



TRICARE
MANAGEMENT ACTIVITY

MB&RB

**OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
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The Department of Defense, Office of the Secretary, has authorized the following addition(s)/revision(s) to 32 CFR Part 199, reissued April 2005.

CHANGE TITLE: TRICARE; ELIMINATION OF CO-PAYMENTS FOR AUTHORIZED PREVENTIVE SERVICES FOR CERTAIN TRICARE STANDARD BENEFICIARIES

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REMOVE PAGE(S)

INSERT PAGE(S)

CHAPTER 4

Table of Contents, pages vii through x

Chapter pages 59 through 80

Table of Contents, pages vii through x

Chapter pages 59 through 81

CHAPTER 17

Table of Contents, pages i and ii

Chapter pages 11 through 20

Table of Contents, pages i and ii

Chapter pages 11 through 20

(15) Morbid obesity. 47

 (i) Conditions for coverage. 48

 (ii) Treatment of complications. 48

 (iii) Exclusions. 48

(16) Maternity care. 48

 (i) Benefit. 48

 (ii) Cost-share. 48

(17) Biofeedback Therapy. 49

 (i) Benefits Provided. 49

 (ii) Limitations. 49

 (iii) Exclusions. 49

 (iv) Provider Requirements. 49

 (v) Implementation Guidelines. 49

(18) Cardiac rehabilitation. 49

 (i) Benefits Provided. 50

 (ii) Limitations. 50

 (iii) Exclusions. 50

 (iv) Providers. 50

 (v) Payment. 50

 (vi) Implementation Guidelines. 50

(19) Hospice care. 50

 (i) Benefit coverage. 51

 (ii) Core services. 52

 (iii) Non-core services. 52

 (iv) Availability of services. 52

 (v) Periods of care. 52

 (vi) Conditions for coverage. 52

 (1) Timing of certification. 52

 (i) Basic requirement. 53

 (ii) Exception. 53

 (2) Sources of certification. 53

 (vii) Appeal rights under hospice benefit. 55

(20) [Reserved] 55

(21) Home health services. 55

 (i) Benefit coverage. 56

 (ii) Conditions for Coverage. 56

(22) Pulmonary rehabilitation. 57

(23) A speech generating device (SGD) 57

(24) A hearing aid, 57

(25) Rehabilitation therapy. 57

(26) National Institutes of Health clinical trials. 58

 (i) Demonstration waiver. 58

 (ii) Continuous waiver. 58

 (A) General. 58

 (B) National Cancer Institute (NCI) sponsored cancer prevention, screening, and early detection clinical trials. 58

(28) Preventive care. 59

(29) Physical examinations. 60

TMA Version - April 2005

TMA Version - April 2005

(f) Beneficiary or sponsor liability--	60
(1) General.	60
(2) Dependents of members of the Uniformed Services.	60
(i) Annual fiscal year deductible for outpatient services and supplies..	60
(1) Individual Deductible:	60
(2) Family Deductible:	60
(1) Individual Deductible:	61
(2) Family Deductible:	61
(D) Allowable Amount does not exceed Deductible Amount.	61
(ii) Inpatient cost-sharing.	62
(A) Inpatient cost-sharing payable with each separate inpatient admission.	62
(B) Multiple family inpatient admissions.	62
(C) Newborn patient in his or her own right.	62
(D) Inpatient cost-sharing for mental health services.	62
(iii) Outpatient cost-sharing.	62
(iv) Ambulatory surgery.	63
(v) Psychiatric partial hospitalization services.	63
(vi) Transitional Assistance Management Program (TAMP).	63
(3) Former members and dependents of former members.	63
(i) Annual fiscal year deductible for outpatient services or supplies.	63
(ii) Inpatient cost-sharing.	63
(A) Services subject to the CHAMPUS DRG-based payment system.	63
(B) Services subject to the CHAMPUS mental health per diem payment system.	63
(C) Other services.	64
(iii) Outpatient cost-sharing.	64
(iv) Psychiatric partial hospitalization services.	64
(4) Former spouses.	64
(i) Annual fiscal year deductible for outpatient services or supplies.	64
(ii) Inpatient cost-sharing.	64
(iii) Outpatient cost-sharing.	64
(5) Cost-Sharing under the Military-Civilian Health Services Partnership Program.	64
(i) External Partnership Agreement.	64
(ii) Internal Partnership Agreement.	64
(6) [Reserved]	64
(7) [Reserved]	64
(8) Cost-sharing for services provided under special discount arrangements--	65
(i) General rule.	65
(ii) Specific applications.	65
(9) Waiver of deductible amounts or cost-sharing not allowed--	65
(i) General rule.	65
(ii) Exception for bad debts.	65
(iii) Remedies for noncompliance.	65
(10) Catastrophic loss protection for basic program benefits.	65
(i) Dependents of active duty members.	65
(ii) All other beneficiaries.	65
(iii) Payment after cap is met.	66
(11) Beneficiary or sponsor liability under the Pharmacy Benefits Program.	66
(12) Elimination of cost-sharing for certain preventive services.	66

(g) Exclusions and limitations. 66

(1) Not medically or psychologically necessary. 66

(2) Unnecessary diagnostic tests. 66

(3) Institutional level of care. 67

(4) Diagnostic admission. 67

(5) Unnecessary postpartum inpatient stay, mother or newborn. 67

(6) Therapeutic absences. 67

(7) Custodial care. 67

(8) Domiciliary care. 67

(9) Rest or rest cures. 67

(10) Amounts above allowable costs or charges. 67

(11) No legal obligation to pay, no charge would be made. 67

(12) Furnished without charge. 67

(13) Furnished by local, state, or Federal Government. 67

(14) Study, grant, or research programs. 68

(15) Unproven drugs, devices, and medical treatments or procedures. 68

 (iii) Care excluded. 69

 (iv) Examples of unproven drugs, devices or medical treatments or
 procedures. 69

(16) Immediate family, household. 73

(17) Double coverage. 73

(18) Nonavailability Statement required. 73

(19) Preauthorization required. 73

(20) Psychoanalysis or psychotherapy, part of education. 73

(21) Runaways. 74

(22) Services or supplies ordered by a court or other government agency. 74

(23) Work-related (occupational) disease or injury. 74

(24) Cosmetic, reconstructive, or plastic surgery. 74

(25) Surgery, psychological reasons. 74

(26) Electrolysis. 74

(27) Dental care. 74

(28) Obesity, weight reduction. 74

(29) Transsexualism or such other conditions as gender dysphoria. 74

(30) Therapy or counseling for sexual dysfunctions or sexual inadequacies. 74

(31) Corns, calluses, and toenails. 74

(32) Dyslexia. 74

(33) Surgical sterilization, reversal. 75

(34) Noncoital reproductive procedures including artificial insemination, in-vitro
fertilization, gamete intrafallopian transfer and all other such reproductive
technologies. 75

(35) Nonprescription contraceptives. 75

(36) Tests to determine paternity or sex of a child. 75

(37) Preventive care. 75

(38) Chiropractors and naturopaths. 76

(39) Counseling. 76

(40) Acupuncture. 76

TMA Version - April 2005

TMA Version - April 2005

(41) Hair transplants, wigs/hair pieces/cranial prosthesis.	76
(i) Benefits provided.	76
(ii) Exclusions.	76
(D) Any diagnostic or therapeutic method or supply intended to encourage hair regrowth.	76
(42) Education or training.	76
(43) Exercise/relaxation/comfort devices.	77
(44) Exercise.	77
(45) [Reserved].	77
(46) Vision care.	77
(47) Eye and hearing examinations.	77
(48) Prosthetic devices.	77
(49) Orthopedic shoes.	77
(50) Eyeglasses.	77
(51) Hearing aids.	77
(52) Telephone services.	77
(53) Air conditioners, humidifiers, dehumidifiers, and purifiers.	78
(54) Elevators or chair lifts.	78
(55) Alterations.	78
(56) Clothing.	78
(57) Food, food substitutes.	78
(58) Enuretic.	78
(59) Duplicate equipment.	78
(60) Autopsy and postmortem.	78
(61) Camping.	78
(62) Housekeeper, companion.	78
(63) Noncovered condition, unauthorized provider.	78
(64) Comfort or convenience.	78
(65) "Stop smoking" programs.	78
(66) Megavitamin psychiatric therapy, orthomolecular psychiatric therapy.	78
(67) Transportation.	78
(68) Travel.	78
(69) Institutions.	78
(70) [Reserved]	79
(71) [Reserved]	79
(72) Inpatient mental health services.	79
(73) Economic interest in connection with mental health admissions.	79
(74) Not specifically listed.	79

(h) Payment and liability for certain potentially excludable services under the Peer Review Organization program--	80
(1) Applicability.	80
(2) Payment for certain potentially excludable expenses.	80
(3) Liability for certain excludable services.	80
(4) Criteria for determining that beneficiary knew or could reasonably have been expected to have known that services were excludable.	80
(5) Criteria for determining that provider knew or could reasonably have been expected to have known that services were excludable.	80

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.

(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.

(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.

TMA Version - April 2005

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

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

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

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

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

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

(iii) Outpatient cost-sharing. Dependents of members of the Uniformed Services are responsible for payment of 20 percent of the CHAMPUS-determined allowable cost or charge beyond the annual fiscal year deductible amount (as described in paragraph (f)(2)(i) of this

section) for otherwise covered services or supplies provided on an outpatient basis by authorized providers.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(6)-(7) [Reserved]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) Not medically or psychologically necessary. Services and supplies that are not medically or psychologically necessary for the diagnosis or treatment of a covered illness (including mental disorder) 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 unproven and cannot be cost-shared by CHAMPUS except as authorized under paragraph 199.4(e)(26) of this part.

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

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

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

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

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

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

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

(C) Unless reliable evidence shows that any medical treatment or procedure has been the subject of well-controlled studies of clinically meaningful endpoints, which have determined its maximum tolerated dose, its toxicity, its safety, and its efficacy as compared with standard

means of treatment or diagnosis. (See the definition of *reliable evidence* in Sec. 199.2 of this part for the procedures used in determining if a medical treatment or procedure is unproven.)

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

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

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

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

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

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

partial list of unproven drugs, devices or medical treatment or procedures the Director, OCHAMPUS will suspend treatment of the procedure as unproven drugs, devices, or medical treatments or procedures. Following is the non-inclusive, partial list of unproven drugs, devices or medical treatment or procedures, all of which are excluded from CHAMPUS benefits:

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

TMA Version - April 2005

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

TMA Version - April 2005

(QQ) Intraoperative monitoring of sensory evoked potentials (SEP). To include visually evoked potentials, brainstem auditory evoked response, somatosensory evoked potentials during spinal and orthopedic surgery, and sensory evoked potentials monitoring of the sciatic nerve during total hip replacement. Recording SEPs in unconscious head injured patients to assess the status of the somatosensory system. The use of SEPs to define conceptional or gestational age in preterm infants.

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

(SS) Radioimmunoguided surgery in the detection of cancer.

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

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

(VV) Signal-averaged ECG.

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

(XX) Extraoperative electrocorticography for stimulation and recording

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

(ZZ) [Reserved]

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

(BBB) Endoscopic third ventriculostomy.

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

(DDD) In utero fetal surgery.

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

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

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

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

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

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

(KKK) Treatment of chronic fatigue syndrome.

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

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

(NNN) Laparoscopic myomectomy.

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

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

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

(2) Ovarian cancer.

(3) Testicular cancer.

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

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

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

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

(20) Psychoanalysis or psychotherapy, part of education. Psychoanalysis or psychotherapy provided to a beneficiary or any member of the immediate family that is

credited towards earning a degree or furtherance of the education or training of a beneficiary or sponsor, regardless of diagnosis or symptoms that may be present.

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

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

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

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

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

(26) Electrolysis.

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

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

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

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

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

(32) Dyslexia.

TMA Version - April 2005

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

provided pursuant to Sec. 199.18(b)(2)) may be provided in connection with immunizations and cancer screening examinations authorized by paragraphs (g)(37)(ii) of this section or (g)(37)(viii) through (x) of this section.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(45) (Reserved).

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

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

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

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

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

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

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

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

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

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

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

care facilities, halfway houses, homes for the aged, or institutions of similar purpose are excluded from consideration as approved facilities under the Basic Program.

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

(70)–(71) [Reserved]

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

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

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

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

TMA Version - April 2005

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

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

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

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

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

(5) Criteria for determining that provider knew or could reasonably have been expected to have known that services were excludable. An institutional or individual provider will be found to have known or been reasonably expected to have known that

services were excludable under this subsection under any one of the following circumstances:

- (i) The PRO or fiscal intermediary had informed the provider that the services provided were excludable or that similar or reasonably comparable services were excludable.
- (ii) The utilization review group or committee for an institutional provider or the beneficiary's attending physician had informed the provider that the services provided were excludable.
- (iii) The provider had informed the beneficiary that the services were excludable.
- (iv) The provider had received written materials, including notices, manual issuances, bulletins, guides, directives or other materials, providing notification of PRO screening criteria specific to the condition of the beneficiary. Attending physicians who are members of the medical staff of an institutional provider will be found to have also received written materials provided to the institutional provider.
- (v) The services that are at issue are the subject of what are generally considered acceptable standards of practice by the local medical community.
- (vi) Preadmission authorization was available but not requested, or concurrent review requirements were not followed.

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

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.

TMA Version - April 2005

TRICARE PROGRAM

(a) Establishment. 1

(1) Purpose. 1

(2) Statutory authority..... 1

(3) Scope of the program..... 1

(4) MTF rules and procedures affected..... 1

(5) Implementation based on local action..... 1

(6) Major features of the TRICARE program..... 2

(i) Comprehensive enrollment system..... 2

(ii) Establishment of a triple option benefit. 2

(iii) Coordination between military and civilian health care delivery systems. ... 2

(iv) Consolidated schedule of charges. 3

(7) Preemption of State laws..... 3

(b) Triple option benefit in general. 3

(1) Choice voluntary. 3

(2) Active duty members..... 4

(3) Automatic enrollment of certain dependents: 4

(c) Eligibility for enrollment. 4

(1) Active duty members..... 4

(2) Dependents of active duty members..... 4

(3) Survivors of Deceased Members. 4

(4) Retired members, dependents of retired members, and survivors. 5

(5) Coverage under Standard..... 5

(d) Health benefits under Prime. 5

(1) Military treatment facility (MTF) care--..... 5

(i) In general. 5

(ii) Special provisions..... 6

(2) Non-MTF care for active duty members..... 6

(3) Benefits covered for CHAMPUS eligible beneficiaries for civilian sector care..... 6

(e) Health benefits under the TRICARE extra plan...... 6

(f) Health benefits under the TRICARE standard plan. 6

(1) Military treatment facility (MTF) care..... 6

(2) Freedom of choice of civilian provider..... 6

(3) CHAMPUS benefits apply. 6

(4) Preferred provider network option for standard participants. 7

(g) TRICARE Prime Remote for Active Duty Family Members...... 7

(1) In general..... 7

(2) Active duty family member. 7

(3) Eligibility. 7

(4) Enrollment..... 8

TMA Version - April 2005

TMA Version - April 2005

- (5) Health care management requirements under TRICARE Prime Remote for Active Duty Family Members. 8
- (6) Cost sharing. 9
- (h) Resource sharing agreements. 9**
- (i) Health care finder. 9**
- (j) General quality assurance, utilization review, and preauthorization requirements under TRICARE program. 10**
- (k) Pharmacy services. 10**
- (l) PRIMUS and NAVCARE clinics-- 10**
 - (1) Description and authority. 10
 - (2) Eligible beneficiaries. 10
 - (3) Services and charges. 10
 - (4) Priority access. 10
- (m) Consolidated schedule of beneficiary charges. 10**
 - (1) Cost sharing for services from TRICARE network providers. 11
 - (2) Cost sharing for non-network providers. 11
 - (3) Cost sharing under internal resource sharing agreements. 11
 - (4) Cost sharing under external resource sharing. 12
 - (5) Prescription drugs. 12
 - (6) Cost share for outpatient services in military treatment facilities. 12
 - (7) Cost sharing for additional beneficiaries under the TRICARE Prime Remote Program. 12
- (n) Additional health care management requirements under TRICARE prime. 13**
 - (1) Primary care manager. 13
 - (2) Restrictions on the use of providers. 13
 - (3) Point-of-service option. 15
- (o) TRICARE program enrollment procedures. 15**
 - (1) Open enrollment. 15
 - (2) Enrollment period. 15
 - (3) Installment payments of enrollment fee. 16
 - (4) Voluntary disenrollment. 16
 - (5) Period revision. 16
 - (6) Effects of failure to enroll. 16
 - (7) Special procedures for certain dependents of active duty members in pay grades E-1 to E-4. 16
- (p) Civilian preferred provider networks. 16**
 - (1) Status of network providers. 16
 - (2) Utilization management policies. 17
 - (3) Quality assurance requirements. 17
 - (4) Provider qualifications. 17
 - (5) Access standards. 18

care programs affiliated with TRICARE will be specified in the applicable affiliation agreements.)

(1) Cost sharing for services from TRICARE network providers. (i) For Prime enrollees, cost sharing is as specified in the Uniform HMO Benefit in Sec. 199.18, except that for care not authorized by the primary care manager or Health Care Finder, rules applicable to the TRICARE point of service option (see paragraph (n)(3) of this section) are applicable. For such unauthorized care, the deductible is \$300 per person and \$600 per family. The beneficiary cost share is 50 percent of the allowable charges for inpatient and outpatient care, after the deductible.

(ii) For Standard participants, TRICARE Extra cost sharing applies. The deductible is the same as standard CHAMPUS. Cost shares are as follows:

(A) For outpatient professional services, cost sharing will be reduced from 20 percent to 15 percent for dependents of active duty members.

(B) For most services for retired members, dependents of retired members, and survivors, cost sharing is reduced from 25 percent to 20 percent.

(C) In fiscal year 1996, the per diem inpatient hospital copayment for retirees, dependents of retirees, and survivors when they use a preferred provider network hospital is \$250 per day, or 25 percent of total charges, whichever is less. There is a nominal copayment for active duty dependents, which is the same as under the CHAMPUS program (see Sec. 199.4). The per diem amount may be updated for subsequent years based on changes in the standard CHAMPUS per diem.

(D) As stated in Sec. 199.4(f)(12), TRICARE Standard beneficiaries who are not Medicare-eligible beneficiaries, shall have no cost sharing requirements for preventive care listed under Sec. 199.4 (e)(28)(i) through (iv).

(iii) For Medicare-eligible beneficiaries, cost sharing will generally be as applicable to Medicare participating providers.

(2) Cost sharing for non-network providers. (i) For TRICARE Prime enrollees, rules applicable to the TRICARE point of service option (see paragraph (n)(3) of this section) are applicable. The deductible is \$300 per person and \$600 per family. The beneficiary cost share is 50 percent of the allowable charges, after the deductible.

(ii) For Standard participants, cost sharing is as specified for the basic CHAMPUS program.

(iii) As stated in Sec. 199.4(f)(12), TRICARE Standard beneficiaries who are not Medicare-eligible beneficiaries, shall have no cost sharing requirements for preventive care listed under Sec. 199.4 (e)(28)(i) through (iv).

(3) Cost sharing under internal resource sharing agreements. (i) For Prime enrollees, cost sharing is as provided in military treatment facilities.

(ii) For Standard participants, cost sharing is as provided in military treatment facilities.

TMA Version - April 2005

(iii) For Medicare eligible beneficiaries, where made applicable by the commander of the *military medical treatment facility* concerned, cost sharing will be as provided in military treatment facilities.

(4) Cost sharing under external resource sharing. (i) For Prime enrollees, cost sharing applicable to services provided by military facility personnel shall be as applicable to services in military treatment facilities; that applicable to institutional and related ancillary charges shall be as applicable to services provided under TRICARE Prime.

(ii) For TRICARE Standard participants, cost sharing applicable to services provided by military facility personnel shall be as applicable to services in military treatment facilities; that applicable to non-military providers, including institutional and related ancillary charges, shall be as applicable to services provided under TRICARE Extra.

(5) Prescription drugs. Cost sharing for prescription drugs is as provided under the Pharmacy Benefits Program in Sec. 199.21.

(6) Cost share for outpatient services in military treatment facilities. (i) For dependents of active duty members in all enrollment categories, there is no charge for outpatient visits provided in military medical treatment facilities.

(ii) For retirees, their dependents, and survivors in all enrollment categories, there is no charge for outpatient visits provided in military medical treatment facilities.

(7) Cost sharing for additional beneficiaries under the TRICARE Prime Remote Program. (i) Active duty family members, defined as the lawful husband or wife of a member, and children, as defined in Sec. 199.3(b)(2)(ii)(A) through (b)(2)(ii)(F) and (b)(2)(ii)(H)(1), (b)(2)(ii)(H)(2), and (b)(2)(ii)(H)(4), residing with their Active Duty Service Member Sponsor who is TRICARE Prime Remote eligible will have cost-shares, co-payments, and deductibles waived for services provided on or after October 30, 2000. Pharmacy Benefits Program cost-shares established under Sec. 199.21 apply to services provided on or after April 1, 2001. Active Duty Service Member Sponsors who are TRICARE Prime Remote eligible are those who receive a remote permanent duty assignment, and pursuant to the assignment, reside at a location that is more than 50 miles, or approximately one hour of driving time from the nearest military medical treatment facility adequate to provide the needed care. Remote permanent duty assignments include permanent duty as a recruiter; permanent duty at an educational institution to instruct, administer a program of instruction, or provide administrative services in support of a program of instruction for the Reserves Officers' Training Corps; permanent duty as a full-time adviser to a unit of a reserve component; or any other permanent duty designated by the Secretary. This waiver applies to TRICARE covered benefits only. Claims processed with a date of service beginning on or after October 30, 2000 will waive the cost-share, copayment, and deductible. Active Duty Family Members residing with TPR eligible Active Duty Service Member (ADSM) have copayments, cost-shares, and deductibles for CHAMPUS covered benefits except pharmacy benefits waived until the implementation of TRICARE Prime Remote for Family Members or October 30, 2001, whichever is later. The claims processor will pay the waived portion of the claim to the eligible family member or to the provider, as appropriate.

(ii) Eligible family members will be able to access their provider without preauthorization. To obtain the waiver of charges, eligible family members are required to use network

providers, where available and within the TRICARE access standards. Failure to do so will result in claims being processed under TRICARE Standard rules. For beneficiaries who are enrolled in TRICARE Prime, existing specialty care preauthorization requirements and Point of Service rules remain in effect.

(iii) To the greatest extent possible, contractors will assist eligible members in finding a TRICARE network, participating, or authorized provider. If a network provider cannot be identified within the access standards established under TRICARE, the eligible family member shall use an authorized provider to be eligible for the waiver.

(n) Additional health care management requirements under TRICARE prime. Prime has additional, special health care management requirements not applicable under Extra, Standard or the CHAMPUS basic program. Such requirements must be approved by the Assistant Secretary of Defense (Health Affairs). In TRICARE, all care may be subject to review for medical necessity and appropriateness of level of care, regardless of whether the care is provided in a military medical treatment facility or in a civilian setting. Adverse determinations regarding care in military facilities will be appealable in accordance with established military medical department procedures, and adverse determinations regarding civilian care will be appealable in accordance with Sec. 199.15.

(1) Primary care manager. (i) All active duty members and Prime enrollees will be assigned or allowed to select a primary care manager pursuant to a system established by the MTF Commander or other authorized official, and consistent with the access standards in paragraph (p)(5)(i) of this section. The primary care manager may be an individual, physician, a group practice, a clinic, a treatment site, or other designation. The primary care manager may be part of the MTF or the Prime civilian provider network. The enrollee will be given the opportunity to register a preference for primary care manager from a list of choices provided by the MTF Commander. This preference will be entered on a TRICARE Prime enrollment form or similar document. Preference requests will be honored subject to availability, under the MTF beneficiary category priority system and other operational requirements established by the commander and other authorized person. MTF PCM nonavailability may be a condition of assignment to a civilian provider network PCM.

(ii) Prime enrollees who are dependents of active duty members in pay grades E-1 through E-4 shall have priority over other active duty dependents for enrollment with MTF PCMs, subject to MTF capacity.

(2) Restrictions on the use of providers. The requirements of this paragraph (n)(2) shall be applicable to health care utilization under TRICARE Prime, except in cases of emergency care and under the point-of-service option (see paragraph (n)(3) of this section).

(i) Prime enrollees must obtain all primary health care from the primary care manager or from another provider to which the enrollee is referred by the primary care manager or an authorized Health Care Finder.

(ii) For any necessary specialty care and nonemergent inpatient care, the primary care manager or the Health Care Finder will assist in making an appropriate referral.

(A) For healthcare services provided under managed care support contracts entered into by the Department of Defense before October 30, 2000, all such nonemergency specialty care

TMA Version - April 2005

and inpatient care must be preauthorized by the primary care manager or the Health Care Finder.

(B) For healthcare services provided under TRICARE contracts entered into by the Department of Defense on or after October 30, 2000, referral requests (consultation requests) for specialty care consultation appointment services for TRICARE Prime beneficiaries must be submitted by primary care managers. Such referrals will be authorized by Health Care Finders (authorization numbers will be assigned so as to facilitate claims processing) but medical necessity preauthorization will not be required for referral consultation appointment services within the TRICARE contractor's network. Some health care services subsequent to consultation appointments (invasive procedures, nonemergent admissions and other health care services as determined by the Director, TRICARE Management Activity, or a designee) will require medical necessity preauthorization. Though referrals for specialty care are generally the responsibility of the primary care managers, subject to discretion exercised by the TRICARE Regional Directors, and established in regional policy or memoranda of understanding, specialist providers may be permitted to refer patients for additional specialty consultation appointment services within the TRICARE contractor's network without prior authorization by primary care managers or subject to medical necessity preauthorization.

(iii) The following procedures will apply to health care referrals and preauthorizations in catchment areas under TRICARE Prime:

(A) The first priority for referral for specialty care or inpatient care will be to the local MTF (or to any other MTF in which catchment area the enrollee resides).

(B) If the local MTF(s) are unavailable for the services needed, but there is another MTF at which the needed services can be provided, the enrollee may be required to obtain the services at that MTF. However, this requirement will only apply to the extent that the enrollee was informed at the time of (or prior to) enrollment that mandatory referrals might be made to the MTF involved for the service involved.

(C) If the needed services are available within civilian preferred provider network serving the area, the enrollee may be required to obtain the services from a provider within the network. Subject to availability, the enrollee will have the freedom to choose a provider from among those in the network.

(D) If the needed services are not available within the civilian preferred provider network serving the area, the enrollee may be required to obtain the services from a designated civilian provider outside the area. However, this requirement will only apply to the extent that the enrollee was informed at the time of (or prior to) enrollment that mandatory referrals might be made to the provider involved for the service involved (with the provider and service either identified specifically or in connection with some appropriate classification).

(E) In cases in which the needed health care services cannot be provided pursuant to the procedures identified in paragraphs (n)(2)(iii)(A) through (D) of this section, the enrollee will receive authorization to obtain services from a CHAMPUS-authorized civilian provider(s) of the enrollee's choice not affiliated with the civilian preferred provider network.

(iv) When Prime is operating in noncatchment areas, the requirements in paragraphs

(n)(2)(iii)(B) through (E) of this section shall apply.

(v) Any health care services obtained by a Prime enrollee, but not obtained in accordance with the utilization management rules and procedures of Prime will not be paid for under Prime rules, but may be covered by the point-of-service option (see paragraph (n)(3) of this section). However, Prime rules may cover such services if the enrollee did not know and could not reasonably have been expected to know that the services were not obtained in accordance with the utilization management rules and procedures of Prime.

(vi) In accordance with guidelines issued by the Assistant Secretary of Defense for Health Affairs, certain travel expenses may be reimbursed when a TRICARE Prime enrollee is referred by the primary care manager for medically necessary specialty care more than 100 miles away from the primary care manager's office received on or after October 30, 2000. Such guidelines shall be consistent with appropriate provisions of generally applicable Department of Defense rules and procedures governing travel expenses.

(3) Point-of-service option. TRICARE Prime enrollees retain the freedom to obtain services from civilian providers on a point-of-service basis. In such cases, all requirements applicable to standard CHAMPUS shall apply, except that there shall be higher deductible and cost sharing requirements (as set forth in paragraphs (m)(1)(i) and (m)(2)(i) of this section).

(o) TRICARE program enrollment procedures. There are certain requirements pertaining to procedures for enrollment in Prime and TRICARE Prime Remote for Active Duty Family Members. (These procedures do not apply to active duty members, whose enrollment is mandatory).

(1) Open enrollment. Beneficiaries will be offered the opportunity to enroll in Prime on a continuing basis.

(2) Enrollment period. (i) Beneficiaries who select the TRICARE Prime option or the TRICARE Prime Remote for Active Duty Family Members option remain enrolled for 12 month increments until: They take action to disenroll; they are no longer eligible for enrollment in TRICARE Prime or TRICARE Prime Remote for Active Duty Family Members; or they are disenrolled for failure to pay required enrollment fees. For those who remain eligible for TRICARE Prime enrollment, no later than 15 days before the expiration date of an enrollment, the sponsor will be sent a written notification of the pending expiration and renewal of the TRICARE Prime enrollment. TRICARE Prime enrollments shall be automatically renewed upon the expiration of the enrollment unless the renewal is declined by the sponsor. Termination of enrollment for failure to pay enrollment fees is addressed in paragraph (o)(3) of this section.

(ii) Exceptions to the 12-month enrollment period.

(A) Beneficiaries who are eligible to enroll in TRICARE Prime but have less than one year of TRICARE eligibility remaining.

(B) The dependents of a Reservist who is called or ordered to active duty or of a member of the National Guard who is called or ordered to full-time federal National Guard duty for a period of more than 30 days.

(3) Installment payments of enrollment fee. The enrollment fee required by Sec. 199.18(c) may be paid in monthly or quarterly installments. Monthly fees may be payable by an allotment from retired or retainer pay, or paid from a financial institution through an electronic transfer of funds. For beneficiaries paying enrollment fees on an installment basis, failure to make a required installment payment on a timely basis [including a grace period, as determined by the Assistant Secretary of Defense (Health Affairs)] will result in termination of the beneficiary's enrollment in Prime and disqualification from future enrollment in Prime for a period of one year.

(4) Voluntary disenrollment. Any non-active duty beneficiary may disenroll at any time. Disenrollment will take effect in accordance with administrative procedures established by the Assistant Secretary of Defense (Health Affairs). Retired beneficiaries and their family members who disenroll prior to their annual enrollment renewal date will not be eligible to reenroll in Prime for a -1-year period from the effective date of the disenrollment. Active Duty family members may change their enrollment status twice in an enrollment year. Any additional disenrollment changes will result in an enrollment lock out for a 1-year period from the effective date of the disenrollment. Enrollment rules may be waived by the Assistant Secretary of Defense (Health Affairs) based on extraordinary circumstances.

(5) Period revision. Periodically, certain features, rules or procedures of Prime, Extra and/or Standard may be revised. If such revisions will have a significant effect on participants' costs or access to care, beneficiaries will be given the opportunity to change their enrollment status coincident with the revisions.

(6) Effects of failure to enroll. Beneficiaries offered the opportunity to enroll in Prime, who do not enroll, will remain in Standard and will be eligible to participate in Extra on a case-by-case basis.

(7) Special procedures for certain dependents of active duty members in pay grades E-1 to E-4. As an exception to other procedures in paragraph (o) of this section, dependents of active duty members in pay grades E-1 to E-4, if such dependents reside in a catchment area of a military hospital, are automatically enrolled in TRICARE Prime. The applicable military hospital shall provide written notice of the automatic enrollment to the member and the affected dependents. The effective date of such automatic enrollment shall be the date of the written notice, unless an earlier effective date is requested by the member or affected dependents, so long as the affected dependents were as of the effective date dependents of an active duty member in pay grades E-1 to E-4 and residents in a catchment area of a military hospital. Dependents who are automatically enrolled under this paragraph may disenroll at any time. Such disenrollment shall remain in effect until such dependents take specific action to reenroll which such dependents may do at any time.

(p) Civilian preferred provider networks. A major feature of the TRICARE program is the civilian preferred provider network.

(1) Status of network providers. Providers in the preferred provider network are not employees or agents of the Department of Defense or the United States Government. Rather, they are independent contractors of the government (or other independent entities having business arrangements with the government). Although network providers must follow numerous rules and procedures of the TRICARE program, on matters of professional judgment and professional practice, the network provider is independent and not operating

under the direction and control of the Department of Defense. Each preferred provider must have adequate professional liability insurance, as required by the Federal Acquisition Regulation, and must agree to indemnify the United States Government for any liability that may be assessed against the United States Government that is attributable to any action or omission of the provider.

(2) Utilization management policies. Preferred providers are required to follow the utilization management policies and procedures of the TRICARE program. These policies and procedures are part of discretionary judgments by the Department of Defense regarding the methods of delivering and financing health care services that will best achieve health and economic policy objectives.

(3) Quality assurance requirements. A number of quality assurance requirements and procedures are applicable to preferred network providers. These are for the purpose of assuring that the health care services paid for with government funds meet the standards called for in the contract or provider agreement.

(4) Provider qualifications. All preferred providers must meet the following qualifications:

(i) They must be CHAMPUS authorized providers and CHAMPUS participating providers.

(ii) All physicians in the preferred provider network must have staff privileges in a hospital accredited by the Joint Commission on Accreditation of Health Care Organizations (JCAHO). This requirement may be waived in any case in which a physician's practice does not include the need for admitting privileges in such a hospital, or in locations where no JCAHO accredited facility exists. However, in any case in which the requirement is waived, the physician must comply with alternative qualification standards as are established by the MTF Commander (or other authorized official).

(iii) All preferred providers must agree to follow all quality assurance, utilization management, and patient referral procedures established pursuant to this section, to make available to designated DoD utilization management or quality monitoring contractors medical records and other pertinent records, and to authorize the release of information to MTF Commanders regarding such quality assurance and utilization management activities.

(iv) All preferred network providers must be Medicare participating providers, unless this requirement is waived based on extraordinary circumstances. This requirement that a provider be a Medicare participating provider does not apply to providers not eligible to be participating providers under Medicare.

(v) The provider must be available to Extra participants.

(vi) The provider must agree to accept the same payment rates negotiated for Prime enrollees for any person whose care is reimbursable by the Department of Defense, including, for example, Extra participants, supplemental care cases, and beneficiaries from outside the area.

(vii) All preferred providers must meet all other qualification requirements, and agree to

comply with all other rules and procedures established for the preferred provider network.

(5) Access standards. Preferred provider networks will have attributes of size, composition, mix of providers and geographical distribution so that the networks, coupled with the MTF capabilities, can adequately address the health care needs of the enrollees. Before offering enrollment in Prime to a beneficiary group, the MTF Commander (or other authorized person) will assure that the capabilities of the MTF plus preferred provider network will meet the following access standards with respect to the needs of the expected number of enrollees from the beneficiary group being offered enrollment:

(i) Under normal circumstances, enrollee travel time may not exceed 30 minutes from home to primary care delivery site unless a longer time is necessary because of the absence of providers (including providers not part of the network) in the area.

(ii) The wait time for an appointment for a well-patient visit or a specialty care referral shall not exceed four weeks; for a routine visit, the wait time for an appointment shall not exceed one week; and for an urgent care visit the wait time for an appointment shall generally not exceed 24 hours.

(iii) Emergency services shall be available and accessible to handle emergencies (and urgent care visits if not available from other primary care providers pursuant to paragraph (p)(5)(ii) of this section), within the service area 24 hours a day, seven days a week.

(iv) The network shall include a sufficient number and mix of board certified specialists to meet reasonably the anticipated needs of enrollees. Travel time for specialty care shall not exceed one hour under normal circumstances, unless a longer time is necessary because of the absence of providers (including providers not part of the network) in the area. This requirement does not apply under the Specialized Treatment Services Program.

(v) Office waiting times in nonemergency circumstances shall not exceed 30 minutes, except when emergency care is being provided to patients, and the normal schedule is disrupted.

(6) Special reimbursement methods for network providers. The Director, OCHAMPUS, may establish, for preferred provider networks, reimbursement rates and methods different from those established pursuant to Sec. 199.14. Such provisions may be expressed in terms of percentage discounts off CHAMPUS allowable amounts, or in other terms. In circumstances in which payments are based on hospital-specific rates (or other rates specific to particular institutional providers), special reimbursement methods may permit payments based on discounts off national or regional prevailing payment levels, even if higher than particular institution-specific payment rates.

(7) Methods for establishing preferred provider networks. There are several methods under which the MTF Commander (or other authorized official) may establish a preferred provider network. These include the following:

(i) There may be an acquisition under the Federal Acquisition Regulation, either conducted locally for that catchment area, in a larger area in concert with other MTF Commanders, regionally as part of a CHAMPUS acquisition, or on some other basis.

TMA Version - April 2005

(ii) To the extent allowed by law, there may be a modification by the Director, OCHAMPUS, of an existing CHAMPUS fiscal intermediary contract to add TRICARE program functions to the existing responsibilities of the fiscal intermediary contractor.

(iii) The MTF Commander (or other authorized official) may follow the “any qualified provider” method set forth in paragraph (q) of this section.

(iv) Any other method authorized by law may be used.

(q) Preferred provider network establishment under any qualified provider method.

The any qualified provider method may be used to establish a civilian preferred provider network. Under this method, any CHAMPUS-authorized provider within the geographical area involved that meets the qualification standards established by the MTF Commander (or other authorized official) may become a part of the preferred provider network. Such standards must be publicly announced and uniformly applied. Also under this method, any provider who meets all applicable qualification standards may not be excluded from the preferred provider network. Qualifications include:

(1) The provider must meet all applicable requirements in paragraph (p)(4) of this section.

(2) The provider must agree to follow all quality assurance and utilization management procedures established pursuant to this section.

(3) The provider must be a Participating Provider under CHAMPUS for all claims.

(4) The provider must meet all other qualification requirements, and agree to all other rules and procedures, that are established, publicly announced, and uniformly applied by the commander (or other authorized official).

(5) The provider must sign a preferred provider network agreement covering all applicable requirements. Such agreements will be for a duration of one year, are renewable, and may be canceled by the provider or the MTF Commander (or other authorized official) upon appropriate notice to the other party. The Director, OCHAMPUS shall establish an agreement model or other guidelines to promote uniformity in the agreements.

(r) General fraud, abuse, and conflict of interest requirements under TRICARE program. All fraud, abuse, and conflict of interest requirements for the basic CHAMPUS program, as set forth in this part 199 (see especially applicable provisions of Sec. 199.9) are applicable to the TRICARE program. Some methods and procedures for implementing and enforcing these requirements may differ from the methods and procedures followed under the basic CHAMPUS program in areas in which the TRICARE program has not been implemented.

(s) Partial implementation. The Assistant Secretary of Defense (Health Affairs) may authorize the partial implementation of the TRICARE program. The following are examples of partial implementation:

(1) The TRICARE Extra Plan and the TRICARE Standard Plan may be offered without the TRICARE Prime Plan.

(2) In remote sites, where complete implementation of TRICARE is impracticable, TRICARE Prime may be offered to a limited group of beneficiaries. In such cases, normal requirements of TRICARE Prime which the Assistant Secretary of Defense (Health Affairs) determines are impracticable may be waived.

(3) The TRICARE program may be limited to particular services, such as mental health services.

(t) Inclusion of Department of Veterans Affairs Medical Centers in TRICARE networks. TRICARE preferred provider networks may include Department of Veterans Affairs health facilities pursuant to arrangements, made with the approval of the Assistant Secretary of Defense (Health Affairs), between those centers and the Director, OCHAMPUS, or designated TRICARE contractor.

(u) Care provided outside the United States to dependents of active duty members. The Assistant Secretary of Defense (Health Affairs) may, in conjunction with implementation of the TRICARE program, authorize a special CHAMPUS program for dependents of active duty members who accompany the members in their assignments in foreign countries. Under this special program, a preferred provider network will be established through contracts or agreements with selected health care providers. Under the network, CHAMPUS covered services will be provided to the covered dependents with all CHAMPUS requirements for deductibles and copayments waived. The use of this authority by the Assistant Secretary of Defense (Health Affairs) for any particular geographical area will be announced in the Federal Register. The announcement will include a description of the preferred provider network program and other pertinent information.

(v) Administration of the TRICARE program in the state of Alaska. In view of the unique geographical and environmental characteristics impacting the delivery of health care in the state of Alaska, administration of the TRICARE program in the state of Alaska will not include financial underwriting of the delivery of health care by a TRICARE contractor. All other provisions of this section shall apply to administration of the TRICARE program in the state of Alaska as they apply to the other 49 states and the District of Columbia.

(w) Administrative procedures. The Assistant Secretary of Defense (Health Affairs), the Director, TRICARE Management Activity, and MTF Commanders (or other authorized officials) are authorized to establish administrative requirements and procedures, consistent with this section, this part, and other applicable DoD Directives or Instructions, for the implementation and operation of the TRICARE program.

[60 FR 52095, Oct 5, 1995, as amended at 63 FR 9142, Feb 24, 1998; 63 FR 48447, Sep 10, 1998; 64 FR 13913, Mar 23, 1999; 65 FR 39805, Jun 28, 2000; 65 FR 45425, Jul 21, 2000; 66 FR 9655, Feb 9, 2001; 66 FR 40608, Aug 3, 2001; 67 FR 5479, Feb 6, 2002; 67 FR 6409, Feb 12, 2002; 68 FR 23033, Apr 30, 2003; 68 FR 32363, May 30, 2003; 68 FR 44883, Jul 31, 2003; 68 FR 44881, Jul 31, 2003; 70 FR 19266, Apr 13, 2005; 71 FR 50349, Aug 25, 2006; 72 FR 2448, Jan 19, 2007; 73 FR 30478, May 28, 2008; 75 FR 47713, Aug 9, 2010; 75 FR 50884, Aug 18, 2010; 76 FR 81370, Dec 28, 2011]

TMA Version - April 2005