal and peritoneal dialysis.

(xvii) Psychological evaluation tests. When required by the diagnosis.

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

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

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

(3) Covered services and supplies provided by special medical treatment institutions or facilities, other than hospitals or RTCs--(i) Room and board. Includes special diets, laundry services, and other general housekeeping support services (inpatient only).

(ii) General staff nursing services.

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

(iv) Durable medical equipment, medical supplies, and dressings. Includes durable medical equipment, sterile trays, casts, orthopedic hardware and dressings. Use of durable medical equipment is restricted to an inpatient basis.

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

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

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

(vii) Physical therapy.

(viii) Oxygen. Includes equipment for its administration.

(ix) Intravenous injections. Includes solution.

(x) Shock therapy.

(xi) Chemotherapy.

(xii) Psychological evaluation tests. When required by the diagnosis.

(xiii) Renal and peritoneal dialysis.

(xiv) Skilled nursing facility (SNF) services. Covered services in SNFs are the same as provided under Medicare under section 1861(h) and (i) of the Social Security Act (42 U.S.C. 1395x(h) and (i)) and 42 CFR part 409, subparts C and D, except that the Medicare limitation on the number of days of coverage under section 1812(a) and (b) of the Social Security Act (42 U.S.C. 1395d(a) and (b)) and 42 CFR 409.61(b) shall not be applicable under TRICARE. Skilled nursing facility care for each spell of illness shall continue to be provided for as long as medically necessary and appropriate. For a SNF admission to be covered under TRICARE, the beneficiary must have a qualifying hospital stay meaning an inpatient hospital stay of three consecutive days or more, not including the hospital leave day. The beneficiary must enter the SNF within 30 days of leaving the hospital, or within such time as it would be medically appropriate to begin an active course of treatment, where the individual's condition is such that SNF care would not be medically appropriate within 30 days after discharge from a hospital. The skilled services must be for a medical condition that was either treated during the qualifying three-day hospital stay, or started while the beneficiary was already receiving covered SNF care. Additionally, an individual shall be deemed not to have been discharged from a SNF, if within 30 days after discharge from a SNF, the individual is again admitted to a SNF. Adoption by TRICARE of most Medicare coverage standards does not include Medicare coinsurance amounts. Extended care services furnished to an inpatient of a SNF by such SNF (except as provided in paragraphs (b)(3)(xiv)(C), (b)(3)(xiv)(F), and (b)(3)(xiv)(G) of this section) include:

(A) Nursing care provided by or under the supervision of a registered professional nurse;

(B) Bed and board in connection with the furnishing of such nursing care;

(C) Physical or occupational therapy or speech-language pathology services furnished by the SNF or by others under arrangements with them by the facility;

(D) Medical social services;

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

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

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

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

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

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

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

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

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

(iv) Psychological evaluation tests.

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

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

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

(A) Patient has a diagnosable psychiatric disorder.

(B) Patient exhibits patterns of disruptive behavior with evidence of disturbances in family functioning or social relationships and persistent psychological and/or emotional disturbances.

(C) RTC services involve active clinical treatment under an individualized treatment plan that provides for:

(1) Specific level of care, and measurable goals/objectives relevant to each of the problems identified;

(2) Skilled interventions by qualified mental health professionals to assist the patient and/or family;

(3) Time frames for achieving proposed outcomes; and

(4) Evaluation of treatment progress to include timely reviews and updates as appropriate of the patient's treatment plan that reflects alterations in the treatment regimen, the measurable goals/objectives, and the level of care required for each of the patient's problems, and explanations of any failure to achieve the treatment goals/objectives.

(D) Unless therapeutically contraindicated, the family and/or guardian must actively participate in the continuing care of the patient either through direct involvement at the facility or geographically distant family therapy. (In the latter case, the treatment center must document that there has been collaboration with the family and/or guardian in all reviews.)

(5) Extent of institutional benefits--(i) Inpatient room accommodations--
(A) Semiprivate. The allowable costs for room and board furnished an individual patient are payable for semiprivate accommodations in a hospital or other authorized institution, subject to appropriate cost-sharing provisions (refer to paragraph (f) of this section). A semiprivate accommodation is a room containing at least two beds. Therefore, if a room publicly is designated by the institution as a semiprivate accommodation and contains multiple beds, it qualifies as semiprivate for the purpose of CHAMPUS.

(B) Private. A room with one bed that is designated as a private room by the hospital or other authorized institutional provider. The allowable cost of a private room accommodation is covered only under the following conditions:

(1) When its use is required medically and when the attending physician certifies that a

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

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

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

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

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

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

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

(iii) ICU. An ICU is a special segregated unit of a hospital in which patients are concentrated, by reason of serious illness, usually without regard to diagnosis. Special lifesaving techniques and equipment are available regularly and immediately within the unit, and patients are under continuous observation by a nursing staff specially trained and selected for the care of this type of patient. The unit is maintained on a continuing, rather than an intermittent or temporary, basis. It is not a postoperative recovery room or a postanesthesia room. In some large or highly specialized hospitals, the ICUs may be refined further for special purposes, such as for respiratory conditions, cardiac surgery, coronary

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(A) Patient poses a serious risk of harm to self and/or others.

(B) Patient is in need of high dosage, intensive medication or somatic and/or psychological treatment, with potentially serious side effects.

(C) Patient has acute disturbances of mood, behavior, or thinking.

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

(A) The patient must be at immediate risk of serious harm to self and or others based on a psychiatric evaluation performed by a physician (or other qualified mental health professional with hospital admission authority); and

(B) The patient requires immediate continuous skilled observation and treatment at the acute psychiatric level of care.

(iii) (Reserved)

(iv) (Reserved)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) Covered services of physicians and other authorized profession providers.
(i) Surgery. Surgery means operative procedures, including related preoperative and postoperative care; reduction of fractures and dislocations; injection and needling procedures of the joints; laser surgery of the eye; and the following procedures:

Bronchoscopy

Laryngoscopy

Thoracoscopy

Catheterization of the heart

Arteriograph thoracic lumbar

Esophagoscopy

Gastroscopy

Proctoscopy

Sigmoidoscopy

Peritoneoscopy

Cystoscopy

Colonscopy

Upper G.I. panendoscopy

Encephalograph

Myelography

Discography

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

Ventriculography

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

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

Intraspinal introduction of air preliminary to pneumoencephalography

Intraspinal introduction of opaque media preliminary to myelography

Intraventricular introduction of air preliminary to ventriculography

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

(ii) Surgical assistance.

(iii) Inpatient medical services.

(iv) Outpatient medical services.

(v) Psychiatric services.

(vi) Consultation services.

(vii) Anesthesia services.

(viii) Radiation therapy services.

(ix) X-ray services.

(x) Laboratory and pathological services.

(xi) Physical medicine services or physiatry services.

(xii) Maternity care.

(xiii) Well-child care.

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

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

(xv) (Reserved)

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

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

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

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

(C) Except that:

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

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

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

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

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

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

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

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

(C) If there were multiple surgical assistants; or

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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(ii) Vision, hearing, and dental screening.

(iii) Developmental appraisal to include body measurement.

(iv) Immunizations as recommenced by the Centers for Disease Control (CDC).

(v) Pediatric risk assessment for lead exposure and blood lead level test.

(vi) Tuberculosis screening.

(vii) Blood pressure screening.

(viii) Measurement of hemoglobin and hematocrit for anemia.

(ix) Urinalysis.

(x) Health guidance and counseling, including breastfeeding and nutrition counseling.

(B) Additional services or visits required because of specific findings or because the particular circumstances of the individual case are covered if medically necessary and otherwise authorized for benefits under CHAMPUS.

(C) The Deputy Assistant Secretary of Defense, Health Services Financing, will determine when such services are separately reimbursable apart from the health supervision visit.

(xii) (Reserved)

(xiii) Physicians in a teaching setting.

(A) Teaching physicians.

(1) General. The services of teaching physicians may be reimbursed on an allowable charge basis only when the teaching physician has established an attending physician relationship between the teaching physician and the patient or when the teaching physician provides distinct, identifiable, personal services (e.g., services rendered as a consultant, assistant surgeon, etc.). Attending physician services may include both direct patient care services or direct supervision of care provided by a physician in training. In order to be considered an attending physician, the teaching physician must:

(i) Review the patient's history and the record of examinations and tests in the institution, and make frequent reviews of the patient's progress; and

(ii) Personally examine the patient; and

(iii) Confirm or revise the diagnosis and determine the course of treatment to be followed; and

(iv) Either perform the physician's services required by the patient or supervise the treatment so as to assure that appropriate services are provided by physicians in training and

that the care meets a proper quality level; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(ii) Is not otherwise excluded by this part.

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

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

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

(iii) Iron lungs.

(iv) Hospital beds.

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

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

(i) Achieving therapeutic benefit for the patient;

(ii) Making the equipment serviceable; or

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

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

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

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

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

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

(v) Any beneficiary who has a condition or suspected condition designated in guidelines issued by the Director, OCHAMPUS, or a designee, for which the in-home use of the cardiorespiratory monitor otherwise meets Basic Program requirements.

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

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

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

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

(iv) Diagnostic testing otherwise authorized by this part.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(3) Prescription contraceptives.

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

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

(1) Prophylactics (condoms).

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

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

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

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

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

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

(1) The mother-to-be is 35 years old or older; or

(2) The mother- or father-to-be has had a previous child born with a congenital abnormality; or

(3) Either the mother- or father-to-be has a family history of congenital abnormalities; or

(4) The mother-to-be contracted rubella during the first trimester of the pregnancy; or

(5) Such other specific situations as may be determined by the Director, OCHAMPUS, or a designee, to fall within the intent of paragraph (e)(3)(ii) of this section.

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

(1) Tests performed to establish paternity of a child.

(2) Tests to determine the sex of an unborn child.

(4) (Reserved)

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

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

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

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

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

(iv) Blood and blood products.

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

(vi) Complications of the transplant procedure, including inpatient care, management of

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.

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

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

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

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

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

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

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

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

(7) (Reserved)

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

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

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

(A) Correction of a congenital anomaly; or

(B) Restoration of body form following an accidental injury; or

(C) Revision of disfiguring and extensive scars resulting from neoplastic surgery.

(D) Reconstructive breast surgery following a medically necessary mastectomy performed for the treatment of carcinoma, severe fibrocystic disease, other nonmalignant tumors or traumatic injuries.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(F) Panniculectomy; body sculpture procedures.

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

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

(I) Chemical peeling for facial wrinkles.

(J) Dermabrasion of the face.

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

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

(M) Removal of tattoos.

(N) Hair transplants.

(O) Electrolysis.

(P) [Reserved]

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

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

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

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

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

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

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

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

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

(1) Intraoral abscesses which extend beyond the dental alveolus.

(2) Extraoral abscesses.

(3) Cellulitis and osteitis which is clearly exacerbating and directly affecting a medical condition currently under treatment.

(4) Removal of teeth and tooth fragments in order to treat and repair facial trauma resulting from an accidental injury.

(5) Myofacial Pain Dysfunction Syndrome.

(6) Total or complete ankyloglossia.

(7) Adjunctive dental and orthodontic support for cleft palate.

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

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

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

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injury or disease (iatrogenic).

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

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

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

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

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

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

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

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

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

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

(C) Treatment of oral or facial cancer.

(D) Treatment of fractures of facial bones.

(E) External (extra-oral) incision and drainage of cellulitis.

(F) Surgery of accessory sinuses, salivary glands, or ducts.

(G) Reduction of dislocations and the excision of the temporomandibular joints, when surgery is a necessary part of the reduction.

(H) Any oral surgical procedure that falls within the cosmetic, reconstructive, or plastic surgery definition is subject to the limitations and requirements set forth in paragraph (e)(8) of this section.

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

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

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

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

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

(ii) (Reserved).

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

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

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

(D) Barbiturates. Examples are Seconal and Nembuttal.

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

(F) Stimulants. Examples are amphetamines.

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

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

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

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

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

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

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

(12) (Reserved)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(i) Conditions for coverage.

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

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

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

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

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

(ii) Treatment of complications.

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

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

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

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

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

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

(B) Ambulatory surgery cost-share formula applies to maternity care ending in childbirth in, or on the way to, a birthing center to which the beneficiary is admitted and from which the beneficiary has received prenatal care, or a hospital-based outpatient birthing room.

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

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

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

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

(A) Adjunctive treatment for Raynaud's Syndrome.

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

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

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

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

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

(18) Cardiac rehabilitation. Cardiac rehabilitation is the process by which individuals are restored to their optimal physical, medical, and psychological status, after a cardiac event. Cardiac rehabilitation is often divided into three phases. Phase I begins during inpatient hospitalization and is managed by the patient's personal physician. Phase II is a medically supervised outpatient program which begins following discharge. Phase III is a lifetime maintenance program emphasizing continuation of physical fitness with periodic follow up. Each phase includes an exercise component, patient education, and risk factor modification. There may be considerable variation in program components, intensity, and duration.

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

(A) Myocardial Infarction.

(B) Coronary Artery Bypass Graft.

(C) Coronary Angioplasty.

(D) Percutaneous Transluminal Coronary Angioplasty

(E) Chronic Stable Angina (see limitations below).

(F) Heart valve surgery.

(G) Heart or Heart-lung Transplantation.

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

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

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

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

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

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

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

(A) Physician services.

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

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

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

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

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

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

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

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

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

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

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

(ii) Core services. The hospice must ensure that substantially all core services are routinely provided directly by hospice employees; i.e., physician services, nursing care,

medical social services, and counseling for individuals and care givers. Refer to paragraphs (e)(19)(i)(A), (e)(19)(i)(B), (e)(19)(i)(C), and (e)(19)(i)(D) of this section.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(iv) The effective date of the election.

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

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

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

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

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

(i) The designated hospice;

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

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

(3) Basic CHAMPUS coverage will be reinstated upon revocation of the hospice election.

(D) A written plan of care must be established by a member of the basic interdisciplinary group assessing the patient's needs. This group must have at least one physician, one registered professional nurse, one social worker, and one pastoral or other counselor.

(1) In establishing the initial plan of care the member of the basic interdisciplinary group who assesses the patient's needs must meet or call at least one other group member before writing the initial plan of care.

(2) At least one of the persons involved in developing the initial plan must be a nurse or physician.

(3) The plan must be established on the same day as the assessment if the day of assessment is to be a covered day of hospice care.

(4) The other two members of the basic interdisciplinary group--the attending physician

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

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

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

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

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

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

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

(20) (Reserved)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(G) TRICARE is the appropriate payer.

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

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

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

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

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

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

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

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

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

trials identified under paragraph (e)(26)(ii) of this section have been authorized a continuous waiver under CHAMPUS.

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

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

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

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

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

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

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

(2) Requirements for Phase I protocols are:

(i) Standard treatment has been or would be ineffective, does not exist, or there is no superior non-investigational treatment alternative; and,

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

authorized NATO dependents.

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

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

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

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

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

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

NOTE: The Secretary of Defense (after consulting with the Secretary of Health and Human Services and the Secretary of Transportation) prescribes the fair charges for inpatient hospital

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care provided through Uniformed Services medical facilities. This determination is made each fiscal year.

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

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

(C) Newborn patient in his or her own right. When a newborn infant remains as an inpatient in his or her own right (usually after the mother is discharged), the newborn child becomes the beneficiary and patient and the extended inpatient stay becomes a separate inpatient admission. In such a situation, a new, separate inpatient cost-sharing amount is applied. If a multiple birth is involved (such as twins or triplets) and two or more newborn infants become patients in their own right, a separate inpatient cost-sharing amount must be applied to the inpatient stay for each newborn child who has remained as an inpatient in his or her own right.

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

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

(v) (Reserved)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(6)–(7) [Reserved]

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

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

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

(B) In the case of services provided by institutional providers normally paid on the basis of a pre-set amount (such as DRG-based amount under Sec. 199.14(a)(1) or per-diem amount

under Sec. 199.14(a)(2)), if the discount rate is lower than the pre-set rate, the cost-share amount that would apply for a beneficiary other than an active duty dependent pursuant to the normal pre-set rate would be reduced by the same percentage by which the pre-set rate was reduced in setting the discount rate.

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

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

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

(A) A claim for services regarding which the provider has waived the beneficiary's liability may be disallowed in full, or, alternatively, the amount payable for such a claim may be reduced by the amount of the beneficiary liability waived.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(5) Unnecessary postpartum inpatient stay, mother or newborn. Postpartum inpatient stay of a mother for purposes of staying with the newborn infant (usually primarily

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(A) Trials published in refereed medical literature.

(B) Formal technology assessments.

(C) National medical policy organization positions.

(D) National professional associations.

(E) National expert opinion organizations.

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

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

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

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

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

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

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

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

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

(22) Services or supplies ordered by a court or other government agency. Services or supplies, including inpatient stays, directed or agreed to by a court or other governmental

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agency. However, those services and supplies (including inpatient stays) that otherwise are medically or psychologically necessary for the diagnosis or treatment of a covered condition and that otherwise meet all CHAMPUS requirements for coverage are not excluded.

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

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

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

(26) Electrolysis.

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

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

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

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

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

(32) Dyslexia.

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

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

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

(35) Nonprescription contraceptives.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(45) (Reserved).

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

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

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

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

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

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

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

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

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

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

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

(54) Elevators or chair lifts.

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

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

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

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

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

(60) Autopsy and postmortem.

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

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

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

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

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

(65) (Reserved)

(66) Megavitamin psychiatric therapy, orthomolecular psychiatric therapy.

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

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

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

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

(70) (Reserved)

(71) (Reserved)

(72) (Reserved)

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

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

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

(h) Payment and liability for certain potentially excludable services under the Peer Review Organization program--(1) Applicability. This subsection provides special rules that apply only to services retrospectively determined under the Peer Review organization (PRO) program (operated pursuant to Sec. 199.15) to be potentially excludable (in whole or in part) from the basic program under paragraph (g) of this section. Services may be excluded by reason of being not medically necessary (paragraph (g)(1) of this section), at an inappropriate level (paragraph (g)(3) of this section), custodial care (paragraph (g)(7) of this section) or other reason relative to reasonableness, necessity or appropriateness (which services shall throughout the remainder of this subsection, be referred to as "not medically necessary"). (Also throughout the remainder of the subsection, "services" includes items and "provider" includes supplier). This paragraph does not apply to coverage determinations made by OCHAMPUS or the fiscal intermediaries which are not based on medical necessity determinations made under the PRO program.

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

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

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

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

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

(5) Criteria for determining that provider knew or could reasonably have been

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expected to have known that services were excludable. An institutional or individual provider will be found to have known or been reasonably expected to have known that services were excludable under this subsection under any one of the following circumstances:

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

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

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

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

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

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

[51 FR 24008, Jul 1, 1986; 67 FR 15725, Apr 3, 2002; 67 FR 18826, Apr 17, 2002; 67 FR 40602, Jun 13, 2002; 67 FR 42720, Jun 25, 2002; 67 FR 45311, Jul 9, 2002; 68 FR 44880, Jul 31, 2003; 68 FR 44883, Jul 31, 2003; 68 FR 65173, Nov 19, 2003; 69 FR 29229, May 21, 2004; 69 FR 44947, Jul 28, 2004; 69 FR 51564, Aug 20, 2004; 69 FR 55359, Sep 14, 2004; 69 FR 60554, Oct 12, 2004; 70 FR 12802, Mar 16, 2005; 70 FR 61377, Oct 24, 2005; 71 FR 31944, Jun 2, 2006; 71 FR 35390, Jun 20, 2006; 72 FR 54353, Sep 25, 2007; 73 FR 46809, Aug 12, 2008; 73 FR 74965, Dec 10, 2008; 74 FR 34696, Jul 17, 2009; 75 FR 47459, Aug 6, 2010; 75 FR 47461, Aug 6, 2010; 75 FR 50882, Aug 18, 2010; 75 FR 2253, Jan 13, 2011; 76 FR 8297, Feb 14, 2011; 76 FR 57642, Sep 16, 2011; 76 FR 80743, Dec 27, 2011; 76 FR 81370, Dec 28, 2011; 77 FR 38175, Jun 27, 2012; 77 FR 38178, Jun 27, 2012; 78 FR 12952, Feb 26, 2013; 78 FR 13240, Feb 27, 2013; 78 FR 62430, Oct 22, 2013; 79 FR 41641, Jul 17, 2014; 79 FR 78707, Dec 31, 2014; 79 FR 78712, Dec 31, 2014; 81 FR 27328, May 6, 2016; 81 FR 61086, Sep 2, 2106]

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