TABLE TO APPENDIX A—EXPLANATION OF FOIA EXEMPTIONS—Continued

Exemption	Explanation
(b)(5)	Applies to records and information of internal records that are deliberative in nature and are part of the decision making process that contain opinions and recommendations.
(b)(6)	Applies to records or information the release of which could reasonably be expected to constitute a clearly unwarranted invasion of the personal privacy of individuals.
(b)(7)	Applies to records or information compiled for law enforcement purposes that could: (a) Reasonably be expected to interfere with law enforcement proceedings; (b) deprive a person of a right to a fair trial or impartial adjudication; (c) reasonably be expected to constitute an unwarranted invasion of the personal privacy of others; (d) disclose the identity of a confidential source; (e) disclose investigative techniques and procedures; or (f) reasonably be expected to endanger the life or physical safety of any individual.
(b)(8)	Applies to records and information for the use of any agency responsible for the regulation or supervision of financial institutions.
(b)(9)	Applies to records and information containing geological and geophysical information (including maps) concerning wells.

(2) *Classification Categories.* Information will not be considered for classification unless its unauthorized disclosure could reasonably be expected to cause identifiable or describable damage to the national security in accordance with section 1.2 of Executive Order 13526, and it pertains to one or more of the following:

(i) Military plans, weapons systems, or operations;

(ii) Foreign government information;

(iii) Intelligence activities (including covert action), intelligence sources or methods, or cryptology;

(iv) Foreign relations or foreign activities of the United States, including confidential sources;

(v) Scientific, technological, or economic matters relating to the national security;

(vi) U.S. Government programs for safeguarding nuclear materials or facilities;

(vii) Vulnerabilities or capabilities of systems, installations, infrastructures, projects, plans, or protection services relating to the national security; or

(viii) The development, production, or use of weapons of mass destruction.

(b) [Reserved]

PART 199—CIVILIAN HEALTH AND MEDICAL PROGRAM OF THE UNIFORMED SERVICES (CHAMPUS)

Sec.

AUTHORITY: 5 U.S.C. 301; 10 U.S.C. chapter 55.

SOURCE: 51 FR 24008, July 1, 1986, unless otherwise noted.

§ 199.1 General provisions.

(a) *Purpose.* This part prescribes guidelines and policies for the administration of the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) for the Army, the Navy, the Air Force, the Marine Corps, the Coast Guard, the Commissioned Corps of the U.S. Public Health Service (USPHS) and the Commissioned Corps of the National Oceanic and Atmospheric Administration (NOAA).

(b) *Applicability*—(1) *Geographic.* This part is applicable geographically within the 50 States of the United States, the District of Columbia, the Commonwealth of Puerto Rico, and the United States possessions and territories, and

in all foreign countries, unless specific exemptions are granted in writing by the Director, OCHAMPUS, or a designee.

(2) *Agency*. The provisions of this part apply throughout the Department of Defense (DoD), the Coast Guard, the Commissioned Corps of the USPHS, and the Commissioned Corps of the NOAA.

(c) *Authority and responsibility*—(1) *Legislative authority*—(i) *Joint regulations*. 10 U.S.C. chapter 55 authorizes the Secretary of Defense, the Secretary of Health and Human Services, and the Secretary of Transportation jointly to prescribe regulations for the administration of CHAMPUS.

(ii) *Administration*. 10 U.S.C. chapter 55 also authorizes the Secretary of Defense to administer CHAMPUS for the Army, Navy, Air Force, and Marine Corps under DoD jurisdiction, the Secretary of Transportation to administer CHAMPUS for the Coast Guard, when the Coast Guard is not operating as a service in the Navy, and the Secretary of Health and Human Services to administer CHAMPUS for the Commissioned Corps of the NOAA and the USPHS.

(2) *Organizational delegations and assignments*—(i) *Assistant Secretary of Defense (Health Affairs) (ASD(HA))*. The Secretary of Defense, by 32 CFR part 367, delegated authority to the ASD(HA) to provide policy guidance, management control and coordination as required for CHAMPUS, and to develop, issue, and maintain regulations with the coordination of the Military Departments and consistent with DoD 5025.1–M.[1] Additional implementing authority is contained in DoD Directive 5105.46.[2]

(ii) *Department of Health and Human Services*. The Secretary of Health and Human Services has delegated authority to the Assistant Secretary for Health, DHHS, to consult with the Secretary of Defense or a designee and to approve and issue joint regulations implementing 10 U.S.C. chapter 55. This delegation was effective April 19, 1976 (41 FR 18698, May 6, 1976).

(iii) *Department of Transportation*. The Secretary of Transportation has delegated authority to the Commandant, United States Coast Guard, to consult with the Secretary of Defense or a designee and to approve an issue joint regulations implementing 10 U.S.C., chapter 55.

(iv) *Office of CHAMPUS (OCHAMPUS)*. By DoD Directive 5105.46, OCHAMPUS was established as an OSD field activity under the policy guidance and direction of the ASD(HA). The Director, OCHAMPUS, is directed to execute the following responsibilities and functions:

(A) Supervise and administer the programs and missions to:

(*1*) Provide technical direction and guidance on organizational, administrative, and operational matters.

(*2*) Conduct studies and research activities in the health care area to assist in formulating policy required to guide OCHAMPUS in carrying out its programs.

(*3*) Enter into agreements through the Department of Defense with respect to the Military Departments or other U.S. Government entities, as required, for the effective performance of CHAMPUS.

(*4*) Supervise and administer OCHAMPUS financial management activities to include:

(*i*) Formulating budget estimates and justifications to be submitted to the Deputy Assistant Secretary of Defense (Administration) (DASD(A)) for inclusion in the overall budget for the Office of the Secretary of Defense.

(*ii*) Ensuring the establishment and maintenance of necessary accounting records and submission of required financial reports to the DASD(A).

(*iii*) Ensuring the effective execution of approved budgets.

(*5*) Contract for claims processing services, studies and research, supplies, equipment, an other services necessary to carry out the CHAMPUS programs.

(*6*) Monitor claims adjudication and processing contracts to ensure that CHAMPUS fiscal intermediaries are fulfilling their obligations.

[1] Copies may be obtained, if needed, from the National Technical Information Service (NTIS), U.S. Department of Commerce, 5285 Port Royal Road, Springfield, VA 22161.

[2] Copies may be obtained; if needed from the Naval Publications and Forms Center, 5801 Tabor Avenue, Code 301, Philadelphia, PA 19120.

(*7*) Convey appropriate CHAMPUS information to providers of care, practitioners, professional societies, health industry organizations, fiscal agents, hospital contractors, and others who have need of such information.

(*8*) Collect, maintain, and analyze program cost and utilization data appropriate for preparation of budgets, fiscal planning, and as otherwise needed to carry out CHAMPUS programs and missions.

(*9*) Arrange for the facilities logistical and administrative support to be provided by the Military Departments.

(*10*) Execute such other functions as appropriate to administer the programs and missions assigned.

(B) Direct and control of the office, activities, and functions of OCHAMPUS Europe (OCHAMPUSEUR).

NOTE: The Director, OCHAMPUS, may also establish similar offices for OCHAMPUS Southern Hemisphere (OCHAMPUSSO) and OCHAMPUS Pacific (OCHAMPUSPAC).

(C) Develop for issuance, subject to approval by the ASD(HA), such policies or regulations as required to administer and manage CHAMPUS effectively.

(v) *Evidence of eligibility.* The Department of Defense, through the Defense Enrollment Eligibility Reporting System (DEERS), is responsible for establishing and maintaining a listing of persons eligible to receive benefits under CHAMPUS. Identification cards or devices bearing information necessary for preliminary evidence of eligibility, subject to verification through the DEERS, shall be issued to eligible persons by the appropriate Uniformed Services (DoD 1341.1–M, ''Defense Enrollment Eligibility Reporting System (DEERS) Program Manual'').

(d) *Medical benefits program.* The CHAMPUS is a program of medical benefits provided by the U.S. Government under public law to specified categories of individuals who are qualified for these benefits by virtue of their relationship to one of the seven Uniformed Services. Although similar in structure in many of its aspects, CHAMPUS is not an insurance program in that it does not involve a contract guaranteeing the indemnification of an insured party against a specified loss in return for a premium paid. Further, CHAMPUS is not subject to those state regulatory bodies or agencies that control the insurance business generally.

(e) *Program funds.* The funds used by CHAMPUS are appropriated funds furnished by the Congress through the annual appropriation acts for the Department of Defense and the DHHS. These funds are further disbursed by agents of the government under contracts negotiated by the Director, OCHAMPUS, or a designee, under the provisions of the Federal Acquisition Regulation (FAR). These agents (referred to in this part as CHAMPUS fiscal intermediaries) receive claims against CHAMPUS and adjudicate the claims under this part and in accordance with administrative procedures and instructions prescribed in their contracts. The funds expended for CHAMPUS benefits are federal funds provided CHAMPUS fiscal intermediaries solely to pay CHAMPUS claims, and are not a part of or obtained from the CHAMPUS fiscal intermediary's funds related to other programs or insurance coverage. CHAMPUS fiscal intermediaries are reimbursed for the adjudication and payment of CHAMPUS claims at a rate (generally fixed-price) prescribed in their contracts.

(f) *Claims adjudication and processing.* The Director, OCHAMPUS, is responsible for making such arrangements as are necessary to adjudicate and process CHAMPUS claims worldwide.

(1) *The United States*—(i) *Contracting out.* The primary method of processing CHAMPUS claims in the United States is through competitively procured, fixed-price contracts. The Director, OCHAMPUS, or a designee, is responsible for negotiating, under the provisions of the FAR, contracts for the purpose of adjudicating and processing CHAMPUS claims (and related supporting activities).

(ii) *In-house.* The Director, OCHAMPUS, or a designee, is authorized to adjudicate and process certain CHAMPUS claims in-house at OCHAMPUS, when it is determined to be in the best interests of CHAMPUS subject to applicable considerations set forth in OMB Circular A–76. Such in-house claims processing may involve

special or unique claims, or all claims for a specific geographic area.

(2) *Outside the United States*—(i) *Special subsidiary office or contracting out.* For adjudicating and processing CHAMPUS claims for services or supplies provided outside the United States, the Director, OCHAMPUS, or a designee, has the option of either setting up a special subsidiary claims paying operation (such as OCHAMPUSEUR) or contracting out as described in paragraph (f)(1)(i) of this section. Such claims paying operations are reviewed periodically to determine whether current arrangements continue to be appropriate and the most effective.

(ii) *Support agreements.* In those situations outside the United States that demand special arrangements, the Director, OCHAMPUS, may enter into support agreements through the Department of Defense with any of the Military Departments or other government agency to process CHAMPUS claims in specific geographic locations. Such agreements may be negotiated for such period of time as the Director, OCHAMPUS, or designee, may determine to be necessary to meet identified special demands.

(g) *Recommendations for change to part.* The Director, OCHAMPUS, or a designee, shall establish procedures for receiving and processing recommendations for changes to this part from interested parties.

(h) *CHAMPUS, claims forms.* The Director, OCHAMPUS, or a designee, is responsible for the development and updating of all CHAMPUS claim forms and any other forms necessary in the administration of CHAMPUS.

(i) *The CHAMPUS handbook.* The Director, OCHAMPUS, or a designee, shall develop the CHAMPUS, Handbook. The CHAMPUS Handbook is a general program guide for the use of CHAMPUS beneficiaries and providers and shall be updated, as required.

(j) *Program integrity.* The Director, OCHAMPUS, or a designee, shall oversee all CHAMPUS personnel, fiscal intermediaries, providers, and beneficiaries to ensure compliance with this part. The Director, OCHAMPUS, or a designee, shall accomplish this by means of proper delegation of authority, separation of responsibilities, establishment of reports, performance evaluations, internal and external management and fiscal audits, personal or delegated reviews of CHAMPUS responsibilities, taking affidavits, exchange of information among state and Federal governmental agencies, insurers, providers and associations of providers, and such other means as may be appropriate. Compliance with law and this part shall include compliance with specific contracts and agreements, regardless of form, and general instructions, such as CHAMPUS policies, instructions, procedures, and criteria relating to CHAMPUS operation.

(k) *Role of CHAMPUS Health Benefits Advisor (HBA).* The CHAMPUS HBA is appointed (generally by the commander of a Uniformed Services medical treatment facility) to serve as an advisor to patients and staff in matters involving CHAMPUS. The CHAMPUS HBA may assist beneficiaries or sponsors in applying for CHAMPUS benefits, in the preparation of claims, and in their relations with OCHAMPUS and CHAMPUS fiscal intermediaries. However, the CHAMPUS HBA is not responsible for CHAMPUS policies and procedures and has no authority to make benefit determinations or obligate Government funds. Advice given to beneficiaries as to determination of benefits or level of payment is not binding on OCHAMPUS or CHAMPUS fiscal intermediaries.

(l) *Cooperation and exchange of information with other Federal programs.* The Director, OCHAMPUS, or a designee, shall disclose to appropriate officers or employees of the DHHS:

(1) *Investigation for fraud.* The name and address of any physician or other individual actively being investigated for possible fraud in connection with CHAMPUS, and the nature of such suspected fraud. An active investigation exists when there is significant evidence supporting an initial complaint but there is need for further investigation.

(2) *Unnecessary services.* The name and address of any provider of medical services, organization, or other person found, after consultation with an appropriate professional association or appropriate peer review body, to have

provided unnecessary services. Such information will be released only for the purpose of conducting an investigation or prosecution, or for the administration of titles XVIII and XIX of the Social Security Act, provided that the information will be released only to the agency's enforcement branch and that the agency will preserve the confidentiality of the information received and will not disclose such information for other than program purposes.

(m) *Disclosure of information to the public.* Records and information acquired in the administration of CHAMPUS are records of the Department of Defense and may be disclosed in accordance with DoD Directive 5400.7[3], DoD 5400.7–R[4], and DoD 5400.11–R[5] (codified in 32 CFR parts 286 and 286a), constituting the applicable DoD Directives and DoD Regulations implementing the Freedom of Information and the Privacy Acts.

(n) *Discretionary authority.* When it is determined to be in the best interest of CHAMPUS, the Director, OCHAMPUS, or a designee, is granted discretionary authority to waive any requirements of this part, except that any requirement specifically set forth in 10 U.S.C. chapter 55, or otherwise imposed by law, may not be waived. It is the intent that such discretionary authority be used only under very unusual and limited circumstances and not to deny any individual any right, benefit, or privilege provided to him or her by statute or this part. Any such exception granted by the Director, OCHAMPUS, or a designee, shall apply only to the individual circumstance or case involved and will in no way be construed to be precedent-setting.

(o) *Demonstration projects*—(1) *Authority.* The Director, OCHAMPUS may waive or alter any requirements of this regulation in connection with the conduct of a demonstration project required or authorized by law except for any requirement that may not be waived or altered pursuant to 10 U.S.C. chapter 55, or other applicable law.

(2) *Procedures.* At least 30 days prior to taking effect, OCHAMPUS shall publish a notice describing the demonstration project, the requirements of this regulation being waived or altered under paragraph (o)(1) of this section and the duration of the waiver or alteration. Consistent with the purpose and nature of demonstration projects, these notices are not covered by public comment practices under DoD Directive 5400.9 (32 CFR part 296) or DoD Instruction 6010.8.

(3) *Definition.* For purposes of this section, a ''demonstration project'' is a project of limited duration designed to test a different method for the finance, delivery or administration of health care activities for the uniformed services. Demonstration projects may be required or authorized by 10 U.S.C. 1092, any other statutory provision requiring or authorizing a demonstration project or any other provision of law that authorizes the activity involved in the demonstration project.''.

(p) *Military-Civilian Health Services Partnership Program.* The Secretary of Defense, or designee, may enter into an agreement (external or internal) providing for the sharing of resources between facilities of the uniformed services and facilities of a civilian health care provider or providers if the Secretary determines that such an agreement would result in the delivery of health care in a more effective, efficient or economical manner. This partnership allows CHAMPUS beneficiaries to receive inpatient and outpatient services through CHAMPUS from civilian personnel providing health care services in military treatment facilities and from uniformed service professional providers in civilian facilities. The policies and procedures by which partnership agreements may be executed are set forth in Department of Defense Instruction (DoDI) 6010.12, ''Military-Civilian Health Services Partnership Program.'' The Director, OCHAMPUS, or a designee, shall issue policies, instructions, procedures, guidelines, standards, or criteria as may be necessary to provide support for implementation of DoDI 6010.12, to promulgate and manage benefit and financial policy issues, and to develop a program evaluation process to ensure the Partnership Program accomplishes the purpose for which it was developed.

[3] See footnote 2 to §199.1(c)(2)(i)
[4] See footnote 1 to §199.1(c)(2)(i)
[5] See footnote 1 to §199.1(c)(2)(i)

(1) *Partnership agreements.* Military treatment facility commanders, based upon the authority provided by their representative Surgeons General of the military departments, are responsible for entering into individual partnership agreements only when they have determined specifically that use of the Partnership Program is more economical overall to the Government than referring the need for health care services to the civilian community under the normal operation of the CHAMPUS Program. All such agreements are subject to the review and approval of the Director, OCHAMPUS, or designee, and the appropriate Surgeon General.

(i) *External partnership agreements.* The external partnership agreement is an agreement between a military treatment facility Commander and a CHAMPUS-authorized institutional provider, enabling Uniformed Services health care personnel to provide otherwise covered medical care to CHAMPUS beneficiaries in a civilian facility. Authorized costs associated with the use of the facility will be financed through CHAMPUS under normal cost-sharing and reimbursement procedures currently applicable under the basic CHAMPUS. Savings will be realized under this type of agreement by using available military health care personnel to avoid the civilian professional provider charges which would otherwise be billed to CHAMPUS.

(ii) *Internal partnership agreements.* The internal partnership agreement is an agreement between a military treatment facility commander and a CHAMPUS-authorized civilian health care provider which enables the use of civilian health care personnel or other resources to provide medical care to CHAMPUS beneficiaries on the premises of a military treatment facility. These internal agreements may be established when a military treatment facility is unable to provide sufficient health care services for CHAMPUS beneficiaries due to shortages of personnel and other required resources. In addition to allowing the military treatment facility to achieve maximum use of available facility space, the internal agreement will result in savings to the Government by using civilian medical specialists to provide inpatient care in Government-owned facilities, thereby avoiding the civilian facility charges which would have otherwise been billed to CHAMPUS.

(2) *Beneficiary cost-sharing.* Beneficiary cost-sharing under the Partnership Program is outlined in §199.4(f)(5) of this part.

(3) *Reimbursement.* Reimbursement under the Partnership Program is outlined in §199.14(f) of this part.

(4) *Beneficiary eligibility and authorized providers.* Existing requirements of this Regulation remain in effect as concerns beneficiary eligibility and authorized providers.

(5) *Range of benefits.* Health care services provided CHAMPUS beneficiaries under the terms of the Partnership Program must be consistent with the CHAMPUS range of benefits outlined in this Regulation. The services rendered must be otherwise covered. Charges allowed for professional services provided under the Partnership Program may include costs of support personnel, equipment, and supplies when specifically outlined in the partnership agreement, However, all CHAMPUS coverage and provider requirements must be met.

(q) *Equality of benefits.* All claims submitted for benefits under CHAMPUS shall be adjudicated in a consistent, fair, and equitable manner, without regard to the rank of the sponsor.

(r) *TRICARE program.* Many rules and procedures established in sections of this part are subject to revision in areas where the TRICARE program is implemented. The TRICARE program is the means by which managed care activities designed to improve the delivery and financing of health care services in the Military Health Services System(MHSS) are carried out. Rules and procedures for the TRICARE program are set forth in §199.17.

[51 FR 24008, July 1, 1986, as amended at 52 FR 38754, Oct. 19, 1987; 53 FR 27961, July 26, 1988; 55 FR 43338, Oct. 29, 1990; 60 FR 52094, Oct. 5, 1995]

§199.2 Definitions.

(a) *General.* In an effort to be as specific as possible as to the word and intent of CHAMPUS, the following definitions have been developed. While

many of the definitions are general and some assign meaning to relatively common terms within the health insurance environment, others are applicable only to CHAMPUS; however, they all appear in this part solely for the purpose of the Program. Except when otherwise specified, the definitions in this section apply generally throughout this part.

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

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

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

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

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

Abused dependent. An eligible spouse or child, who meets the criteria in §199.3 of this part, of a former member who received a dishonorable or bad-conduct discharge or was dismissed from a Uniformed Service as a result of a court-martial conviction for an offense involving physical or emotional abuse or was administratively discharged as a result of such an offense, *or* of a member or former member who has had their entitlement to receive retired pay terminated because of misconduct involving physical or emotional abuse.

Accidental injury. Physical bodily injury resulting from an external force, blow or fall, or the ingestion of a foreign body or harmful substance, requiring immediate medical treatment. Accidental injury also includes animal and insect bites and sunstrokes. For the purpose of CHAMPUS, the breaking of a tooth or teeth does not constitute a physical bodily injury.

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

Active duty member. A person on active duty in a Uniformed Service under a call or order that does not specify a period of 30 days or less.

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

Acupuncture. The practice of inserting needles into various body parts to pierce specific peripheral nerves for the

production of counter-irritation to relieve the discomfort of pain, induce surgical anesthesia, or for other treatment purposes.

NOTE: Acupuncture is not covered by CHAMPUS.

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

Adequate medical documentation, mental health records. Adequate medical documentation provides the means for measuring the type, frequency, and duration of active treatment mechanisms employed and progress under the treatment plan. Under CHAMPUS, it is required that adequate and sufficient clinical records be kept by the provider to substantiate that specific care was actually and appropriately furnished, was medically or psychologically necessary (as defined by this part), and to identify the individual(s) who provided the care. Each service provided or billed must be documented in the records. In determining whether medical records are adequate, the records will be reviewed under the generally acceptable standards (*e.g.*, the standards of an accrediting organization approved by the Director, and the provider's state or local licensing requirements) and other requirements specified by this part. The psychiatric and psychological evaluations, physician orders, the treatment plan, integrated progress notes (and physician progress notes if separate from the integrated progress notes), and the discharge summary are the more critical elements of the mental health record. However, nursing and staff notes, no matter how complete, are not a substitute for the documentation of services by the individual professional provider who furnished treatment to the beneficiary. In general, the documentation requirements of a professional provider are not less in the outpatient setting than the inpatient setting. Furthermore, even though a hospital that provides psychiatric care may be accredited under The Joint Commission (TJC) manual for hospitals rather than the behavioral health standards manual, the critical elements of the mental health record listed above are required for CHAMPUS claims.

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

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

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

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

All-inclusive per diem rate. The OCHAMPUS determined rate that encompasses the daily charge for inpatient care and, unless specifically excepted, all other treatment determined

necessary and rendered as part of the treatment plan established for a patient, and accepted by OCHAMPUS.

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

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

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

Ambulatory Payment Classifications (APCs). Payment of services under the TRICARE OPPS is based on grouping outpatient procedures and services into ambulatory payment classification groups based on clinical and resource homogeneity, provider concentration, frequency of service and minimal opportunities for upcoding and code fragmentation. Nationally established rates for each APC are calculated by multiplying the APC's relative weight derived from median costs for procedures assigned to the APC group, scaled to the median cost of the APC group representing the most frequently provided services, by the conversion factor.

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

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

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

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

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

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

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

Approved teaching programs. For purposes of CHAMPUS, an approved teaching program is a program of graduate medical education which has been duly approved in its respective specialty or subspecialty by the Accreditation

Council for Graduate Medical Education of the American Medical Association, by the Committee on Hospitals of the Bureau of Professional Education of the American Osteopathic Association, by the Council on Dental Education of the American Dental Association, or by the Council on Podiatry Education of the American Podiatry Association.

Assistant Secretary of Defense (Health Affairs). An authority of the Assistant Secretary of Defense (Health Affairs) includes any person designated by the Assistant Secretary to exercise the authority involved.

Assistive technology devices. Equipment that generally does not treat an underlying injury, illness, disease or their symptoms. Assistive technology devices are authorized only under the Extended Care Health Option (ECHO). Assistive technology devices help an ECHO beneficiary overcome or remove a disability and are used to increase, maintain, or improve the functional capabilities of an individual. Assistive technology devices may include nonmedical devices but do not include any structural alterations (*e.g.*, permanent structure of wheelchair ramps or alterations to street curbs) service animals (*e.g.*, Seeing Eye dogs, hearing/handicapped assistance animals, etc.) or specialized equipment and devices whose primary purpose is to enable the individual to engage in sports or recreational events. Assistive technology devices are authorized only under coverage criteria determined by the Director, TRICARE Management Activity to assist in the reduction of the disabling effects of a qualifying condition for individuals eligible to receive benefits under the ECHO program, as provided in §199.5.

Attending physician. The physician who has the primary responsibility for the medical diagnosis and treatment of the patient. A consultant or an assistant surgeon, for example, would not be an attending physician. Under very extraordinary circumstances, because of the presence of complex, serious, and multiple, but unrelated, medical conditions, a patient may have more than one attending physician concurrently rendering medical treatment during a single period of time. An attending physician also may be a teaching physician.

Augmentative communication device (ACD). A voice prosthesis as determined by the Secretary of Defense to be necessary because of significant conditions resulting from trauma, congenital anomalies, or disease. Also referred to as Speech Generating Device.

Authorized provider. A hospital or institutional provider, physician, or other individual professional provider, or other provider of services or supplies specifically authorized to provide benefits under CHAMPUS in §199.6 of this part.

Automobile liability insurance. Automobile liability insurance means insurance against legal liability for health and medical expenses resulting from personal injuries arising from operation of a motor vehicle. Automobile liability insurance includes:

(1) Circumstances in which liability benefits are paid to an injured party only when the insured party's tortious acts are the cause of the injuries; and

(2) Uninsured and underinsured coverage, in which there is a third-party tortfeasor who caused the injuries (i.e., benefits are not paid on a no-fault basis), but the insured party is not the tortfeasor.

Backup hospital. A hospital which is otherwise eligible as a CHAMPUS institutional provider and which is fully capable of providing emergency care to a patient who develops complications beyond the scope of services of a given category of CHAMPUS-authorized freestanding institutional provider and which is accessible from the site of the CHAMPUS-authorized freestanding institutional provider within an average transport time acceptable for the types of medical emergencies usually associated with the type of care provided by the freestanding facility.

Balance billing. A provider seeking any payment, other than any payment relating to applicable deductible and cost sharing amounts, from a beneficiary for CHAMPUS covered services for any amount in excess of the applicable CHAMPUS allowable cost or charge.

Bariatric Surgery. Surgical procedures performed to treat co-morbid conditions associated with morbid obesity.

Bariatric surgery is based on two principles: (1) Divert food from the stomach to a lower part of the digestive tract where the normal mixing of digestive fluids and absorption of nutrients cannot occur (i.e., Malabsorptive surgical procedures); or (2) Restrict the size of the stomach and decrease intake (i.e., Restrictive surgical procedures).

Basic program. The primary medical benefits set forth in §199.4, generally referred to as the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) as authorized under chapter 55 of title 10 United States Code, were made available to eligible beneficiaries under this part.

Beneficiary. An individual who has been determined to be eligible for CHAMPUS benefits, as set forth in §199.3 of this part.

Beneficiary liability. The legal obligation of a beneficiary, his or her estate, or responsible family member to pay for the costs of medical care or treatment received. Specifically, for the purposes of services and supplies covered by CHAMPUS, beneficiary liability includes any annual deductible amount, cost-sharing amounts, or, when a provider does not submit a claim on a participating basis on behalf of the beneficiary, amounts above the CHAMPUS-determined allowable cost or charge. Beneficiary liability also includes any expenses for medical or related services and supplies not covered by CHAMPUS.

Biotelemetry. A diagnostic or monitoring procedure for the detection or measurement of human physiologic functions from a distance using a biotelemetry device to remotely monitor various vital signs of ambulatory patients. Biotelemetry may also be referred to as remote physiologic monitoring of physiologic parameters. See §199.4.

Birthing center. A health care provider which meets the applicable requirements established by §199.6(b) of this part.

Birthing room. A room and environment designed and equipped to provide care, to accommodate support persons, and within which a woman with a low-risk, normal, full-term pregnancy can labor, deliver and recover with her infant.

Brace. An orthopedic appliance or apparatus (an orthosis) used to support, align, or hold parts of the body in correct position. For the purposes of CHAMPUS, it does not include orthodontic or other dental appliances.

CAHs. A small facility that provides limited inpatient and outpatient hospital services primarily in rural areas and meets the applicable requirements established by §199.6(b)(4)(xvi).

Capped rate. The maximum per diem or all-inclusive rate that CHAMPUS will allow for care.

Case management. Case management is a collaborative process which assesses, plans, implements, coordinates, monitors, and evaluates the options and services required to meet an individual's health needs, including mental health and substance use disorder needs, using communication and available resources to promote quality, cost effective outcomes.

Case-mix index. Case-mix index is a scale that measures the relative difference in resources intensity among different groups receiving home health services.

Certified nurse-midwife. An individual who meets the applicable requirements established by §199.6(c) of this part.

Certified psychiatric nurse specialist. A licensed, registered nurse who meets the criteria in §199.6(c)(3)(iii)(G).

CHAMPUS DRG-Based Payment System. A reimbursement system for hospitals which assigns prospectively-determined payment levels to each DRG based on the average cost of treating all CHAMPUS patients in a given DRG.

CHAMPUS fiscal intermediary. An organization with which the Director, OCHAMPUS, has entered into a contract for the adjudication and processing of CHAMPUS claims and the performance of related support activities.

CHAMPUS Health Benefits Advisors (HBAs). Those individuals located at Uniformed Services medical facilities (on occasion at other locations) and assigned the responsibility for providing CHAMPUS information, information concerning availability of care from the Uniformed Services direct medical care system, and generally assisting beneficiaries (or sponsors). The term

also includes ''Health Benefits Counselor'' and ''CHAMPUS Advisor.''

Chemotherapy. The administration of approved antineoplastic drugs for the treatment of malignancies (cancer) via perfusion, infusion, or parenteral methods of administration.

Child. An unmarried child of a member or former member, who meets the criteria (including age requirements) in §199.3 of this part.

Chiropractor. A practitioner of chiropractic (also called chiropraxis); essentially a system of therapeutics based upon the claim that disease is caused by abnormal function of the nerve system. It attempts to restore normal function of the nerve system by manipulation and treatment of the structures of the human body, especially those of the spinal column.

NOTE: Services of chiropractors are not covered by CHAMPUS.

Christian science nurse. An individual who has been accredited as a Christian Science Nurse by the Department of Care of the First Church of Christ, Scientist, Boston, Massachusetts, and listed (or eligible to be listed) in the Christian Science Journal at the time the service is provided. The duties of Christian Science nurses are spiritual and are nonmedical and nontechnical nursing care performed under the direction of an accredited Christian Science practitioner. There exist two levels of Christian Science nurse accreditation:

(i) *Graduate Christian Science nurse*. This accreditation is granted by the Department of Care of the First Church of Christ, Scientist, Boston, Massachusetts, after completion of a 3-year course of instruction and study.

(ii) *Practical Christian Science nurse*. This accreditation is granted by the Department of Care of the First Church of Christ, Scientist, Boston, Massachusetts, after completion of a 1-year course of instruction and study.

Christian Science practitioner. An individual who has been accredited as a Christian Science Practitioner for the First Church, Scientist, Boston, Massachusetts, and listed (or eligible to be listed) in the Christian Science Journal at the time the service is provided. An individual who attains this accreditation has demonstrated results of his or her healing through faith and prayer rather than by medical treatment. Instruction is executed by an accredited Christian Science teacher and is continuous.

Christian Science sanatorium. A sanatorium either operated by the First Church of Christ, Scientist, or listed and certified by the First Church of Christ, Scientist, Boston, Massachusetts.

Chronic medical condition. A medical condition that is not curable, but which is under control through active medical treatment. Such chronic conditions may have periodic acute episodes and may require intermittent inpatient hospital care. However, a chronic medical condition can be controlled sufficiently to permit generally continuation of some activities of persons who are not ill (such as work and school).

Chronic renal disease (CRD). The end stage of renal disease which requires a continuing course of dialysis or a kidney transplantation to ameliorate uremic symptoms and maintain life.

Clinical psychologist. A psychologist, certified or licensed at the independent practice level in his or her state, who meets the criteria in §199.6(c)(3)(iii)(A).

Clinical social worker. An individual who is licensed or certified as a clinical social worker and meets the criteria listed in §199.6.

Clinically meaningful endpoints. As used the definition of *reliable evidence* in this paragraph (b) and §199.4(g)(15), the term clinically meaningful endpoints means objectively measurable outcomes of clinical interventions or other medical procedures, expressed in terms of survival, severity of illness or condition, extent of adverse side effects, diagnostic capability, or other effect on bodily functions directly associated with such results.

Collateral visits. Sessions with the patient's family or significant others for purposes of information gathering or implementing treatment goals.

Combined daily charge. A billing procedure by an inpatient facility that uses an inclusive flat rate covering all professional and ancillary charges without any itemization.

Complications of pregnancy. One of the following, when commencing or exacerbating during the term of the pregnancy:

(i) Caesarean delivery; hysterectomy.

(ii) Pregnancy terminating before expiration of 26 weeks, except a voluntary abortion.

(iii) False labor or threatened miscarriage.

(iv) Nephritis or pyelitis of pregnancy.

(v) Hyperemesis gravidarum.

(vi) Toxemia.

(vii) Aggravation of a heart condition or diabetes.

(viii) Premature rupture of membrane.

(ix) Ectopic pregnancy.

(x) Hemorrhage.

(xi) Other conditions as may be determined by the Director, OCHAMPUS, or a designee.

Confinement. That period of time from the day of admission to a hospital or other institutional provider, to the day of discharge, transfer, or separation from the facility, or death. Successive admissions also may qualify as one confinement provided not more than 60 days have elapsed between the successive admissions, except that successive admissions related to a single maternity episode shall be considered one confinement, regardless of the number of days between admissions.

Conflict of interest. Includes any situation where an active duty member (including a reserve member while on active duty) or civilian employee of the United States Government, through an official federal position, has the apparent or actual opportunity to exert, directly or indirectly, any influence on the referral of CHAMPUS beneficiaries to himself or herself or others with some potential for personal gain or appearance of impropriety. For purposes of this part, individuals under contract to a Uniformed Service may be involved in a conflict of interest situation through the contract position.

Congenital anomaly. A condition existing at or from birth that is a significant deviation from the common form or norm and is other than a common racial or ethnic feature. For purposes of CHAMPUS, congenital anomalies do not include anomalies relating to teeth (including malocclusion or missing tooth buds) or structures supporting the teeth, or to any form of hermaphroditism or sex gender confusion. Examples of congenital anomalies are harelip, birthmarks, webbed fingers or toes, or such other conditions that the Director, OCHAMPUS, or a designee, may determine to be congenital anomalies.

NOTE: Also refer to §199.4(e)(7) of this part.

Consultation. A deliberation with a specialist physician, dentist, or qualified mental health provider requested by the attending physician primarily responsible for the medical care of the patient, with respect to the diagnosis or treatment in any particular case. A consulting physician or dentist or qualified mental health provider may perform a limited examination of a given system or one requiring a complete diagnostic history and examination. To qualify as a consultation, a written report to the attending physician of the findings of the consultant is required.

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

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

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

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

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

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

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

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

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

(1) Can be rendered safely and reasonably by a person who is not medically skilled; or

(2) Is or are designed mainly to help the patient with the activities of daily living.

Days. Calendar days.

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

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

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

Deductible. Payment by an individual beneficiary or family of a specific first dollar amount of the TRICARE allowable amount for otherwise covered outpatient services or supplies obtained in any program year. The dollar amount of deductible per individual or family is calculated as specified by law.

Deductible certificate. A statement issued to the beneficiary (or sponsor) by a TRICARE contractor certifying to deductible amounts satisfied by a beneficiary for any applicable program year.

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

(1) Enrolling members, former members and their dependents, and

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

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

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

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

Deserter or desertion status. A service member is a deserter, or in a desertion status, when the Uniformed Service concerned has made an administrative determination to that effect, or the member's period of unauthorized absence has resulted in a court-martial conviction of desertion. Administrative declarations of desertion normally are made when a member has been an unauthorized absentee for over 30 days, but particular circumstances may result in an earlier declaration. Entitlement to CHAMPUS benefits ceases as of 12:01 a.m. on the day following the

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

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

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

Director. The Director of the Defense Health Agency, Director, TRICARE Management Activity, or Director, Office of CHAMPUS. Any references to the Director, Office of CHAMPUS, or OCHAMPUS, or TRICARE Management Activity, shall mean the Director, Defense Health Agency (DHA). Any reference to Director shall also include any person designated by the Director to carry out a particular authority. In addition, any authority of the Director may be exercised by the Assistant Secretary of Defense (Health Affairs).

Director, OCHAMPUS. An authority of the Director, OCHAMPUS includes any person designated by the Director, OCHAMPUS to exercise the authority involved.

Director, TRICARE Management Activity. This term includes the Director, TRICARE Management Activity, the official sometimes referred to in this part as the Director, Office of CHAMPUS (or OCHAMPUS), or any designee of the Director, TRICARE Management Activity or the Assistant Secretary of Defense for Health Affairs who is designated for purposes of an action under this part.

Doctor of Dental Medicine (D.M.D.). A person who has received a degree in dentistry, that is, that department of the healing arts which is concerned with the teeth, oral cavity, and associated structures.

Doctor of Medicine (M.D.). A person who has graduated from a college of allopathic medicine and who is entitled legally to use the designation M.D.

Doctor of Osteopathy (D.O.). A practitioner of osteopathy, that is, a system of therapy based on the theory that the body is capable of making its own remedies against disease and other toxic conditions when it is in normal structural relationship and has favorable environmental conditions and adequate nutrition. It utilizes generally accepted physical, medicinal, and surgical methods of diagnosis and therapy, while placing chief emphasis on the importance of normal body mechanics and manipulative methods of detecting and correcting faulty structure.

Domiciliary care. The term ''domiciliary care'' means care provided to a patient in an institution or homelike environment because:

(1) Providing support for the activities of daily living in the home is not available or is unsuitable; or

(2) Members of the patient's family are unwilling to provide the care.

Donor. An individual who supplies living tissue or material to be used in another body, such as a person who furnishes a kidney for renal transplant.

Double coverage. When a CHAMPUS beneficiary also is enrolled in another insurance, medical service, or health plan that duplicates all or part of a beneficiary's CHAMPUS benefits.

Double coverage plan. The specific insurance, medical service, or health plan under which a CHAMPUS beneficiary has entitlement to medical benefits that duplicate CHAMPUS benefits in whole or in part. Double coverage plans do not include:

(i) Medicaid.

(ii) Coverage specifically designed to supplement CHAMPUS benefits.

(iii) Entitlement to receive care from the Uniformed Services medical facilities;

(iv) Entitlement to receive care from Veterans Administration medical care facilities; or

(v) Part C of the Individuals with Disabilities Education Act for services and items provided in accordance with Part C of the IDEA that are medically or psychologically necessary in accordance with the Individual Family Service Plan and that are otherwise allowable under the CHAMPUS Basic Program or the Extended Care Health Option (ECHO).

Dual compensation. Federal Law (5 U.S.C. 5536) prohibits active duty members or civilian employees of the United States Government from receiving additional compensation from the government above their normal pay and allowances. This prohibition applies to CHAMPUS cost-sharing of medical care provided by active duty members or civilian government employees to CHAMPUS beneficiaries.

Duplicate equipment. An item of durable equipment, durable medical equipment, or assistive technology items, as defined in this section that serves the same purpose that is served by an item of durable equipment, durable medical equipment, or assistive technology item previously cost-shared by TRICARE. For example, various models of stationary oxygen concentrators with no essential functional differences are considered duplicate equipment, whereas stationary and portable oxygen concentrators are not considered duplicates of each other because the latter is intended to provide the user with mobility not afforded by the former. Also, a manual wheelchair and electric wheelchair, both of which otherwise meet the definition of durable equipment or durable medical equipment, would not be considered duplicates of each other if each is found to provide an appropriate level of mobility. For the purpose of this Part, durable equipment, durable medical equipment, or assistive technology items that are essential in providing a failsafe in-home life support system or that replace in-like-kind an item of equipment that is not serviceable due to normal wear, accidental damage, a change in the beneficiary's condition, or has been declared adulterated by the U.S. FDA, or is being or has been recalled by the manufacturer is not considered duplicate equipment.

Durable equipment. Equipment that—

(1) Is a medically necessary item, which can withstand repeated use;

(2) Is primarily and customarily used to serve a medical purpose; and

(3) Is generally not useful to an individual in the absence of an illness or injury. It includes durable medical equipment as defined in §199.2, wheelchairs, iron lungs, and hospital beds. It does not include equipment (including wheelchairs) used or designed primarily for use in sports or recreational activities.

Durable medical equipment. Durable equipment that is medically appropriate to—

(1) Improve, restore, or maintain the function of a malformed, diseased, or injured body part or can otherwise minimize or prevent the deterioration of the beneficiary's function or condition; or

(2) Maximize the beneficiary's function consistent with the beneficiary's physiological or medical needs.

Economic interest. (1) Any right, title, or share in the income, remuneration, payment, or profit of a CHAMPUS-authorized provider, or of an individual or entity eligible to be a CHAMPUS-authorized provider, resulting, directly or indirectly, from a referral relationship; or any direct or indirect ownership, right, title, or share, including a mortgage, deed of trust, note, or other obligation secured (in whole or in part) by one entity for another entity in a referral or accreditation relationship, which is equal to or exceeds 5 percent of the total property and assets of the other entity.

(2) A referral relationship exists when a CHAMPUS beneficiary is sent, directed, assigned or influenced to use a specific CHAMPUS-authorized provider, or a specific individual or entity eligible to be a CHAMPUS-authorized provider.

(3) An accreditation relationship exists when a CHAMPUS-authorized accreditation organization evaluates for

accreditation an entity that is an applicant for, or recipient of CHAMPUS-authorized provider status.

Emergency inpatient admission. An unscheduled, unexpected, medically necessary admission to a hospital or other authorized institutional provider for treatment of a medical condition meeting the definition of medical emergency and which is determined to require immediate inpatient treatment by the attending physician.

Entity. For purposes of §199.9(f)(1), ''entity'' includes a corporation, trust, partnership, sole proprietorship or other kind of business enterprise that is or may be eligible to receive reimbursement either directly or indirectly from CHAMPUS.

Essential Access Community Hospital (EACH). A hospital that is designated by the Centers for Medicare and Medicaid Services (CMS) as an EACH and meets the applicable requirements established by §199.14(a)(7)(vi).

Extended Care Health Option (ECHO). The TRICARE program of supplemental benefits for qualifying active duty family members as described in §199.5.

External Partnership Agreement. The External Partnership Agreement is an agreement between a military treatment facility commander and a CHAMPUS authorized institutional provider, enabling Uniformed Services health care personnel to provide otherwise covered medical care to CHAMPUS beneficiaries in a civilian facility under the Military-Civilian Health Services Partnership Program. Authorized costs associated with the use of the facility will be financed through CHAMPUS under normal cost-sharing and reimbursement procedures currently applicable under the basic CHAMPUS.

External Resource Sharing Agreement. A type External Partnership Agreement, established in the context of the TRICARE program by agreement of a military medical treatment facility commander and an authorized TRICARE contractor. External Resource Sharing Agreements may incorporate TRICARE features in lieu of standard CHAMPUS features that would apply to standard External Partnership Agreements.

Extramedical individual providers of care. Individuals who do counseling or nonmedical therapy and whose training and therapeutic concepts are outside the medical field, as specified in §199.6 of this part.

Extraordinary physical or psychological condition. A complex physical or psychological clinical condition of such severity which results in the beneficiary being homebound as defined in this section.

Facility charge. The term ''facility charge'' means the charge, either inpatient or outpatient, made by a hospital or other institutional provider to cover the overhead costs of providing the service. These costs would include building costs, *i.e.* depreciation and interest; staffing costs; drugs and supplies; and overhead costs, *i.e.*, utilities, housekeeping, maintenance, etc.

Former member. An individual who is eligible for, or entitled to, retired pay, at age 60, for non-Regular service in accordance with chapter 1223, title 10, United States Code but who has been discharged and who maintains no military affiliation. These former members, at age 60, and their eligible dependents are entitled to medical care, commissary, exchange, and MWR privileges. Under age 60, they and their eligible dependents are entitled to commissary, exchange, and MWR privileges only.

Former spouse. A former husband or wife of a Uniformed Service member or former member who meets the criteria as set forth in §199.3(b)(2)(ii) of this part.

Fraud. For purposes of this part, fraud is defined as (1) a deception or misrepresentation by a provider, beneficiary, sponsor, or any person acting on behalf of a provider, sponsor, or beneficiary with the knowledge (or who had reason to know or should have known) that the deception or misrepresentation could result in some unauthorized CHAMPUS benefit to self or some other person, or some unauthorized CHAMPUS payment, or (2) a claim that is false or fictitious, or includes or is supported by any written statement which asserts a material fact which is false or fictitious, or includes or is supported by any written statement that (a) omits a material fact and (b) is

false or fictitious as a result of such omission and (c) is a statement in which the person making, presenting, or submitting such statement has a duty to include such material fact. It is presumed that, if a deception or misrepresentation is established *and* a CHAMPUS claim is filed, the person responsible for the claim had the requisite knowledge. This presumption is rebuttable only by substantial evidence. It is further presumed that the provider of the services is responsible for the actions of all individuals who file a claim on behalf of the provider (for example, billing clerks); this presumption may only be rebutted by clear and convincing evidence.

Freestanding. Not ''institution-affiliated'' or ''institution-based.''

Full-time course of higher education. A complete, progressive series of studies to develop attributes such as knowledge, skill, mind, and character, by formal schooling at a college or university, and which meets the criteria set out in §199.3 of this part. To qualify as full-time, the student must be carrying a course load of a minimum of 12 credit hours or equivalent each semester.

General staff nursing service. All nursing care (other than that provided by private duty nurses) including, but not limited to, general duty nursing, emergency room nursing, recovery room nursing, intensive nursing care, and group nursing arrangements performed by nursing personnel on the payroll of the hospital or other authorized institution.

Good faith payments. Those payments made to civilian sources of medical care who provided medical care to persons purporting to be eligible beneficiaries but who are determined later to be ineligible for CHAMPUS benefits. (The ineligible person usually possesses an erroneous or illegal identification card.) To be considered for good faith payments, the civilian source of care must have exercised reasonable precautions in identifying a person claiming to be an eligible beneficiary.

Habilitation. The provision of functional capacity, absent from birth due to congenital anomaly or developmental disorder, which facilitates performance of an activity in the manner, or within the range considered normal, for a human being.

Handicap. For the purposes of this part, the term ''handicap'' is synonymous with the term ''disability.''

High-risk pregnancy. A pregnancy is high-risk when the presence of a currently active or previously treated medical, anatomical, physiological illness or condition may create or increase the likelihood of a detrimental effect on the mother, fetus, or newborn and presents a reasonable possibility of the development of complications during labor or delivery.

Homebound. A beneficiary's condition is such that there exists a normal inability to leave home and, consequently, leaving home would require considerable and taxing effort. Any absence of an individual from the home attributable to the need to receive health care treatment—including regular absences for the purpose of participating in therapeutic, psychosocial, or medical treatment in an adult day-care program that is licensed or certified by a state, or accredited to furnish adult day-care services in the—state shall not disqualify an individual from being considered to be confined to his home. Any other absence of an individual from the home shall not disqualify an individual if the absence is infrequent or of relatively short duration. For purposes of the preceding sentence, any absence for the purpose of attending a religious service shall be deemed to be an absence of infrequent or short duration. Also, absences from the home for non-medical purposes, such as an occasional trip to the barber, a walk around the block or a drive, would not necessarily negate the beneficiary's homebound status if the absences are undertaken on an infrequent basis and are of relatively short duration. An exception is made to the above homebound definitional criteria for beneficiaries under the age of 18 and those receiving maternity care. The only homebound criteria for these special beneficiary categories is written certification from a physician attesting to the fact that leaving the home would place the beneficiary at medical risk. In addition to the above, absences, whether regular or infrequent,

from the beneficiary's primary residence for the purpose of attending an educational program in a public or private school that is licensed and/or certified by a state, shall not negate the beneficiary's homebound status.

Home health discipline. One of six home health disciplines covered under the home health benefit (skilled nursing services, home health aide services, physical therapy services, occupational therapy services, speech-language pathology services, and medical social services).

Home health market basket index. An index that reflects changes over time in the prices of an appropriate mix of goods and services included in home health services.

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

Hospital, acute care (general and special). An institution that meets the criteria as set forth in §199.6(b)(4)(i) of this part.

Hospital, psychiatric. An institution that meets the criteria as set forth in §199.6(b)(4)(ii) of this part.

Illegitimate child. A child not recognized as a lawful offspring; that is, a child born of parents not married to each other.

Immediate family. The spouse, natural parent, child and sibling, adopted child and adoptive parent, stepparent, stepchild, grandparent, grandchild, stepbrother and stepsister, father-in-law, mother-in-law of the beneficiary, or provider, as appropriate. For purposes of this definition only, to determine who may render services to a beneficiary, the step-relationship continues to exist even if the marriage upon which the relationship is based terminates through divorce or death of one of the parents.

Independent laboratory. A freestanding laboratory approved for participation under Medicare and certified by the Health Care Financing Administration.

Infirmaries. Facilities operated by student health departments of colleges and universities to provide inpatient or outpatient care to enrolled students. When specifically approved by the Director, OCHAMPUS, or a designee, a boarding school infirmary also is included.

Initial determination. A formal written decision on a CHAMPUS claim, a request for benefit authorization, a request by a provider for approval as an authorized CHAMPUS provider, or a decision disqualifying or excluding a provider as an authorized provider under CHAMPUS. Rejection of a claim or a request for benefit or provider authorization for failure to comply with administrative requirements, including failure to submit reasonably requested information, is not an initial determination. Responses to general or specific inquiries regarding CHAMPUS benefits are not initial determinations.

In-out surgery. Surgery performed in the outpatient department of a hospital or other institutional provider, in a physician's office or the office of another individual professional provider, in a clinic, or in a ''freestanding'' ambulatory surgical center which does not involve a formal inpatient admission for a period of 24 hours or more.

Inpatient. A patient who has been admitted to a hospital or other authorized institution for bed occupancy for purposes of receiving necessary medical care, with the reasonable expectation that the patient will remain in the institution at least 24 hours, and with the registration and assignment of an inpatient number or designation. Institutional care in connection with in and out (ambulatory) surgery is not included within the meaning of inpatient whether or not an inpatient number or designation is made by the hospital or other institution. If the patient has been received at the hospital, but death occurs before the actual admission occurs, an inpatient admission exists as if the patient had lived and had been formally admitted.

Inpatient Rehabilitation Facility (IRF). A facility classified by CMS as an IRF and meets the applicable requirements established by §199.6(b)(4)(xx) (which includes the requirement to be a Medicare participating provider).

Institution-affiliated. Related to a CHAMPUS-authorized institutional provider through a shared governing body but operating under a separate and distinct license or accreditation.

Institution-based. Related to a CHAMPUS-authorized institutional provider through a shared governing body and operating under a common license and shared accreditation.

Institutional provider. A health care provider which meets the applicable requirements established by §199.6(b) of this part.

Intensive care unit (ICU). A special segregated unit of a hospital in which patients are concentrated by reason of serious illness, usually without regard to diagnosis. Special lifesaving techniques and equipment regularly and immediately are available within the unit, and patients are under continuous observation by a nursing staff specially trained and selected for the care of this type patient. The unit is maintained on a continuing rather than an intermittent or temporary basis. It is not a postoperative recovery room nor a postanesthesia room. In some large or highly specialized hospitals, the ICUs may be further refined for special purposes, such as for respiratory conditions, cardiac surgery, coronary care, burn care, or neurosurgery. For the purposes of CHAMPUS, these specialized units would be considered ICUs if they otherwise conformed to the definition of an ICU.

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

Intern. A graduate of a medical or dental school serving in a hospital in preparation to being licensed to practice medicine or dentistry.

Internal Partnership Agreement. The Internal Partnership Agreement is an agreement between a military treatment facility commander and a CHAMPUS-authorized civilian health care provider which enables the use of civilian health care personnel or other resources to provide medical care to CHAMPUS beneficiaries on the premises of a military treatment facility under the Military-Civilian Health Services Partnership Program. These internal agreements may be established when a military treatment facility is unable to provide sufficient health care services for CHAMPUS beneficiaries due to shortages of personnel and other required resources.

Internal Resource Sharing Agreement. A type of Internal Partnership Agreement, established in the context of the TRICARE program by agreement of a military medical treatment facility commander and authorized TRICARE contractor. Internal Resource Sharing Agreements may incorporate TRICARE features in lieu of standard CHAMPUS features that would apply to standard Internal Partnership Agreements.

Item, Service, or Supply. Includes (1) any item, device, medical supply, or service claimed to have been provided to a beneficiary (patient) and listed in an itemized claim for CHAMPUS payment or a request for payment, or (2) in the case of a claim based on costs, any entry or omission in a cost report, books of account, or other documents supporting the claim.

Laboratory and pathological services. Laboratory and pathological examinations (including machine diagnostic tests that produce hard-copy results) when necessary to, and rendered in connection with medical, obstetrical, or surgical diagnosis or treatment of an illness or injury, or in connection with well-baby care.

Legitimized child. A formerly illegitimate child who is considered legitimate by reason of qualifying actions recognized in law.

Licensed practical nurse (L.P.N.). A person who is prepared specially in the scientific basis of nursing; who is a

graduate of a school of practical nursing; whose qualifications have been examined by a state board of nursing; and who has been authorized legally to practice as an L.P.N. under the supervision of a physician.

Licensed vocational nurse (L.V.N.) A person who specifically is prepared in the scientific basis or nursing; who is a graduate of a school of vocational nursing; whose qualifications have been examined by a state board of nursing; and who has been authorized legally to practice as a L.V.N. under the supervision of a physician.

Long Term Care Hospital (LTCH). A hospital that is classified by the Centers for Medicare and Medicaid Services (CMS) as an LTCH and meets the applicable requirements established by §199.6(b)(4)(v) (which includes the requirement to be a Medicare participating provider).

Low-risk pregnancy. A pregnancy is low-risk when the basis for the ongoing clinical expectation of a normal uncomplicated birth, as defined by reasonable and generally accepted criteria of maternal and fetal health, is documented throughout a generally accepted course of prenatal care.

Major life activity. Breathing, cognition, hearing, seeing, and age appropriate ability essential to bathing, dressing, eating, grooming, speaking, stair use, toilet use, transferring, and walking.

Marriage and family therapist, certified. An extramedical individual provider who meets the requirements outlined in §199.6.

Maternity care. Care and treatment related to conception, delivery, and abortion, including prenatal and postnatal care (generally through the 6th post-delivery week), and also including treatment of the complications of pregnancy.

Medicaid. Those medical benefits authorized under Title XIX of the Social Security Act provided to welfare recipients and the medically indigent through programs administered by the various states.

Medical. The generally used term which pertains to the diagnosis and treatment of illness, injury, pregnancy, and mental disorders by trained and licensed or certified health professionals. For purposes of CHAMPUS, the term ''medical'' should be understood to include ''medical, psychological, surgical, and obstetrical,'' unless it is specifically stated that a more restrictive meaning is intended.

Medical emergency. The sudden and unexpected onset of a medical condition or the acute exacerbation of a chronic condition that is threatening to life, limb, or sight, and requires immediate medical treatment or which manifests painful symptomatology requiring immediate palliative efforts to alleviate suffering. Medical emergencies include heart attacks, cardiovascular accidents, poisoning, convulsions, kidney stones, and such other acute medical conditions as may be determined to be medical emergencies by the Director, OCHAMPUS, or a designee. In the case of a pregnancy, a medical emergency must involve a sudden and unexpected medical complication that puts the mother, the baby, or both, at risk. Pain would not, however, qualify a maternity case as an emergency, nor would incipient birth after the 34th week of gestation, unless an otherwise qualifying medical condition is present. Examples of medical emergencies related to pregnancy or delivery are hemorrhage, ruptured membrane with prolapsed cord, placenta previa, abruptio placenta, presence of shock or unconsciousness, suspected heart attack or stroke, or trauma (such as injuries received in an automobile accident).

Medically or psychologically necessary preauthorization. A pre (or prior) authorization for payment for medical/surgical or psychological services based upon criteria that are generally accepted by qualified professionals to be reasonable for diagnosis and treatment of an illness, injury, pregnancy, and mental disorder.

Medical supplies and dressings (consumables). Necessary medical or surgical supplies (exclusive of durable medical equipment) that do not withstand prolonged, repeated use and that are needed for the proper medical management of a condition for which benefits are otherwise authorized under CHAMPUS, on either an inpatient or

outpatient basis. Examples include disposable syringes for a diabetic, colostomy sets, irrigation sets, and ace bandages.

Medically or psychologically necessary. The frequency, extent, and types of medical services or supplies which represent appropriate medical care and that are generally accepted by qualified professionals to be reasonable and adequate for the diagnosis and treatment of illness, injury, pregnancy, and mental disorders or that are reasonable and adequate for well-baby care.

Medicare. These medical benefits authorized under Title XVIII of the Social Security Act provided to persons 65 or older, certain disabled persons, or persons with chronic renal disease, through a national program administered by the DHHS, Health Care Financing Administration, Medicare Bureau.

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

Member. An individual who is affiliated with a Service, either an active duty member, Reserve member, active duty retired member, or Retired Reserve member. Members in a retired status are not former members. Also referred to as the sponsor.

Mental disorder, to include substance use disorder. For purposes of the payment of CHAMPUS benefits, a mental disorder is a nervous or mental condition that involves a clinically significant behavioral or psychological syndrome or pattern that is associated with a painful symptom, such as distress, and that impairs a patient's ability to function in one or more major life activities. A substance use disorder is a mental condition that involves a maladaptive pattern of substance use leading to clinically significant impairment or distress; impaired control over substance use; social impairment; and risky use of a substance(s). Additionally, the mental disorder must be one of those conditions listed in the current edition of the Diagnostic and Statistical Manual of Mental Disorders. ''Conditions Not Attributable to a Mental Disorder,'' or V codes, are not considered diagnosable mental disorders. Co-occurring mental and substance use disorders are common and assessment should proceed as soon as it is possible to distinguish the substance related symptoms from other independent conditions.

Mental health therapeutic absence. A therapeutically planned absence from the inpatient setting. The patient is not discharged from the facility and may be away for periods of several hours to several days. The purpose of the therapeutic absence is to give the patient an opportunity to test his or her ability to function outside the inpatient setting before the actual discharge.

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

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

Morbid obesity. A body mass index (BMI) equal to or greater than 40 kilograms per meter squared (kg/m^2), or a BMI equal to or greater than 35 kg/m^2 in conjunction with high-risk comorbidities, which is based on the guidelines established by the National Heart, Lung and Blood Institute on the Identification and Management of Patients with Obesity.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Official formularies. A book of official standards for certain pharmaceuticals

and preparations that are not included in the *U.S. Pharmacopeia*.

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

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

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

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

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

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

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

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

(1) Has directly or indirectly a 5 percent or more ownership interest in the entity; or

(2) Is the owner of a whole or part interest in any mortgage, deed of trust, note, or other obligation secured (in whole or in part) by the entity or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property and assets of the entity; or

(3) Is an officer or director of the entity if the entity is organized as a corporation; or

(4) Is a partner in the entity if the entity is organized as a partnership.

Partial hospitalization. A treatment setting capable of providing an interdisciplinary program of medically monitored therapeutic services, to include management of withdrawal symptoms, as medically indicated. Services may include day, evening, night and weekend treatment programs

which employ an integrated, comprehensive and complementary schedule of recognized treatment approaches. Partial hospitalization is a time-limited, ambulatory, active treatment program that offers therapeutically intensive, coordinated, and structured clinical services within a stable therapeutic environment. Partial hospitalization is an appropriate setting for crisis stabilization, treatment of partially stabilized mental disorders, to include substance disorders, and a transition from an inpatient program when medically necessary.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) 40 dB HL or greater in one or both ears when tested at 500, 1,000, 1,500, 2,000, 3,000, or 4,000Hz; or

(2) 26 dB HL or greater in one or both ears at any three or more of those frequencies; or

(3) A speech recognition score less than 94 percent.

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

Program year. The appropriate year (*e.g.*, calendar year, fiscal year, rolling 12-month period, etc.) specified in the administration of TRICARE programs for application of unique requirements or limitations (*e.g.*, enrollment fees, deductibles, catastrophic loss protection, etc.) on covered health care services obtained or provided during the designated time period.

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

Prosthetic device (prosthesis). An artificial substitute for a missing body part.

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

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

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

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

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

Psychiatric emergency. A psychiatric inpatient admission is an emergency when, based on a psychiatric evaluation performed by a physician (or other qualified mental health care professional with hospital admission authority), the patient is at immediate risk of serious harm to self or others as a result of a mental disorder and requires immediate continuous skilled observation at the acute level of care.

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

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

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

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

(1) Develops process standards and outcome standards for health care delivery programs, or knowledge standards and skill standards for health care professional certification testing, using experts both from within and outside of the health care program area or individual specialty to which the standards are to be applied;

(2) Creates measurable criteria that demonstrate compliance with each standard;

(3) Publishes the organization's standards, criteria and evaluation processes so that they are available to the general public;

(4) Performs on-site evaluations of health care delivery programs, or provides testing of individuals, to measure

the extent of compliance with each standard;

(5) Provides on-site evaluation or individual testing on a national or international basis;

(6) Provides to evaluated programs and tested individuals time-limited written certification of compliance with the organization's standards;

(7) Excludes certification of any program operated by an organization which has an economic interest, as defined in this section, in the accreditation organization or in which the accreditation organization has an economic interest;

(8) Publishes promptly the certification outcomes of each program evaluation or individual test so that it is available to the general public; and

(9) Has been found by the Director, OCHAMPUS, or designee, to apply standards, criteria, and certification processes which reinforce CHAMPUS provider authorization requirements and promote efficient delivery of CHAMPUS benefits.

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

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

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

Referral. The act or an instance of referring a TRICARE beneficiary to another authorized provider to obtain necessary medical treatment. Generally, when a referral is required to qualify health care as a covered benefit, only a TRICARE-authorized physician may make such a referral unless this regulation specifically allows another category of TRICARE-authorized provider to make a referral as allowed within the scope of the provider's license. In addition to referrals which may be required for certain health care to be a covered TRICARE benefit, the TRICARE Prime program under §199.17 generally requires Prime enrollees to obtain a referral for care through a primary care manager (PCM) or other authorized care coordinator to avoid paying higher deductible and cost-sharing for otherwise covered TRICARE benefits.

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

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

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

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

(i) Well controlled studies of clinically meaningful endpoints, published in refereed medical literature.

(ii) Published formal technology assessments.

(iii) The published reports of national professional medical associations.

(iv) Published national medical policy organization positions; and

(v) The published reports of national expert opinion organizations.

(2) The hierarchy of reliable evidence of proven medical effectiveness, established by (1) through (5) of this paragraph, is the order of the relative weight to be given to any particular source. With respect to clinical studies, only those reports and articles containing scientifically valid data and published in the refereed medical and scientific literature shall be considered as meeting the requirements of reliable evidence. Specifically not included in

the meaning of reliable evidence are reports, articles, or statements by providers or groups of providers containing only abstracts, anecdotal evidence or personal professional opinions. Also not included in the meaning of reliable evidence is the fact that a provider or a number of providers have elected to adopt a drug, device, or medical treatment or procedure as their personal treatment or procedure of choice or standard of practice.

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

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

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

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

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

Retired category. Retirees and their family members who are beneficiaries covered by 10 U.S.C. 1086(c), other than Medicare-eligible beneficiaries as described in 10 U.S.C. 1086(d).

Retiree. For ease of reference in this part only, and except as otherwise specified in this part, the term means a member or former member of a Uniformed Service who is entitled to retired, retainer, or equivalent pay based on duty in a Uniformed Service.

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

Sanction. For purpose of §199.9, ''sanction'' means a provider exclusion, suspension, or termination.

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

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

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

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

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

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

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

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

Sponsor. A member or former member of a Uniformed Service upon whose status his or her dependents' eligibility for CHAMPUS is based. A sponsor also includes a person who, while a member of the Uniformed Services and after becoming eligible to be retired on the basis of years of service, has his or her eligibility to receive retired pay terminated as a result of misconduct involving abuse of a spouse or dependent

child. It also includes NATO members who are stationed in or passing through the United States on official business when authorized. It also includes individuals eligible for CHAMPUS under the Transitional Assistance Management Program.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Surgery. Medically appropriate operative procedures, including related preoperative and postoperative care; reduction of fractures and dislocations; injections and needling procedures of

the joints; laser surgery of the eye; and those certain procedures listed in §199.4(c)(2)(i) of this part.

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

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

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

Telephonic consultations: A covered consultation service conducted via telephone call between TRICARE-authorized providers, including a verbal and written report to the patient's treating/requesting physician or other TRICARE-authorized provider.

Telephonic office visits. A covered service provided via a telephone call between a beneficiary who is an established patient and a TRICARE-authorized provider. See §199.4.

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

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

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

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

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

Treatment plan. A detailed description of the medical care being rendered or expected to be rendered a CHAMPUS beneficiary seeking approval for inpatient and other benefits for which preauthorization is required as set forth in §199.4(b). Medical care described in the plan must meet the requirements of medical and psychological necessity. A treatment plan must include, at a minimum, a diagnosis (either current International Statistical Classification of Diseases and Related Health Problems (ICD) or current Diagnostic and Statistical Manual of Mental Disorders (DSM)); detailed reports of prior treatment, medical history, family history, social history, and physical examination; diagnostic

test results; consultant's reports (if any); proposed treatment by type (such as surgical, medical, and psychiatric); a description of who is or will be providing treatment (by discipline or specialty); anticipated frequency, medications, and specific goals of treatment; type of inpatient facility required and why (including length of time the related inpatient stay will be required); and prognosis. If the treatment plan involves the transfer of a CHAMPUS patient from a hospital or another inpatient facility, medical records related to that inpatient stay also are required as a part of the treatment plan documentation.

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

TRICARE Extra. The preferred-provider option of the TRICARE program made available prior to January 1, 2018, under which TRICARE Standard beneficiaries may obtain discounts on cost sharing as a result of using TRICARE network providers.

TRICARE for Life. The Medicare wraparound coverage option of the TRICARE program made available to an eligible beneficiary by reason of 10 U.S.C. 1086(d).

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

TRICARE Prime. The managed care option of the TRICARE program established under §199.17.

TRICARE program. The program established under §199.17.

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

TRICARE Retired Reserve. The program established under 10 U.S.C. 1076e and §199.25.

TRICARE Select. The self-managed, preferred-provider network option under the TRICARE Program established by 10 U.S.C. 1075 and §199.17 to replace TRICARE Extra and Standard after December 31, 2017.

TRICARE Standard. The TRICARE program made available prior to January 1, 2018, covering health benefits contracted for under the authority of 10 U.S.C. section 1079(a) or 1086(a) and subject to the same rates and conditions as apply to persons covered under those sections.

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

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

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

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

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

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

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

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

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

X-ray services. An x-ray examination from which an x-ray film or other

image is produced, ordered by the attending physician when necessary and rendered in connection with a medical or surgical diagnosis or treatment of an illness or injury, or in connection with maternity or well-baby care.

[51 FR 24008, July 1, 1986]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §199.2, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

EFFECTIVE DATE NOTE: At 88 FR 19854, Apr. 4, 2023, §199.2 was amended in paragraph (b) by adding in alphabetical order definitions for ''Ambulatory Surgery Center (ASC)'', ''Cancer hospital'', and ''Children's hospital'', effective Oct. 1, 2023. For the convenience of the user, the added and revised text is set forth as follows:

§199.2 Definitions.

* * * * *

(b) * * *

Ambulatory Surgery Center (ASC). Any distinct entity that is classified by the Centers for Medicare and Medicaid Services (CMS) as an Ambulatory Surgical Center (ASC) under 42 CFR part 416 and meets the applicable requirements established by §199.6(b)(4)(x). Any ASC that would otherwise meet the CMS classification as an ASC but does not have a participation agreement with Medicare due to the nature of the patients they treat (*e.g.*, pediatric) must meet the applicable requirements established by §199.6(b)(4)(x) in order to be a TRICARE authorized ASC. All ASCs must also enter into participation agreements with TRICARE as required by §199.6(b)(4)(x) in order to be an authorized TRICARE provider of ASC services. Additionally, ASCs are prohibited from billing TRICARE beneficiaries for procedures that are not included in Medicare's ASC list of procedures allowable for facility fee payment in an ASC setting, unless the beneficiary agreed in advance in writing to pay for the non-covered services, in accordance with the ''hold harmless'' provision under §199.6(b)(4)(x)(B)(*1*)(*ii*) and (*iii*).

* * * * *

Cancer hospital. A specialty hospital that is classified by CMS as a Cancer Hospital as specified in 42 CFR 412.23 and meets the applicable requirements established by §199.6(b)(4)(i).

* * * * *

Children's hospital. A specialty hospital that is classified by CMS as a Children's Hospital as specified in 42 CFR 412.23 and meets the applicable requirements established by §199.6(b)(4)(i).

* * * * *

§199.3 Eligibility.

(a) *General.* This section sets forth those persons who, by the provisions of 10 U.S.C. chapter 55, and the NATO Status of Forces Agreement, are eligible for CHAMPUS benefits. A determination that a person is eligible does not automatically entitle such a person to CHAMPUS payments. Before any CHAMPUS benefits may be extended, additional requirements, as set forth in other sections of this part, must be met. Additionally, the use of CHAMPUS may be denied if a Uniformed Service medical treatment facility capable of providing the needed care is available. CHAMPUS relies primarily on the Defense Enrollment Eligibility Reporting System (DEERS) for eligibility verification.

(b) *CHAMPUS eligibles*—(1) *Retiree.* A member or former member of a Uniformed Service who is entitled to retired, retainer, or equivalent pay based on duty in a Uniformed Service.

(2) *Dependent.* Individuals whose relationship to the sponsor leads to entitlement to benefits. CHAMPUS eligible dependents include the following:

(i) *Spouse.* A lawful husband or wife of a member or former member. The spouse of a deceased member or retiree must not be remarried. A former spouse also may qualify for benefits as a dependent spouse. A former spouse is a spouse who was married to a military member, or former member, but whose marriage has been terminated by a final decree of divorce, dissolution or annulment. To be eligible for CHAMPUS benefits, a former spouse must meet the criteria described in paragraphs (b)(2)(i)(A) through (b)(2)(i)(E) of this section *and* must qualify under the group defined in paragraph (b)(2)(i)(F)(*1*) or (b)(2)(i)(F)(*2*) of this section.

(A) Must be unremarried; and

(B) Must not be covered by an employer-sponsored health plan; and

(C) Must have been married to a member or former member who performed at least 20 years of service

which can be credited in determining the member's or former member's eligibility for retired or retainer pay; and

(D) Must not be eligible for Part A of Title XVIII of the Social Security Act (Medicare) except as provided in paragraphs (b)(3), (f)(3)(vii), (f)(3)(viii), and (f)(3)(ix) of this section; and

(E) Must not be the dependent of a NATO member; *and*

(F) Must meet the requirements of paragraph (b)(2)(i)(F)(*1*) or (b)(2)(i)(F)(*2*) of this section:

(*1*) The former spouse must have been married to the same member or former member for at least 20 years, at least 20 of which were creditable in determining the member's or former member's eligibility for retired or retainer pay. Eligibility continues indefinitely unless affected by any of the conditions of paragraphs (b)(2)(i)(A) through (b)(2)(i)(E) of this section.

(*i*) If the date of the final decree of divorce, dissolution, or annulment was before February 1, 1983, the former spouse is eligible for CHAMPUS coverage of health care received on or after January 1, 1985.

(*ii*) If the date of the final decree of the divorce, dissolution, or annulment was on or after February 1, 1983, the former spouse is eligible for CHAMPUS coverage of health care which is received on or after the date of the divorce, dissolution, or annulment.

(*2*) The former spouse must have been married to the same member or former member for at least 20 years, and at least 15, but less than 20 of those married years were creditable in determining the member's or former member's eligibility for retired or retainer pay.

(*i*) If the date of the final decree of divorce, dissolution, or annulment is before April 1, 1985, the former spouse is eligible only for care received on or after January 1, 1985, or the date of the divorce, dissolution, or annulment, whichever is later. Eligibility continues indefinitely unless affected by any of the conditions of paragraphs (b)(2)(i)(A) through (b)(2)(i)(E) of this section.

(*ii*) If the date of the final decree of divorce, dissolution or annulment is on or after April 1, 1985, but before September 29, 1988, the former spouse is eligible only for care received from the date of the decree of divorce, dissolution, or annulment until December 31, 1988, or for two years from the date of the divorce, dissolution, or annulment, whichever is later.

(*iii*) If the date of the final decree of divorce, dissolution, or annulment is on or after September 29, 1988, the former spouse is eligible only for care received within the 365 days (366 days in the case of a leap year) immediately following the date of the divorce, dissolution, or annulment.

(ii) *Child.* A dependent child is an unmarried child of a member or former member who has not reached his or her twenty-first (21st) birthday, except an incapacitated adopted child meeting the requirements of paragraph (b)(2)(ii)(H)(*2*) of this section, and who bears one of the following relationships to a member or former member of one of the Uniformed Services:

(A) A legitimate child; or

(B) An adopted child whose adoption has been legally completed on or before the child's twenty-first (21st) birthday; or

(C) A legitimate stepchild; or

(D) An illegitimate child of a *member or former member* whose paternity/maternity *has been* determined judicially, and the member or former member directed to support the child; or

(E) An illegitimate child of a *member or former member* whose paternity/maternity *has not been* determined judicially, who resides with or in the home provided by the member or former member, and is or continues to be dependent upon the member or former member for over one-half of his or her support, or who was so dependent on the former member at the time of the former member's death; or

(F) An illegitimate child of a *spouse of a member* who resides with or in a home provided by the member and is, and continues to be dependent upon the member for over one-half of his or her support; or

(G) An illegitimate child of a *spouse of a former member* who resides with or in a home provided by a former member or the former member's spouse at the time of death of the former member, and is, or continues to be, or was, dependent upon the former member for

more than one-half of his or her support at the time of death; or

(H) An individual who falls into one of the following classes:

(*1*) *A student.* A child determined to be a member of one of the classes in paragraphs (b)(2)(ii)(A) through (b)(2)(ii)(G) of this section, who is not married, has passed his or her 21st birthday but has not passed his or her 23rd birthday, is dependent upon the member or former member for over 50 percent of his or her support or was dependent upon the member or former member for over 50 percent of his or her support on the date of the member's or former member's death, and is pursuing a full-time course of education in an institution of higher learning approved by the Secretary of Defense or the Department of Education (as appropriate) or by a state agency under 38 U.S.C. chapters 34 and 35.

NOTE: Courses of education offered by institutions listed in the ''Education Directory,'' ''Higher Education'' or ''Accredited Higher Institutions'' issued periodically by the Department of Education meet the criteria approved by the Administering Secretary or the Secretary of Education. For determination of approval of courses offered by a foreign institution, by an institution not listed in either of the above directories, or by an institution not approved by a state agency pursuant to 38 U.S.C. chapters 34 and 35, a statement may be obtained from the Department of Education, Washington, D.C. 20202.

(*2*) *An incapacitated child.* A child determined to be a member of one of the classes in paragraphs (b)(2)(ii)(A) through (b)(2)(ii)(G) of this section, who is not married and is incapable of self-support because of a mental or physical disability that:

(*i*) Existed before the child's twenty-first (21st) birthday; or

(*ii*) Occurred between the ages of 21 and 23 while the child was enrolled in a full-time course of study in an institution of higher learning approved by the Administering Secretary or the Department of Education (see NOTE to paragraph (b)(2)(ii)(H)(*2*)(*iii*) of this section), and is or was at the time of the member's or former member's death dependent on the member or former member for over one-half of his or her support; and

(*iii*) The incapacity is continuous. (If the incapacity significantly improves or ceases at any time, CHAMPUS eligibility cannot be reinstated on the basis of the incapacity, unless the incapacity recurs and the beneficiary is under age 21, or is under age 23 and is enrolled as a full-time student under paragraph (b)(2)(ii)(H)(*2*)(*ii*) of this section. If the child was not incapacitated after that date, no CHAMPUS eligibility exists on the basis of the incapacity. However, incapacitated children who marry and who subsequently become unmarried through divorce, annulment, or death of spouse, may be reinstated as long as they still meet all other requirements).

NOTE: An institution of higher learning is a college, university, or similar institution, including a technical or business school, offering post-secondary level academic instruction that leads to an associate or higher degree, if the school is empowered by the appropriate State education authority under State law to grant an associate, or higher, degree. When there is no State law to authorize the granting of a degree, the school may be recognized as an institution of higher learning if it is accredited for degree programs by a recognized accrediting agency. The term also shall include a hospital offering educational programs at the post-secondary level regardless of whether the hospital grants a post-secondary degree. The term also shall include an educational institution that is not located in a State, that offers a course leading to a standard college degree, or the equivalent, and that is recognized as such by the Secretary of Education (or comparable official) of the country, or other jurisdiction, in which the institution is located (38 U.S.C. chapter 34, section 1661, and chapter 35, section 1701.

Courses of education offered by institutions listed in the ''Education Directory,'' ''Higher Education'' or ''Accredited Higher Institutions'' issued periodically by the Department of Education meet the criteria approved by the Administering Secretary or the Secretary of Education. For determination of approval of courses offered by a foreign institution, by an institution not listed in either of the above directories, or by an institution not approved by a state agency pursuant to chapters 34 and 35 of 38 U.S.C., a statement may be obtained from the Department of Education, Washington, D.C. 20202.

(*3*) *A child of a deceased reservist.* A child, who is determined to be a member of one of the classes in paragraphs (b)(2)(ii)(A) through (b)(2)(ii)(G) of this section, of a reservist in a Uniformed

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

(*4*) *An unmarried person.* An unmarried person placed in the home of a member or former member prior to adoption. To be a dependent child, the unmarried person must not have reached the age of 21 (or otherwise meets the requirements of a student or incapacitated child set out in paragraphs (b)(2)(ii)(H)(*1*) or (b)(2)(ii)(H)(*2*) of this section) and has been placed in the home of the member or former member by a recognized placement agency or by any other source authorized by State or local law to provide adoption placement, in anticipation of legal adoption by the member or former member.

(iii) *Abused dependents*—(A) *Categories of abused dependents.* An abused dependent may be either a spouse or a child. Eligibility for either class of abused dependent results from being either:

(*1*) The spouse (including a former spouse) or child of a member who has received a dishonorable or bad-conduct discharge, or dismissal from a Uniformed Service as a result of a court-martial conviction for an offense involving physical or emotional abuse of the spouse or child, or was administratively discharged as a result of such an offense. Until October 17, 1998, Medical benefits are limited to care related to the physical or emotional abuse and for a period of 12 months following the member's separation from the Uniformed Service. On or after October 17, 1998, medical benefits can include all under the Basic Program and under the Extended Care Health Option for the period that the spouse or child is in receipt of transitional compensation under section 1059 of title 10 U.S.C.

(*2*) The spouse (including a former spouse) or child of a member or former member who while a member and as a result of misconduct involving abuse of the spouse or child has eligibility to receive retired pay on the basis of years of service terminated.

(B) *Requirements for categories of abused dependents*—(*1*) *Abused spouse.* As long as the spouse is receiving payments from the DoD Military Retirement Fund under court order, the spouse is eligible for health care under the same conditions as any spouse of a retired member. The abused spouse must:

(*i*) Under paragraph (b)(2)(iii)(A)(*1*) of this section, be a lawful husband or wife or a former spouse of the member; or

(*ii*) Under paragraph (b)(2)(iii)(A)(*2*) of this section, be a lawful husband or wife or a former spouse of the member or former member, and the spouse is receiving payments from the Department of Defense Military Retirement Fund under 10 U.S.C. 1408(h) pursuant to a court order; and

(*A*) Be a victim of the abuse; and

(*B*) Have been married to the member or former member at the time of the abuse; or

(*C*) Be the natural or adoptive parent of a dependent child of the member or former member who was the victim of the abuse.

(*2*) *Abused child.* The abused child must:

(*i*) Under paragraph (b)(2)(iii)(A)(*1*) of this section, be a dependent child of the member or former member.

(*ii*) Under paragraph (b)(2)(iii)(A)(*2*) of this section,

(*A*) Have been a member of the household where the abuse occurred; and

(*B*) Be an unmarried legitimate child, including an adopted child or stepchild of the member or former member; and

(*C*) Be under the age of 18; or

(*D*) Be incapable of self support because of a mental or physical incapacity that existed before becoming 18 years of age and be dependent on the member or former member for over one-half of his or her support; or

(*E*) If enrolled in a full-time course of study in an institution of higher learning recognized by the Secretary of Defense (for the purposed of 10 U.S.C. 1408(h)), be under 23 years of age and be dependent on the member or former member for over one-half of his or her support.

(*F*) The dependent child is eligible for health care, regardless of whether any court order exists, under the same conditions as any dependent of a retired member.

(*3*) *TAMP eligibles.* A former member, including his or her dependents, who is eligible under the provisions of the Transitional Assistance Management Program as described in paragraph (e) of this §199.3.

(iv) An unmarried person who is placed in the legal custody of a member or former member by a court of competent jurisdiction in the United States (or possession of the United States) for a period of at least 12 consecutive months. The unmarried person shall be considered a dependent of the member or former member under this section provided he or she otherwise meets the following qualifications:

(A) Has not reached the age of 21 unless he or she otherwise meets the requirements of a student set out in paragraph (b)(2)(ii)(H)(*1*) of this section or the requirements for being incapacitated as set out in paragraph (b)(2)(ii)(H)(*2*) of this section and the incapacitation occurred while he or she was a dependent of the member or former member through court ordered legal custody;

(B) Is dependent on the member or former member for over one-half of the person's support;

(C) Resides with the member or former member unless separated by the necessity of military service or to receive institutional care as a result of disability or incapacitation or under such other authorized circumstances; and,

(D) Is not a dependent of a member or former member under any other provision of law or regulation.

(3) *Eligibility under TRICARE Senior Pharmacy Program.* Section 711 of the National Defense Authorization Act for Fiscal Year 2001 (Public Law 106–398, 114 Stat. 1654) established the TRICARE Senior Pharmacy Program effective April 1, 2001. To be eligible for this program, a person is required to be:

(i) Medicare eligible, who is:

(A) 65 years of age or older; and

(B) Entitled to Medicare Part A; and

(C) Enrolled in Medicare Part B, except for a person who attained age 65 prior to April 1, 2001, is not required to enroll in Part B; and

(ii) Otherwise qualified under one of the following categories:

(A) A retired uniformed service member who is entitled to retired or retainer pay, or equivalent pay including survivors who are annuitants; or

(B) A dependent of a member of the uniformed services described in one of the following:

(*1*) A member who is on active duty for a period of more than 30 days or died while on such duty; or

(*2*) A member who died from an injury, illness, or disease incurred or aggravated while the member was:

(*i*) On active duty under a call or order to active duty of 30 days or less, on active duty for training, or on inactive duty training; or

(*ii*) Traveling to or from the place at which the member was to perform or had performed such active duty, active duty for training, or inactive duty training.

NOTE TO PARAGRAPH (b)(3)(ii)(B): Dependent under Section 711 of the National Defense Authorization Act for Fiscal Year 2001 includes spouse, unremarried widow/widower, child, parent/parent-in-law, unremarried former spouse, and unmarried person in the legal custody of a member or former member, as those terms of dependency are defined and periods of eligibility are set forth in 10 U.S.C. 1072(2).

(4) *Medal of Honor recipients.* (i) A former member of the armed forces who is a Medal of Honor recipient and who is not otherwise entitled to medical and dental benefits has the same CHAMPUS eligibility as does a retiree.

(ii) *Immediate dependents.* CHAMPUS eligible dependents of a Medal of Honor Recipient are those identified in paragraphs (b)(2)(i) of this section (except for former spouses) and (b)(2)(ii) of this section (except for a child placed in legal custody of a Medal of Honor recipient under (b)(2)(ii)(H)(*4*) of this section).

(iii) *Effective date.* The CHAMPUS eligibility established by paragraphs (b)(4)(i) and (ii) of this section is applicable to health care services provided on or after October 30, 2000.

(5) *Reserve Component Members issued delayed-effective-date orders*—(i) *Member.* A member of a reserve component of the armed forces who is ordered to active duty for a period of more than 30 consecutive days in support of a contingency operation under a provision of

law referred to in section 101(a)(13)(B) of Title 10, United States Code, that provides for active-duty service to begin on a date after the date of the issuance of the order.

(ii) *Dependents.* CHAMPUS eligible dependents under this paragraph (b)(5) are those identified in paragraphs (b)(2)(i) (except former spouses) and (b)(2)(ii) of this section.

(iii) *Effective date.* The eligibility established by paragraphs (b)(5)(i) and (ii) of this section shall begin on or after November 6, 2003, and shall be effective on the later of the date that is:

(A) The date of issuance of the order referred to in paragraph (b)(5)(i) of this section; or

(B) 180 days before the date on which the period of active duty is to begin.

(iv) *Termination date.* The eligibility established by paragraphs (b)(5)(i) and (ii) of this section ends upon entry of the member onto active duty (at which time CHAMPUS eligibility for the dependents of the member is established under paragraph (b)(2) of this section) or upon cancellation or amendment of the orders referred to in paragraph (b)(5)(i) of this section such that they no longer meet the requirements of that paragraph (b)(5)(i).

(c) *Beginning dates of eligibility.* (1) Beginning dates of eligibility depend on the class to which the individual belongs and the date the individual became a member of the class. Those who join after the class became eligible attain individual eligibility on the date they join.

(2) Beginning dates of eligibility for each class of spouse (*excluding spouses who are victims of abuse and eligible spouses of certain deceased reservists*) are as follows:

(i) A spouse of a member for:

(A) Medical benefits authorized by the Dependents' Medical Care Act of 1956, December 7, 1956;

(B) Outpatient medical benefits under the Basic Program, October 1, 1966;

(C) Inpatient medical benefits under the Basic Program *and* benefits under the Extended Care Health Option, January 1, 1967;

(ii) A spouse of a former member:

(A) For medical benefits under the Basic Program, January 1, 1967.

(B) Ineligible for benefits under the Extended Care Health Option.

(iii) A former spouse:

(A) For medical benefits under the Basic Program, dates of beginning eligibility are as indicated for each category of eligible former spouse identified within paragraph (b)(2)(i) of this section.

(B) Ineligible for benefits under the Extended Care Health Option.

(3) Beginning dates of eligibility for spouses who are victims of abuse (*excluding spouses who are victims of abuse of certain deceased reservists*) are as follows:

(i) An abused spouse meeting the requirements of paragraph (b)(2)(iii)(A)(*1*) of this section, including an eligible former spouse:

(A) For medical and dental care for problems associated with the physical or emotional abuse under the Basic Program for a period of up to one year (12 months) following the person's separation from the Uniformed Service, November 14, 1986.

(B) For all medical and dental benefits under the Basic Program for the period that the spouse is in receipt of transitional compensation under section 1059 of title 10 U.S.C., October 17, 1998.

(C) For medical and dental care for problems associated with the physical or emotional abuse under the Extended Care Health Option for a period up to one year (12 months) following the person's separation from the Uniformed Service, November 14, 1986.

(D) For all medical and dental benefits described in section 199.5 for the period that the spouse is in receipt of transitional compensation under section 1059 of title 10 U.S.C., October 17, 1998.

(ii) An abused spouse meeting the requirements of paragraphs (b)(2)(iii)(A)(*2*) of this section, including an eligible former spouse:

(A) For all benefits under the CHAMPUS Basic Program, October 23, 1992.

(B) Ineligible for benefits under the Extended Care Health Option.

(4) Beginning dates of eligibility for spouses of certain deceased reservists, *including spouses who are victims of*

abuse of certain deceased reservists, are as follows:

(i) A spouse meeting the requirements of paragraph (b)(2)(i) of this section, including an eligible former spouse:

(A) For benefits under the Basic Program, November 14, 1986.

(B) Ineligible for benefits under the Extended Care Health Option.

(ii) An abused spouse of certain deceased reservists, meeting the requirements of paragraphs (b)(2)(iii) of this section, including an eligible former spouse, *for the limited benefits and period of eligibility* described in paragraphs (b)(2)(iii) of this section:

(A) For benefits under the Basic Program, November 14, 1986.

(B) For benefits under the Extended Care Health Option, November 14, 1986.

(iii) An abused spouse of certain deceased reservists, including an eligible former spouse, meeting the requirements of paragraphs (b)(2)(iii) of this section:

(A) For benefits under the Basic Program, October 23, 1992.

(B) Ineligible for benefits under the Extended Care Health Option.

(5) Beginning dates of eligibility for each class of dependent children, (*excluding dependent children of certain deceased reservists, abused children and incapacitated children whose incapacity occurred between the ages of 21 and 23 while enrolled in a full-time course of study in an institution of higher learning*), are as follows:

(i) Legitimate child, adopted child, or legitimate stepchild of a *member*, for:

(A) Medical benefits authorized by the Dependents' Medical Care Act of 1956, December 7, 1956;

(B) Outpatient medical benefits under the Basic Program, October 1, 1966;

(C) Inpatient medical benefits under the Basic Program *and* benefits under the Extended Care Health Option, January 1, 1967;

(ii) Legitimate child, adopted child or legitimate stepchild of *former members*:

(A) For medical benefits under the Basic Program, January 1, 1967.

(B) Ineligible for benefits under the Extended Care Health Option.

(iii) Illegitimate child of a male or female *member or former member* whose paternity/maternity has been determined judicially and the member or former member has been directed to support the child, for:

(A) All benefits for which otherwise entitled, August 31, 1972.

(B) Extended Care Health Option benefits limited to dependent children of *members* only, August 31, 1972.

(iv) Illegitimate child of:

(A) A male member or former member whose paternity *has not been* determined judicially:

(B) A female member or former member who resides with, or in a home provided by the member or former member, or who was residing in a home provided by the member or former member at the time of the member's or former member's death, and who is or continues to be dependent on the member for over one-half of his or her support, or was so dependent on the member or former member at the time of death;

(C) A spouse of a member or former member who resides with or in a home provided by the member or former member, or the parent who is the spouse of the member or former member or was the spouse of a member or former member at the time of death, and who is and continues to be dependent upon the member or former member for over one-half of his or her support, or was so dependent on the member or former member at the time of death; for:

(*1*) All benefits for which otherwise eligible, January 1, 1969.

(*2*) Extended Care Health Option limited to dependent children of *members* only, January 1, 1969.

(6) Beginning dates of eligibility for children of certain deceased reservists who meet the requirements of paragraph (b)(2)(ii)(H)(*3*) of this section, *excluding incapacitated children* who meet the requirements of paragraph (b)(2)(ii)(H)(*2*) of this section, for:

(i) Benefits under the Basic program, November 14, 1986.

(ii) Not eligible for benefits under the Extended Care Health Option.

(7) Beginning dates of eligibility for children who are victims of abuse, *including incapacitated children* who meet

the requirements of paragraph (b)(2)(ii)(H)(*2*) of this section are as follows:

(i) An abused child meeting the requirements of paragraph (b)(*2*)(iii)(A)(*1*) of this section:

(A) Medical and dental care for problems associated with the physical or emotional abuse under the Basic Program for a period of up to one year (12 months) following the person's separation from the Uniformed Service, November 14, 1986.

(B) For all medical and dental benefits under the Basic Program for the period that the child is in receipt of transitional compensation under section 1059 of title 10 U.S.C., October 17, 1998.

(C) Medical and dental care for problems associated with the physical or emotional abuse under the Extended Care Health Option for a period up to one year (12 months) following the person's separation from the Uniformed Service, November 14, 1986.

(D) For all medical and dental benefits described in section 199.5 for the period that the child is in receipt of transitional compensation under section 1059 of title 10 U.S.C., October 17, 1998.

(ii) An abused child meeting the requirements of paragraphs (b)(2)(iii)(A)(*2*) of this section:

(A) For all benefits under the CHAMPUS Basic Program, October 23, 1992.

(B) Ineligible for benefits under the Extended Care Health Option.

(8) Beginning dates of eligibility for incapacitated children who meet the requirements of paragraph (b)(2)(ii)(H)(*2*) of this section, whose incapacity occurred between the ages of 21 and 23 while enrolled in a full-time course of study in an institution of higher learning approved by the Administering Secretary or the Department of Education, and, are or were at the time of the member's or former member's death, dependent on the member or former member for over one-half of their support, for:

(i) All benefits for which otherwise entitled, October 23, 1992.

(ii) Extended Care Health Option benefits limited to children of *members* only, October 23, 1992.

(9) Beginning dates of eligibility for a child who meets the requirements of paragraph (b)(2)(ii)(H)(*4*) and:

(i) Has been placed in custody by a court:

(A) All benefits for which entitled, July 1, 1994.

(B) Extended Care Health Option benefits limited to children of *members* only, July 1, 1994.

(ii) Has been placed in custody by a recognized adoption agency:

(A) All benefits for which entitled, October 5, 1994.

(B) Extended Care Health Option benefits limited to children of *members* only, October 5, 1994.

(iii) Has been placed in the home of a member by a placement agency or by any other source authorized by State or local law to provide adoption placement, in anticipation of the legal adoption of the member:

(A) All benefits for which entitled, January 6, 2006.

(B) Extended Care Health Option benefits limited to children of members only, January 6, 2006.

(10) Beginning dates of eligibility for a retiree for:

(i) Medical benefits under the Basic Program January 1, 1967.

(ii) Retirees and their dependents are not eligible for benefits under the Extended Care Health Option.

(d) *Dual eligibility.* Dual eligibility occurs when a person is entitled to benefits from two sources. For example, when an active duty member is also the dependent of another active duty member, a retiree, or a deceased active duty member or retiree, dual eligibility, that is, entitlement to direct care from the Uniformed Services medical care system and CHAMPUS is the result. Since the active duty status is primary, and it is the intent that all medical care be provided an active duty member through the Uniformed Services medical care system, CHAMPUS eligibility is terminated as of 12:01 a.m. on the day following the day the dual eligibility begins. However, any dependent children in a marriage of two active duty persons or of an active duty member and a retiree, are CHAMPUS eligible in the same manner as dependent children of a marriage involving only one CHAMPUS

sponsor. Should a spouse or dependent who has dual eligibility leave active duty status, that person's CHAMPUS eligibility is reinstated as of 12:01 a.m. of the day active duty ends, if he or she otherwise is eligible as a dependent of a CHAMPUS sponsor.

NOTE: No CHAMPUS eligibility arises as the result of the marriage of two active duty members.

(e) *Eligibility under the Transitional Assistance Management Program (TAMP).* (1) A member of the armed forces is eligible for transitional health care if the member is:

(i) A member who is involuntarily separated from active duty.

(ii) A member of a Reserve component who is separated from active duty to which called or ordered in support of a contingency operation if the active duty is active duty for a period of more than 30 consecutive days.

(iii) A member who is separated from active duty for which the member is involuntarily retained under 10 U.S.C. 12305 in support of a contingency operation; or

(iv) A member who is separated from active duty served pursuant to a voluntary agreement of the member to remain on active duty for a period of less than 1 year in support of a contingency operation.

(v) A member who receives a sole survivorship discharge (as defined in section 1174(i) of this title).

(vi) A member who is separated from Active Duty who agrees to become a member of the Selected Reserve of the Ready Reserve of a reserve component.

(2) A spouse (as described in paragraph (b)(2)(i) of this section except former spouses) and child (as described in paragraph (b)(2)(ii) of this section) of a member described in paragraph (e)(1) of this section is also eligible for TAMP benefits under TRICARE.

(3) TAMP benefits under TRICARE begin on the day after the member is separated from active duty, and, if such separation occurred on or after November 6, 2003, end 180 days after such date. TRICARE benefits available to both the member and eligible family members are generally those available to family members of members of the uniformed services under this Part. However, during TAMP eligibility, a member of a Reserve Component as described in paragraph (e)(1)(ii) of this section, is entitled to dental care to which a member of the uniformed services on active duty for more than 30 days is entitled. Each branch of service will determine eligibility for its members and eligible family members and provide data to DEERS.

(f) *Changes in status which result in termination of CHAMPUS eligibility.* Changes in status which result in a loss of CHAMPUS eligibility as of 12:01 a.m. of the day following the day the event occurred, unless otherwise indicated, are as follows:

(1) *Changes in the status of a member.* (i) When an active duty member's period of active duty ends, excluding retirement or death.

(ii) When an active duty member is placed on desertion status (eligibility is reinstated when the active duty member is removed from desertion status and returned to military control).

NOTE: A member serving a sentence of confinement in conjunction with a sentence of punitive discharge is still considered on active duty until such time as the discharge is executed.

(2) *Changes in the status of a retiree.* (i) When a retiree ceases to be entitled to retired, retainer, or equivalent pay for any reason, the retiree's dependents lose their eligibility unless the dependent is otherwise eligible (e.g., some former spouses, some dependents who are victims of abuse and some incapacitated children as outlined in paragraph (b)(2)(ii)(H)(*2*) of this section).

(ii) A retiree also loses eligibility when no longer entitled to retired, retainer, or equivalent pay.

NOTE: A retiree who waives his or her retired, retainer or equivalent pay is still considered a retiree for the purposes of CHAMPUS eligibility.

(iii) Attainment of entitlement to hospital insurance benefits (Part A) under Medicare except as provided in paragraphs (b)(3), (f)(3)(vii), (f)(3)(viii) and (f)(3)(ix) of this section.

(3) *Changes in the status of a dependent.* (i) Divorce, except for certain classes of former spouses as provided in paragraph (b)(2)(i) of this section and the member or former member's *own* children (i.e., legitimate, adopted, and

judicially determined illegitimate children).

NOTE: An unadopted stepchild loses eligibility as of 12:01 a.m. of the day following the day the divorce becomes final.

(ii) Annulment, except for certain classes of former spouse as provided in paragraph (b)(2)(i) of this section and the member or former member's *own* children (i.e., legitimate, adopted, and judicially determined illegitimate children).

NOTE: An unadopted stepchild loses eligibility as of 12:01 a.m. of the day following the day the annulment becomes final.

(iii) Adoption, except for adoptions occurring after the death of a member or former member.

(iv) Marriage of a child, except when the marriage is terminated by death, divorce, or annulment before the child is 21 or 23 if an incapacitated child as provided in paragraph (b)(2)(ii)(H)(*2*) of this section.

(v) Marriage of a widow or widower, except for the child of the widow or widower who was the stepchild of the deceased member or former member at the time of death. The stepchild continues CHAMPUS eligibility as other classes of dependent children.

(vi) Attainment of entitlement to hospital insurance benefits (Part A) under Medicare except as provided in paragraphs (b)(3), (f)(3)(vii), (f)(3)(viii), and (f)(3)(ix) of this section. (This also applies to individuals living outside the United States where Medicare benefits are not available.)

(vii) Attainment of age 65, except for dependents of active duty members, beneficiaries not entitled to part A of Medicare, beneficiaries entitled to Part A of Medicare who have enrolled in Part B of Medicare, and as provided in paragraph (b)(3) of this section. For those who do not retain CHAMPUS, CHAMPUS eligibility is lost at 12:01 a.m. on the first day of the month in which the beneficiary becomes entitled to Medicare.

NOTE: If the person is not eligible for Part A of Medicare, he or she must file a Social Security Administration, ''Notice of Disallowance'' certifying to that fact with the Uniformed Service responsible for the issuance of his or her identification card so a new card showing CHAMPUS eligibility can be issued. Individuals entitled only to supplementary medical insurance (Part B) of Medicare, but not Part A, or Part A through the Premium HI provisions (provided for under the 1972 Amendments to the Social Security Act) retain eligibility under CHAMPUS (refer to §199.8 for additional information when a double coverage situation is involved).

(viii) End stage renal disease. All beneficiaries, except dependents of active duty members, lose their CHAMPUS eligibility when Medicare coverage becomes available to a person because of chronic renal disease unless the following conditions have been met. CHAMPUS eligibility will continue if:

(A) The individual is under 65 years old;

(B) The individual became eligible for Medicare under the provisions of 42 U.S.C. 426–1(a);

(C) The individual is enrolled in Part B of Medicare; and

(D) The individual has applied and qualified for continued CHAMPUS eligibility through the Defense Enrollment Eligibility Reporting System (DEERS).

(ix) Individuals with certain disabilities. Each case relating to Medicare eligibility resulting from being disabled requires individual investigation. All beneficiaries except dependents of active duty members lose their CHAMPUS eligibility when Medicare coverage becomes available to a disabled person unless the following conditions have been met. CHAMPUS eligibility will continue if:

(A) The individual is under 65 years old;

(B) The individual became eligible for Medicare under the provisions of 42 U.S.C. 426(b)(2);

(C) The individual is enrolled in Part B of Medicare except that in the case of a retroactive determination of entitlement to Medicare Part A hospital insurance benefits for a person under 65 years of age there is no requirement to enroll in Medicare Part B from the Medicare Part A entitlement date until the issuance of such retroactive determination; and

(D) The individual has applied and qualified for continued CHAMPUS eligibility through the Defense Enrollment Eligibility Reporting System (DEERS).

(x) Disabled students, that is children age 21 or 22, who are pursuing a full-time course of higher education and who, either during the school year or between semesters, suffer a disabling illness or injury with resultant inability to resume attendance at the institution remain eligible for CHAMPUS medical benefits for 6 months after the disability is removed or until the student passes his or her 23rd birthday, whichever occurs first. However, if recovery occurs before the 23rd birthday and there is resumption of a full-time course of higher education, CHAMPUS benefits can be continued until the 23rd birthday. The normal vacation periods during an established school year do not change the eligibility status of a dependent child 21 or 22 years old in a full time student status. Unless an incapacitating condition existed before, and at the time of, a dependent child's 21st birthday, a dependent child 21 or 22 years old in student status *does not* have eligibility and *may not* qualify for eligibility under the requirements related to mental or physical incapacity as described in paragraph (b)(2)(ii)(H)(*2*) of this section.

(g) *Reinstatement of CHAMPUS eligibility*. Circumstances which result in reinstatement of CHAMPUS eligibility are as follows:

(1) *End Stage renal disease.* Unless CHAMPUS eligibility has been continued under paragraph (f)(3)(viii) of the section, when Medicare eligibility ceases for end-stage renal disease patients, CHAMPUS eligibility resumes if the person is otherwise still eligible. He or she is required to take action to be reinstated as a CHAMPUS beneficiary and to obtain a new identification card.

(2) *Disability*. Some disabilities are permanent, others temporary. Each case must be reviewed individually. Unless CHAMPUS eligibility has been continued under paragraph (f)(3)(ix) of this section, when disability ends and Medicare eligibility ceases, CHAMPUS eligibility resumes if the person is otherwise still eligible. Again, he or she is required to take action to obtain a new CHAMPUS identification card.

(3) *Enrollment in Medicare Part B.* For individuals whose CHAMPUS eligibility has terminated pursuant to paragraph (f)(2)(iii) or (f)(3)(vi) of this section due to beneficiary action to decline Part B of Medicare, CHAMPUS eligibility resumes, effective on the date Medicare Part B coverage begins, if the person subsequently enrolls in Medicare Part B and the person is otherwise still eligible.

(h) *Determination of eligibility status.* Determination of an individual's eligibility as a CHAMPUS beneficiary is the primary responsibility of the Uniformed Service in which the member or former member is, or was, a member, or in the case of dependents of a NATO military member, the Service that sponsors the NATO member. For the purpose of program integrity, the appropriate Uniformed Service shall, upon request of the Director, OCHAMPUS, review the eligibility of a specific person when there is reason to question the eligibility status. In such cases, a report on the results of the review and any action taken will be submitted to the Director, OCHAMPUS, or a designee.

(i) *Procedures for determination of eligibility*. Procedures for the determination of eligibility are prescribed within the Department of Defense Instruction 1000.13 available at local military facilities personnel offices.

(j) *CHAMPUS procedures for verification of eligibility*. (1) Eligibility for CHAMPUS benefits will be verified through the Defense Enrollment Eligibility Reporting System (DEERS) maintained by the Uniformed Services, except for abused dependents as set forth in paragraph (b)(2)(iii) of this section. It is the responsibility of the CHAMPUS beneficiary, or parent, or legal representative, when appropriate, to provide the necessary evidence required for entry into the DEERS file to establish CHAMPUS eligibility and to ensure that all changes in status that may affect eligibility be reported immediately to the appropriate Uniformed Service for action.

(2) Ineligibility for CHAMPUS benefits may be presumed in the absence of

prescribed eligibility evidence in the DEERS file.

(3) The Director, OCHAMPUS, shall issue guidelines as necessary to implement the provisions of this section.

[64 FR 46135, Aug. 24, 1999, as amended at 66 FR 9654, Feb. 9, 2001; 66 FR 16400, Mar. 26, 2001; 66 FR 40606, Aug. 3, 2001; 67 FR 15725, Apr. 3, 2002; 68 FR 23032, Apr. 30, 2003; 68 FR 32361, May 30, 2003; 69 FR 51564, Aug. 20, 2004; 69 FR 60554, Oct. 12, 2004; 70 FR 12802, Mar. 16, 2005; 72 FR 2447, Jan. 19, 2007; 75 FR 50883, Aug. 18, 2010; 76 FR 81367, Dec. 28, 2011; 77 FR 38176, June 27, 2012; 80 FR 55254, Sept. 15, 2015]

§ 199.4 Basic program benefits.

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

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

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

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

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

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

(5) *Right to information.* As a condition precedent to the provision of benefits hereunder, OCHAMPUS or its CHAMPUS fiscal intermediaries shall be entitled to receive information from a physician or hospital or other person, institution, or organization (including a local, state, or U.S. Government agency) providing services or supplies to the beneficiary for which claims or requests for approval for benefits are submitted. Such information and records may relate to the attendance, testing, monitoring, or examination or diagnosis of, or treatment rendered, or services and supplies furnished to a beneficiary, and shall be necessary for the accurate and efficient administration of CHAMPUS benefits. Before a determination will be made on a request for preauthorization or claim of benefits, a beneficiary or sponsor must provide particular additional information relevant to the requested determination, when necessary. The recipient of such information shall in every case hold such records confidential except when:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(A) When and for what services a NAS is required. However, a NAS may not be required for services otherwise available at an MTF located within a 40-mile radius of the beneficiary's residence when another insurance plan or program provides the beneficiary's primary coverage for the services. This requirement for an NAS does not apply to beneficiaries enrolled in TRICARE Prime, even when those beneficiaries use the point-of-service option under §199.17(n)(3) of this part; and

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

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

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

(10) [Reserved]

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

(12) [Reserved]

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

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

Health Agency, or a designee, necessary to determine benefits on a claim for treatment of substance use disorder, the claim will be denied.

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

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

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

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

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

(v) *General or special education not covered.* Services and supplies related to the provision of either regular or special education generally are not covered. Such exclusion applies whether a separate charge is made for education or whether it is included as a

part of an overall combined daily charge of an institution. In the latter instance, that portion of the overall combined daily charge related to education must be determined, based on the allowable costs of the educational component, and deleted from the institution's charges before CHAMPUS benefits can be extended. The only exception is when appropriate education is not available from or not payable by the cognizant public entity. Each case must be referred to the Director, OCHAMPUS, or a designee, for review and a determination of the applicability of CHAMPUS benefits.

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

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

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

(ii) *General staff nursing services.*

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

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

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

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

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

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

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

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

(x) *Radiation therapy.* Includes radioisotopes.

(xi) *Physical therapy.*

(xii) *Oxygen.* Includes equipment for its administration.

(xiii) *Intravenous injections.* Includes solution.

(xiv) *Shock therapy.*

(xv) *Chemotherapy.*

(xvi) *Renal and peritoneal dialysis.*

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

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

(xix) *Medication assisted treatment.* Covered drugs and medicines for the treatment of substance use disorder include the substitution of a therapeutic drug, with addictive potential, for a

drug addiction when medically or psychologically necessary and appropriate medical care for a beneficiary undergoing supervised treatment for a substance use disorder.

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

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

(ii) *General staff nursing services.*

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

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

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

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

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

(vii) *Physical therapy.*

(viii) *Oxygen.* Includes equipment for its administration.

(ix) *Intravenous injections.* Includes solution.

(x) *Shock therapy.*

(xi) *Chemotherapy.*

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

(xiii) *Renal and peritoneal dialysis.*

(xiv) *Skilled nursing facility (SNF) services.* Covered services in SNFs are the same as provided under Medicare under section 1861(h) and (i) of the Social Security Act (42 U.S.C. 1395x(h) and (i)) and 42 CFR part 409, subparts C and D, except that the Medicare limitation on the number of days of coverage under section 1812(a) and (b) of the Social Security Act (42 U.S.C. 1395d(a) and (b)) and 42 CFR 409.61(b) shall not be applicable under TRICARE. Skilled nursing facility care for each spell of illness shall continue to be provided for as long as medically necessary and appropriate. For a SNF admission to be covered under TRICARE, the beneficiary must have a qualifying hospital stay meaning an inpatient hospital stay of three consecutive days or more, not including the hospital leave day. (The three-day hospital stay requirement is waived for the duration of the President's national emergency for the coronavirus disease 2019 (COVID–19) outbreak.) The beneficiary must enter the SNF within 30 days of leaving the hospital, or within such time as it would be medically appropriate to begin an active course of treatment, where the individual's condition is such that SNF care would not be medically appropriate within 30 days after discharge from a hospital. The skilled services must be for a medical condition that was either treated during the qualifying three-day hospital stay, or started while the beneficiary was already receiving covered SNF care. Additionally, an individual shall be deemed not to have been discharged from a SNF, if within 30 days after discharge from a SNF, the individual is again admitted to a SNF. Adoption by TRICARE of most Medicare coverage standards does not include Medicare coinsurance amounts. Extended care services furnished to an inpatient of a SNF by such SNF (except as provided in paragraphs (b)(3)(xiv)(C), (b)(3)(xiv)(F), and (b)(3)(xiv)(G) of this section) include:

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

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

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

(D) Medical social services;

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

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

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

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

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

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

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

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

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

(iv) *Psychological evaluation tests.*

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

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

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

(A) Patient has a diagnosable psychiatric disorder.

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

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

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

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

(*3*) Time frames for achieving proposed outcomes; and

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

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

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

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

(*1*) When its use is required medically and when the attending physician certifies that a private room is necessary medically for the proper care and treatment of a patient; or

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

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

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

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

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

(ii) *General staff nursing services*. General staff nursing services cover all nursing care (other than that provided

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

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

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

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

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

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

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

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

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

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

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

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

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

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

such services is made through the facility.

(6) *Inpatient mental health services.* Inpatient mental health services are those services furnished by institutional and professional providers for treatment of a nervous or mental disorder (as defined in §199.2) to a patient admitted to a CHAMPUS-authorized acute care general hospital; a psychiatric hospital; or, unless otherwise exempted, a special institutional provider.

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

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

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

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

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

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

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

(iii)–(iv)[Reserved]

(7) *Emergency inpatient hospital services.* In the case of a medical emergency, benefits can be extended for medically necessary inpatient services and supplies provided to a beneficiary by a hospital, including hospitals that do not meet CHAMPUS standards or comply with the nondiscrimination requirements under title VI of the Civil Rights Act and other nondiscrimination laws applicable to recipients of federal financial assistance, or satisfy other conditions herein set forth. In a medical emergency, medically necessary inpatient services and supplies are those that are necessary to prevent the death or serious impairment of the health of the patient, and that, because of the threat to the life or health of the patient, necessitate, the use of the most accessible hospital available and equipped to furnish such services. Emergency services are covered when medically necessary for the active medical treatment of the acute phases of substance withdrawal (detoxification), for stabilization and for treatment of medical complications for substance use disorder. The availability of benefits depends upon the following three separate findings and continues only as long as the emergency exists, as determined by medical review. If the case qualified as an emergency at the time of admission to an unauthorized institutional provider and the emergency subsequently is determined no longer to exist, benefits will be extended up through the date of notice to the beneficiary and provider that

CHAMPUS benefits no longer are payable in that hospital.

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

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

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

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

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

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

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

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

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

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

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

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

(iv) *Case management required.* The facility must provide case management that helps to assure arrangement of community based support services, referral of suspected child or elder abuse

or domestic violence to the appropriate state agencies, and effective after care arrangements, at a minimum.

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

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

(9) *Psychiatric and substance use disorder partial hospitalization services*—(i) *In general.* Partial hospitalization services are those services furnished by a TRICARE authorized partial hospitalization program and authorized mental health providers for the active treatment of a mental disorder. All services must follow a medical model and vest patient care under the general direction of a licensed TRICARE authorized physician employed by the partial hospitalization program to ensure medication and physical needs of all the patients are considered. The primary or attending provider must be a TRICARE authorized mental health provider (see paragraph (c)(3)(ix) of this section), operating within the scope of his/her license. These categories include physicians, clinical psychologists, certified psychiatric nurse specialists, clinical social workers, marriage and family counselors, TRICARE certified mental health counselors, pastoral counselors, and supervised mental health counselors. All categories practice independently except pastoral counselors and supervised mental health counselors who must practice under the supervision of TRICARE authorized physicians. Partial hospitalization services and interventions are provided at a high degree of intensity and restrictiveness of care, with medical supervision and medication management. Partial hospitalization services are covered as a basic program benefit only if they are provided in accordance with paragraph (b)(9) of this section. Such programs must enter into a participation agreement with TRICARE; and be accredited and in substantial compliance with the specified standards of an accreditation organization approved by the Director.

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

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

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

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

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

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

(A) *Board.* Includes use of the partial hospital facilities such as food service,

supervised therapeutically constructed recreational and social activities, and other general services as considered appropriate by the Director, or a designee.

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

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

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

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

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

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

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

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

(ii) *Criteria for determining medical or psychological necessity of intensive outpatient services.* In determining the medical or psychological necessity of intensive outpatient services, the evaluation conducted by the Director, or

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

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

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

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

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

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

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

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

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

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

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

(11) *Opioid treatment programs*—(i) *In general.* Outpatient treatment and management of withdrawal symptoms for substance use disorder provided at a TRICARE authorized opioid treatment program are covered. If the patient is medically in need of management of

withdrawal symptoms, but does not require the personnel or facilities of a general hospital setting, services for management of withdrawal symptoms are covered. The medical necessity for the management of withdrawal symptoms must be documented. Any services to manage withdrawal symptoms provided by the opioid treatment program must be under general medical supervision.

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

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

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

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

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

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

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

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

(iii) *Telehealth services.* Health care services covered by TRICARE and provided through the use of telehealth modalities including telephone services for: telephonic office visits; telephonic consultations; electronic transmission of data or biotelemetry or remote physiologic monitoring services and

supplies, are covered services to the same extent as if provided in person at the location of the patient if those services are medically necessary and appropriate for such modalities. The Director will establish special procedures for payment for such services. Additionally, where appropriate, in order to incentive the use of telehealth services, the Director may modify the otherwise applicable beneficiary cost-sharing requirements in paragraph (f) of this section which otherwise apply.

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

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

Bronchoscopy
Laryngoscopy
Thoracoscopy
Catheterization of the heart
Arteriograph thoracic lumbar
Esophagoscopy
Gastroscopy
Proctoscopy
Sigmoidoscopy
Peritoneoscopy
Cystoscopy
Colonscopy
Upper G.I. panendoscopy
Encephalograph
Myelography
Discography
Visualization of intracranial aneurysm by intracarotid injection of dye, with exposure of carotid artery, unilateral
Ventriculography
Insufflation of uterus and fallopian tubes for determination of tubal patency (Rubin's test of injection of radiopaque medium or for dilation)
Introduction of opaque media into the cranial arterial system, preliminary to cerebral arteriography, or into vertebral and subclavian systems
Intraspinal introduction of air preliminary to pneumoencephalography
Intraspinal introduction of opaque media preliminary to myelography
Intraventricular introduction of air preliminary to ventriculography

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

(ii) *Surgical assistance.*

(iii) *Inpatient medical services.*

(iv) *Outpatient medical services.*

(v) *Psychiatric services.*

(vi) *Consultation services.*

(vii) *Anesthesia services.*

(viii) *Radiation therapy services.*

(ix) *X-ray services.*

(x) *Laboratory and pathological services.*

(xi) *Physical medicine services or physiatry services.*

(xii) *Maternity care.*

(xiii) *Well-child care.*

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

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

(xv) [Reserved]

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

(3) *Extent of professional benefits—*

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

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

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

(C) Except that:

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

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

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

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

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

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

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

(C) If there were multiple surgical assistants; or

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

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

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

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

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

consultation and surgery (performed by the same physician), benefits may be extended for the consultation, subject to review.

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

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

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

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

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

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

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

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

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

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

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

(*9*) *Medication assisted treatment.* Medication assisted treatment, combining pharmacotherapy and holistic care, to include provision in office-based opioid treatment by an authorized TRICARE provider, is covered. The practice of an individual physician in office-based treatment is regulated by the Department of Health and Human Services' 42 CFR 8.12,the Center for Substance Abuse Treatment (CSAT), and the Drug Enforcement Administration (DEA), along with individual state and local regulations.

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

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

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

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

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

(A) The services are prescribed and monitored by a physician, certified physician assistant, certified nurse practitioner or Doctor of Podiatric Medicine (Podiatrist) acting within the scope of their license.

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

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

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

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

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

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

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

(*ii*) Vision, hearing, and dental screening.

(*iii*) Developmental appraisal to include body measurement.

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

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

(*vi*) Tuberculosis screening.

(*vii*) Blood pressure screening.

(*viii*) Measurement of hemoglobin and hematocrit for anemia.

(*ix*) Urinalysis.

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

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

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

(xii) [Reserved]

(xiii) *Physicians in a teaching setting*.

(A) *Teaching physicians*.

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

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

(*ii*) Personally examine the patient; and

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

(*iv*) Either perform the physician's services required by the patient or supervise the treatment so as to assure that appropriate services are provided by physicians in training and that the care meets a proper quality level; and

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

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

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

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

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

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

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

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

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

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

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

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

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

(*ii*) Is not otherwise excluded by this part.

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

(*i*) Durable medical equipment as defined in §199.2;

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

(*iii*) Iron lungs.

(*iv*) Hospital beds.

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

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

(*i*) Achieving therapeutic benefit for the patient;

(*ii*) Making the equipment serviceable; or

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

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

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

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

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

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

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

(*2*) The following types of services and items may be cost-shared when

provided in conjunction with an otherwise authorized cardiorespiratory monitor:

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

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

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

(*iv*) Diagnostic testing otherwise authorized by this part.

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

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

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

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

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

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

NOTE 1 TO PARAGRAPH (d)(3)(iii)(A): Generally, the allowable charge of a medical supply item will be under $100. Any item over this amount must be reviewed to determine whether it would qualify as a DME item. If it is, in fact, a medical supply item and does not represent an excessive charge, it can be considered for benefits under paragraph (d)(3)(iii) of this section.

(B) *Medically necessary food and medical equipment and supplies necessary to administer such food (other than durable medical equipment and supplies) when prescribed for dietary management of a covered disease or condition.* (*1*) Medically necessary food, including a low protein modified food product or an amino acid preparation product, may be covered when:

(*i*) Furnished pursuant to the prescription, order, or recommendation of a TRICARE authorized provider acting within the provider's scope of license/certificate of practice, for the dietary management of a covered disease or condition;

(*ii*) Is a specifically formulated and processed product (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of an individual by means of oral intake or enteral feeding by tube;

(*iii*) Is intended for the dietary management of an individual who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone;

(*iv*) Is intended to be used under medical supervision, which may include in a home setting; and

(*v*) Is intended only for an individual receiving active and ongoing medical supervision under which the individual requires medical care on a recurring basis for, among other things, instructions on the use of the food.

(*2*) Medically necessary food does not include:

(*i*) Food taken as part of an overall diet designed to reduce the risk of a disease or medical condition or as weight-loss products, even if the food is recommended by a physician or other health care professional;

(*ii*) Food marketed as gluten-free for the management of celiac disease or non-celiac gluten sensitivity;

(*iii*) Food marketed for the management of diabetes; or

(*iv*) Such other products as the Director, Defense Health Agency determines appropriate.

(*3*) Covered disease or condition under paragraph (d)(3)(iii)(B) of this section means:

(*i*) Inborn errors of metabolism;

(*ii*) Medical conditions of malabsorption;

(*iii*) Pathologies of the alimentary tract or the gastrointestinal tract;

(*iv*) A neurological or physiological condition; and

(*v*) Such other diseases or conditions the Director, Defense Health Agency determines appropriate.

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

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

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

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

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

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

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

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

(vi) *Drugs and medicines.* Drugs and medicines that by United States law require a prescription are also referred to as ''legend drugs.'' Legend drugs are covered when prescribed by a physician or other authorized individual professional provider acting within the scope of the provider's license and ordered or prescribed in connection with an otherwise covered condition or treatment, and not otherwise excluded by TRICARE. This includes Rh immune globulin.

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

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

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

(D) Medically necessary vitamins used for the management of a covered disease or condition pursuant to a prescription, order, or recommendation of a TRICARE authorized provider acting within the provider's scope of license/certificate of practice. For purposes of this paragraph (d)(3)(vi)(D), the term ''covered disease or condition'' means:

(*1*) Inborn errors of metabolism;

(*2*) Medical conditions of malabsorption;

(*3*) Pathologies of the alimentary tract or the gastrointestinal tract;

(*4*) A neurological or physiological condition;

(*5*) Pregnancy in relation to prenatal vitamins, with the limitation the prenatal vitamins that require a prescription in the United States may be covered for prenatal care only;

(*6*) Such other disease or conditions the Director, Defense Health Agency determines appropriate.

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

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

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

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

(D) Replacement of the device if the device is lost or irreparably damaged

or the cost of repair would exceed 60 percent of the cost of replacement.

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

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

Coverage limitations on the provision of this benefit will be as determined by the Director, TRICARE Management Activity, or designee.

(e) *Special benefit information*—(1) *General.* There are certain circumstances, conditions, or limitations that impact the extension of benefits and that require special emphasis and explanation. This paragraph (e) sets forth those benefits and limitations recognized to be in this category. The benefits and limitations herein described also are subject to all applicable definitions, conditions, limitations, exceptions, and exclusions as set forth in this or other sections of this part, except as otherwise may be provided specifically in this paragraph (e).

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

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

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

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

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

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

(*3*) Prescription contraceptives.

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

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

(*1*) Prophylactics (condoms).

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

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

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

(ii) *Genetic testing.* Genetic testing essentially is preventive rather than related to active medical treatment of an illness or injury. However, under the family planning benefit, genetic testing is covered when performed in certain high risk situations. For the purpose of CHAMPUS, genetic testing includes to detect developmental abnormalities as well as purely genetic defects.

(A) *Benefits provided.* Benefits may be extended for genetic testing performed on a pregnant beneficiary under the

following prescribed circumstances. The tests must be appropriate to the specific risk situation and must meet one of the following criteria:

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

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

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

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

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

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

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

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

(4) [Reserved]

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

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

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

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

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

(*iv*) Blood and blood products.

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

(*vi*) Complications of the transplant procedure, including inpatient care, management of infection and rejection episodes.

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

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

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

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

(*3*) Donor costs are payable when:

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

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

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

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

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

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

(B) [Reserved]

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

(6) *Eyeglasses, spectacles, contact lenses, or other optical devices.* Eyeglasses, spectacles, contact lenses, or

other optical devices are excluded under the Basic Program except under very limited and specific circumstances.

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

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

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

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

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

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

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

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

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

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

(7) [Reserved]

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

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

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

(A) Correction of a congenital anomaly; or

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(F) Panniculectomy; body sculpture procedures.

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

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

(I) Chemical peeling for facial wrinkles.

(J) Dermabrasion of the face.

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

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

(M) Removal of tattoos.

(N) Hair transplants.

(O) Electrolysis.

(P) [Reserved]

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

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

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

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

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

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

(10) *Dental.* TRICARE/CHAMPUS does not include a dental benefit. However, in connection with dental treatment for patients with developmental, mental, or physical disabilities or for pediatric patients age 5 or under, only institutional and anesthesia services may be provided as a benefit. Under very limited circumstances, benefits are available for dental services and supplies when the dental services are adjunctive to otherwise covered medical treatment.

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

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

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

(*2*) Extraoral abscesses.

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

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

(*5*) Myofacial Pain Dysfunction Syndrome.

(*6*) Total or complete ankyloglossia.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(C) Treatment of oral or facial cancer.

(D) Treatment of fractures of facial bones.

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

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

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

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

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

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

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

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

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

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

(ii) [Reserved]

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

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

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

(D) *Barbiturates.* Examples are Seconal and Nembuttal.

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

(F) *Stimulants.* Examples are amphetamines.

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

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

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

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

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

(v) *Unethical or illegal provider practices related to drugs.* Any such investigation into a possible drug abuse that uncovers unethical or illegal drug dispensing practices on the part of an institution, a pharmacy, or physician will be referred to the professional or investigative agency having jurisdiction. CHAMPUS fiscal intermediaries

are directed to withhold payment of all CHAMPUS claims for services and supplies rendered by a provider under active investigation for possible unethical or illegal drug dispensing activities.

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

(12) [Reserved]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(15) *Morbid obesity.* The TRICARE morbid obesity benefit is limited to those bariatric surgical procedures for which the safety and efficacy has been proven comparable or superior to conventional therapies and is consistent with the generally accepted norms for

medical practice in the United States medical community. (See the definition of *reliable evidence* in §199.2 of this part for the procedures used in determining if a medical treatment or procedure is unproven.)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(i) *Benefits Provided.* CHAMPUS benefits are payable for services and supplies in connection with electrothermal, electromyograph and

electrodermal biofeedback therapy when there is documentation that the patient has undergone an appropriate medical evaluation, that their present condition is not responding to or no longer responds to other forms of conventional treatment, and only when provided as treatment for the following conditions:

(A) Adjunctive treatment for Raynaud's Syndrome.

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

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

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

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

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

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

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

(A) Myocardial Infarction.

(B) Coronary Artery Bypass Graft.

(C) Coronary Angioplasty.

(D) Percutaneous Transluminal Coronary Angioplasty

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

(F) Heart valve surgery.

(G) Heart or Heart-lung Transplantation.

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

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

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

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

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

(19) *Hospice care.* Hospice care is a program which provides an integrated set of services and supplies designed to care for the terminally ill. This type of

care emphasizes palliative care and supportive services, such as pain control and home care, rather than cure-oriented services provided in institutions that are otherwise the primary focus under CHAMPUS. The benefit provides coverage for a humane and sensible approach to care during the last days of life for some terminally ill patients.

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

(A) Physician services.

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

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

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

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

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

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

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

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

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

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

(H) Short-term inpatient care provided in a Medicare participating hospice inpatient unit, or a Medicare participating hospital, skilled nursing facility (SNF) or, in the case of respite care, a Medicaid-certified nursing facility that additionally meets the special hospice standards regarding staffing and patient areas. Services provided in an inpatient setting must conform to the written plan of care. Inpatient care

may be required for procedures necessary for pain control or acute or chronic symptom management. Inpatient care may also be furnished to provide respite for the individual's family or other persons caring for the individual at home. Respite care is the only type of inpatient care that may be provided in a Medicaid-certified nursing facility. The limitations on custodial care and personal comfort items applicable to other CHAMPUS services are not applicable to hospice care.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(*iv*) The effective date of the election.

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

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

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

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

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

(*i*) The designated hospice;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(20) [Reserved]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(G) TRICARE is the appropriate payer.

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

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

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

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

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

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

(26) *National Institutes of Health clinical trials.* By law, and pursuant to an agreement between the Department of Defense and the Department of Health and Human Services, the general prohibition against CHAMPUS cost-sharing of unproven drugs, devices, and medical treatments or procedures may be

waived by the Secretary of Defense in connection with clinical trials sponsored or approved by the National Institutes of Health (NIH) or an NIH Institute or Center if it is determined that such a waiver will promote access by covered beneficiaries to promising new treatments and contribute to the development of such treatments. A waiver shall only be exercised as authorized under this paragraph.

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

(ii) *Continuous waiver.* (A) *General.* As a result of a demonstration project under which a waiver has been granted in connection with a National Institutes of Health National Cancer Institute clinical trial, a determination may be made that it is in the best interest of the government and CHAMPUS beneficiaries to end the demonstration and continue to provide a waiver for CHAMPUS cost-sharing of the specific clinical trial. Only those specified clinical trials identified under paragraph (e)(26)(ii) of this section have been authorized a continuous waiver under CHAMPUS.

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

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

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

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

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

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

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

(*2*) Requirements for Phase I protocols are:

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

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

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

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

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

(*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.

(iii) *Public Health Emergency Waiver.*

(A) *General.* During public health emergencies (*e.g.*, a national state of emergency declared by the President), TRICARE may cover cost-sharing for TRICARE-eligible patients who participate in Phase I, II, III, or IV trials that are sponsored by the NIH or an NIH Institute for the purposes of treatment or prevention of the pandemic or public health emergency.

(B) *National Institute of Allergy and Infectious Diseases (NIAID)-sponsored clinical trials for COVID–19.* For the duration of the President's national emergency regarding the COVID–19 outbreak, TRICARE will cover cost-sharing for those TRICARE-eligible patients selected to participate in NIAID-sponsored Phase I, II, III, and IV studies examining the treatment or prevention of COVID–19 and its associated sequelae (*e.g.*, cardiac and pulmonary issues). TRICARE will continue to cover cost-sharing for any eligible beneficiary enrolled in such a study until the conclusion of that study, even if the national emergency ends before the conclusion of the study.

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

(*i*) Such treatments are NIAID-sponsored Phase I, Phase II, Phase III, or Phase IV protocols;

(*ii*) The patient continues to meet entry criteria for said protocol;

(*iii*) The institutional and individual providers are TRICARE-authorized providers; and

(*iv*) The requirements for Phase I protocols in paragraph (e)(26)(iii)(B)(*2*) of this section are met.

(*2*) Requirements for Phase I protocols are:

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

(*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;

(*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)(iii)(B)(*2*)(*i*) through (*iii*) of this section.

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

(*4*) Cost-shares and deductibles applicable to TRICARE will also apply under the NIAID-sponsored clinical trials.

(*5*) The Director, Defense Health Agency (or designee), shall issue procedures and guidelines establishing NIAID-sponsorship of clinical trials and the administrative process by which individual patients apply for and receive cost-sharing under NIAID-sponsored COVID–19 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 §199.17(f)(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).

(v) Breastfeeding support, supplies (including breast pumps and associated equipment), and counseling.

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

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

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

(iii) Other types of physical examinations not listed above are excluded including routine, annual, or employment-requested physical examinations and routine screening procedures that are not part of medically necessary care or treatment or otherwise specifically authorized by statute.

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

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

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

(A) *Pharmaceutical agents.* Products available under this program are identified through the DoD Pharmacy and Therapeutics Committee, consistent with the DoD Uniform Formulary in §199.21. Smoking cessation pharmaceutical agents, including FDA-approved over-the-counter (OTC) pharmaceutical agents, are available through the TRICARE Mail Order Pharmacy (TMOP) or the MTF at no cost to the beneficiary. Smoking cessation pharmaceuticals through the TRICARE program will not be available at any retail pharmacies. A prescription from

a TRICARE-authorized provider is required to obtain any pharmaceutical agent used for smoking cessation, including OTC agents. For overseas Prime beneficiaries, pharmaceutical agents may be provided either in the MTF or through the TMOP where such facility or service is available.

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

(C) *Toll-free quit line.* Access to a nonmedical toll-free quit line 7 days a week, 24 hours a day will be available. The quit line will be staffed with smoking cessation counselors trained to assess a beneficiary's readiness to quit, identify barriers to quitting, and provide specific suggested actions and motivational counseling to enhance the chances of a successful quit attempt. When appropriate, quit line counselors will refer beneficiaries to a TRICARE-authorized provider for medical intervention. The quit line may, at the discretion of the Director, TMA, include the opportunity for the beneficiary to request individual follow-up contact initiated by quit line personnel; however, the beneficiary is not required to participate in the quit line initiated follow-up. Printed educational materials on the effects of tobacco use will be provided to the beneficiary upon request. This benefit may be made available to overseas Prime beneficiaries should the ASD(HA) exercise his authority to do so and provide appropriate notice in the FEDERAL REGISTER.

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

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

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

(i) *Annual calendar 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 calendar year.

(*2*) *Family Deductible:* The total deductible amount for all members of a family with the same sponsor during one calendar 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 calendar year.

(*2*) *Family Deductible:* The total deductible amount for all members of a

family with the same sponsor during one calendar 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 calendar 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 calendar 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 calendar 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 calendar 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)(B)(2)(i) 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 calendar 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 §199.3.

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

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

(A) *Inpatient cost-sharing payable with each separate inpatient admission*. A separate cost-sharing amount (as described in paragraph (f)(2) of this section) is payable for each inpatient admission to a hospital or other authorized institution, regardless of the purpose of the admission (such as medical

or surgical), regardless of the number of times the beneficiary is admitted, and regardless of whether or not the inpatient admissions are for the same or related conditions; except that successive inpatient admissions shall be deemed one inpatient confinement for the purpose of computing the inpatient cost-share payable, provided not more than 60 days have elapsed between the successive admissions. However, notwithstanding this provision, all admissions related to a single maternity episode shall be considered one confinement, regardless of the number of days between admissions (refer to paragraph (b) of this section).

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

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

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

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

(v) [Reserved]

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

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

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

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

(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 calendar year deductible amount (as described in paragraph (f)(2)(i) of this section) for otherwise covered services or supplies provided on an outpatient basis by authorized providers.

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

(i) *Annual calendar 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 calendar 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 calendar 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 §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 §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 §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 §199.14(a)(1) or per-diem amount under §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.* Calendar 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 calendar year.

(ii) *All other beneficiaries.* For all other categories of beneficiary families (including those eligible under CHAMPVA) the calendar 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 calendar year, CHAMPUS will pay allowable amounts for remaining covered services through the end of that calendar 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 § 199.21.

(12) *Elimination of cost-sharing for certain preventive services.*

(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.

(13) *Special transition rule for the last quarter of calendar year 2017.* In order to transition deductibles and catastrophic caps from a fiscal year basis to a calendar year basis, the deductible amount and the catastrophic cap amount specified in paragraph (f) of this section will be applicable to the 15-month period of October 1, 2016 through December 31, 2017.

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

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

(2) *Unnecessary diagnostic tests.* X-ray, laboratory, and pathological services

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

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

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

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

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

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

(7) *Custodial care.* Custodial care as defined in §199.2.

(8) *Domiciliary care.* Domiciliary care as defined in §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 §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 §199.8 of this part).

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

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

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

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

NOTE TO PARAGRAPH (G)(15)(I)(A): 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. For the duration of the President's national emergency in response to the COVID–19 outbreak, TRICARE will cost-share investigational drugs provided for the treatment of COVID–19 under expanded access.

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

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

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

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

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

(A) Trials published in refereed medical literature.

(B) Formal technology assessments.

(C) National medical policy organization positions.

(D) National professional associations.

(E) National expert opinion organizations.

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

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

(B) Treatment which is necessary follow-up to the unproven drug, device or medical treatment or procedure but

which might have been necessary in the absence of the unproven treatment.

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

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

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

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

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

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

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

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

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

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

(26) *Electrolysis.*

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

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

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

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

(31) *Corns, calluses, and toenails.* Removal of corns or calluses or trimming of toenails and other routine podiatry services, except those required as a result of a diagnosed systemic medical

disease affecting the lower limbs, such as severe diabetes.

(32) *Dyslexia.*

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

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

(35) *Nonprescription contraceptives.*

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

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

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

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

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

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

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

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

(v) Medical nutritional therapy (also referred to as medical nutritional counseling) required in the administration of the medically necessary foods, services and supplies authorized in paragraph (d)(3)(iii)(B) of this section, medically necessary vitamins authorized in paragraph (d)(3)(vi)(D) of this section, or when medically necessary for other authorized covered services.

(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 §199.4, paragraph (b)(1)(v) relating to general or special education, apply.

(43) *Exercise/relaxation/comfort/sporting items or sporting devices.* Exercise equipment, to include items primarily and customarily designed for use in sports

or recreational activities, spas, whirlpools, hot tubs, swimming pools health club memberships or other such charges or items.

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

(45) [Reserved]

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

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

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

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

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

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

((52) *Telephone services.* Services or advice rendered by telephone are excluded. Exceptions:

(i) Medically necessary and appropriate Telephonic office visits are covered as authorized in paragraph (c)(1)(iii) of this section.

(ii) 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:

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

(B) 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

(C) The each data transmission or biotelemetry devices 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 consistent use 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, except as authorized in paragraphs (d)(3)(iii)(B) and (d)(3)(vi)(D) of this section.

(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 §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) *Non-covered condition/treatment, unauthorized provider.* All services and supplies (including inpatient institutional costs) related to a non-covered condition or treatment, including any necessary follow-on care or the treatment of complications, are excluded from coverage except as provided under paragraph (e)(9) of this section. In addition, all services and supplies provided by an unauthorized provider are excluded.

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

(65) [Reserved]

(66) *Megavitamin psychiatric therapy, orthomolecular psychiatric therapy.*

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

(68) *Travel.* All travel even though prescribed by a physician and even if its purpose is to obtain medical care, except as specified in paragraph (a)(6) of this section in connection with a CHAMPUS-required physical examination and as specified in §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) [Reserved]

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

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

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

(h) *Payment and liability for certain potentially excludable services under the Peer Review Organization program*—(1) *Applicability.* This subsection provides special rules that apply only to services retrospectively determined under the Peer Review organization (PRO) program (operated pursuant to §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, July 1, 1986]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §199.4, see the List of CFR Sections Affected, which appears in the

Finding Aids section of the printed volume and at *www.govinfo.gov*.

§ 199.5 TRICARE Extended Care Health Option (ECHO).

(a) *General*. (1) The TRICARE ECHO is essentially a supplemental program to the TRICARE Basic Program. It does not provide acute care nor benefits available through the TRICARE Basic Program.

(2) The purpose of the ECHO is to provide an additional financial resource for an integrated set of services and supplies designed to assist in the reduction of the disabling effects of the ECHO-eligible dependent's qualifying condition. Services include those necessary to maintain, minimize or prevent deterioration of function of an ECHO-eligible dependent.

(3) The Government's cost-share for ECHO or ECHO home health benefits during any program year is limited as stated in this section. In order to transition the program year from a fiscal year to a calendar year basis, the Government's annual cost-share limitation specified in paragraph (f) of this section shall be prorated for the last quarter of calendar year 2018 as authorized by 10 U.S.C. 1079(f)(2)(A).

(b) *Eligibility*. (1) The following categories of TRICARE/CHAMPUS beneficiaries with a qualifying condition are ECHO-eligible dependents:

(i) A spouse, child, or unmarried person (as described in §199.3(b)(2)(i), (b)(2)(ii), or (b)(2)(iv)) of a member of the Uniformed Services on active duty for a period of more than 30 days.

(ii) An abused dependent as described in §199.3(b)(2)(iii).

(iii) A spouse, child, or unmarried person (as described in §199.3(b)(2)(i), (b)(2)(ii), or (b)(2)(iv)), of a member of the Uniformed Services who dies while on active duty for a period of more than 30 days and whose death occurs on or after October 7, 2001. In such case, an eligible surviving spouse remains eligible for benefits under the ECHO for a period of 3 years from the date the active duty sponsor dies. Any other eligible surviving dependent remains eligible for benefits under the ECHO for a period of three years from the date the active duty sponsor dies or until the surviving eligible dependent:

(A) Attains 21 years of age, or

(B) Attains 23 years of age or ceases to pursue a full-time course of study prior to attaining 23 years of age, if, at 21 years of age, the eligible surviving dependent is enrolled in a full-time course of study in a secondary school or in a full-time course of study in an institution of higher education approved by Secretary of Defense and was, at the time of the sponsor's death, in fact dependent on the member for over one-half of such dependent's support.

(iv) A spouse, child, or unmarried person (as defined in paragraphs §199.3(b)(2)(i), (b)(2)(ii), or (b)(2)(iv)) of a deceased member of the Uniformed Services who, at the time of the member's death was receiving benefits under ECHO, and the member at the time of death was eligible for receipt of hostile-fire pay, or died as a result of a disease or injury incurred while eligible for such pay. In such a case, the surviving dependent remains eligible for benefits under ECHO through midnight of the dependent's twenty-first birthday.

(2) *Qualifying condition*. The following are qualifying conditions:

(i) *Mental retardation*. A diagnosis of moderate or severe mental retardation made in accordance with the criteria of the current edition of the ''Diagnostic and Statistical Manual of Mental Disorders'' published by the American Psychiatric Association.

(ii) *Serious physical disability*. A serious physical disability as defined in §199.2.

(iii) *Extraordinary physical or psychological condition*. An extraordinary physical or psychological condition as defined in §199.2.

(iv) *Infant/toddler*. Beneficiaries under the age of 3 years who are diagnosed with a neuromuscular developmental condition or other condition that is expected to precede a diagnosis of moderate or severe mental retardation or a serious physical disability, shall be deemed to have a qualifying condition for the ECHO. The Director, TRICARE Management Activity or designee shall establish criteria for ECHO eligibility in lieu of the requirements of paragraphs (b)(2)(i), (ii) or (iii) of this section.

(v) *Multiple disabilities.* The cumulative effect of multiple disabilities, as determined by the Director, TRICARE Management Activity or designee shall be used in lieu of the requirements of paragraphs (b)(2)(i), (ii) or (iii) of this section to determine a qualifying condition when the beneficiary has two or more disabilities involving separate body systems.

(3) *Loss of ECHO eligibility.* Eligibility for ECHO benefits ceases as of 12:01 a.m. of the day following the day that:

(i) The sponsor ceases to be an active duty member for any reason other than death; or

(ii) Eligibility based upon the abused dependent provisions of paragraph (b)(1)(ii) of this section expires; or

(iii) Eligibility based upon the deceased sponsor provisions of paragraphs (b)(1)(iii) or (iv) of this section expires; or

(iv) Eligibility based upon a beneficiary's participation in the Transitional Assistance Management Program ends; or

(v) The Director, TRICARE Management Activity or designee determines that the beneficiary no longer has a qualifying condition.

(c) *ECHO benefit.* Items and services that the Director, TRICARE Management Activity or designee has determined are capable of confirming, arresting, or reducing the severity of the disabling effects of a qualifying condition, includes, but are not limited to:

(1) Diagnostic procedures to establish a qualifying condition or to measure the extent of functional loss resulting from a qualifying condition.

(2) Medical, habilitative, rehabilitative services and supplies, durable equipment and assistive technology (AT) devices that assist in the reduction of the disabling effects of a qualifying condition. Benefits shall be provided in the beneficiary's home or another environment, as appropriate. An AT device may be covered only if it is recommended in a beneficiary's Individual Educational Program (IEP) or, if the beneficiary is not eligible for an IEP, the AT device is an item or educational learning device normally included in an IEP and is preauthorized under ECHO as an integral component of the beneficiary's individual comprehensive health care services plan (including rehabilitation) as prescribed by a TRICARE authorized provider.

(i) An AT device may be covered under ECHO only if it is not otherwise covered by TRICARE as durable equipment, a prosthetic, augmentation communication device, or other benefits under §199.4.

(ii) An AT device may include an educational learning device directly related to the beneficiary's qualifying condition when recommended by an IEP and not otherwise provided by State or local government programs. If an individual is not eligible for an IEP, an educational learning device normally included in the IEP may be authorized as if directly related to the beneficiary's qualifying condition and prescribed by a TRICARE authorized provider as part of the beneficiary's individual comprehensive health care services plan.

(iii) Electronic learning devices may include the hardware and software as appropriate. The Director, DHA, shall determine the types and (or) platforms of electronic devices and the replacement lifecycle of the hardware and its supporting software. All upgrades or replacements shall require a recommendation from the individual's IEP or the individual's comprehensive health care services plan.

(iv) Duplicative or redundant hardware platforms are not authorized.

NOTE TO PARAGRAPH (c)(2)(iv): When one or more electronic platforms such as a desktop computer, laptop, notebook or tablet can perform the same functions in relation to the teaching or educational objective directly related to the qualifying condition, it is the intent of this provision to allow only one electronic platform that may be chosen by the beneficiary. Duplicative or redundant platforms are not allowed; however, a second platform may be obtained, if the individual's IEP recommends one platform such as a computer for the majority of the learning objectives, but there exists another objective, which cannot be performed on that platform. In these limited circumstances, the beneficiary may submit a request with the above justification to the Director, TMA, who may authorize a second device.

(v) AT devices damaged through improper use of the device may not be replaced until the device would next be eligible for a lifecycle replacement.

(vi) AT devices do not include equipment or devices whose primary purpose is to assist the individual to engage in sports or recreational activities.

(3) Training that teaches the use of assistive technology devices or to acquire skills that are necessary for the management of the qualifying condition. Such training is also authorized for the beneficiary's immediate family. Vocational training, in the beneficiary's home or a facility providing such, is also allowed.

(4) Special education as provided by the Individuals with Disabilities Education Act and defined at 34 CFR 300.26 and that is specifically designed to accommodate the disabling effects of the qualifying condition.

(5) Institutional care within a state, as defined in §199.2, in private nonprofit, public, and state institutions and facilities, when the severity of the qualifying condition requires protective custody or training in a residential environment. For the purpose of this section protective custody means residential care that is necessary when the severity of the qualifying condition is such that the safety and well-being of the beneficiary or those who come into contact with the beneficiary may be in jeopardy without such care.

(6) Transportation of an ECHO beneficiary receiving benefits under paragraph (c)(5), and a medical attendant when necessary to assure the beneficiary's safety, to or from a facility or institution to receive authorized ECHO services or items.

(7) *Respite care.* TRICARE beneficiaries enrolled in ECHO are eligible for a maximum of 16 hours of respite care per month. Respite care is defined in § 199.2. Respite care services will be provided by a TRICARE-authorized HHA and will be designed to provide health care services for the covered beneficiary. The benefit will not be cumulative, that is, any respite hours not used in one month will not be carried over or banked for use on another occasion.

(i) TRICARE-authorized home health agencies must provide and bill for all authorized ECHO respite care services through established TRICARE claims' mechanisms. No special billing arrangements will be authorized in conjunction with coverage that may be provided by Medicaid or other federal, state, community or private programs.

(ii) For authorized ECHO respite care, TRICARE will reimburse the allowable charges or negotiated rates.

(iii) The Government's cost-share incurred for these services accrues to the program year benefit limit of $36,000.

(8) *Other services.* (i) *Assistive services.* Services of qualified personal assistants, such as an interpreter or translator for ECHO beneficiaries who are deaf or mute and readers for ECHO beneficiaries who are blind, when such services are necessary in order for the ECHO beneficiary to receive authorized ECHO benefits.

(ii) *Equipment adaptation.* The allowable equipment and an AT device purchase shall include such services and modifications to the equipment as necessary to make the equipment usable for a particular ECHO beneficiary.

(iii) *Equipment maintenance.* Reasonable repairs and maintenance of the beneficiary owned or rented DE or AT devices provided by this section shall be allowed while a beneficiary is registered in the ECHO Program. Repairs of DE and/or AT devices damaged while using the item in a manner inconsistent with its common use, and replacement of lost or stolen rental DE are not authorized coverage as an ECHO benefit. In addition, repairs and maintenance of deluxe, luxury, or immaterial features of DE or AT devices are not authorized coverage as an ECHO benefit.

(d) *ECHO Exclusions*—(1) *Basic Program.* Benefits allowed under the TRICARE Basic Program will not be provided through the ECHO.

(2) *Inpatient care.* Inpatient acute care for medical or surgical treatment of an acute illness, or of an acute exacerbation of the qualifying condition, is excluded.

(3) *Structural alterations.* Alterations to living space and permanent fixtures attached thereto, including alterations necessary to accommodate installation of equipment or AT devices to facilitate entrance or exit, are excluded.

(4) *Homemaker services.* Services that predominantly provide assistance with household chores are excluded.

(5) *Dental care or orthodontic treatment.* Both are excluded.

(6) *Deluxe travel or accommodations.* The difference between the price for travel or accommodations that provide services or features that exceed the requirements of the beneficiary's condition and the price for travel or accommodations without those services or features is excluded.

(7) *Equipment.* Purchase or rental of DE and AT devices otherwise allowed by this section is excluded when:

(i) The beneficiary is a patient in an institution or facility that ordinarily provides the same type of equipment or AT devices to its patients at no additional charge in the usual course of providing services; or

(ii) The item is available to the beneficiary from a Uniformed Services Medical Treatment Facility; or

(iii) The item has deluxe, luxury, immaterial or nonessential features that increase the cost to the Department relative to a similar item without those features; or

(iv) The item is a duplicate DE or an AT device, as defined in §199.2.

(v) The item (or charge for access to such items through health club membership or other activities) is exercise equipment including an item primarily and customarily designed for use in sports or recreational activities, spa, whirlpool, hot tub, swimming pool, an electronic device used to locate or monitor the location of the beneficiary, or other similar items or charges.

(8) *Maintenance agreements.* Maintenance agreements for beneficiary owned or rented equipment or AT device are excluded.

(9) *No obligation to pay.* Services or items for which the beneficiary or sponsor has no legal obligation to pay are excluded.

(10) *Public facility or Federal government.* Services or items paid for, or eligible for payment, directly or indirectly by a public facility, as defined in §199.2, or by the Federal government, other than the Department of Defense, are excluded for training, rehabilitation, special education, assistive technology devices, institutional care in private nonprofit, public, and state institutions and facilities, and if appropriate, transportation to and from such institutions and facilities, except when such services or items are eligible for payment under a state plan for medical assistance under Title XIX of the Social Security Act (Medicaid). Rehabilitation and assistive technology services or supplies may be available under the TRICARE Basic Program.

(11) *Study, grant, or research programs.* Services and items provided as a part of a scientific clinical study, grant, or research program are excluded.

(12) *Unproven status.* Drugs, devices, medical treatments, diagnostic, and therapeutic procedures for which the safety and efficacy have not been established in accordance with §199.4 are excluded.

(13) *Immediate family or household.* Services or items provided or prescribed by a member of the beneficiary's immediate family, or a person living in the beneficiary's or sponsor's household, are excluded.

(14) *Court or agency ordered care.* Services or items ordered by a court or other government agency, which are not otherwise an allowable ECHO benefit, are excluded.

(15) *Excursions.* Excursions are excluded regardless of whether or not they are part of a program offered by a TRICARE-authorized provider. The transportation benefit available under ECHO is specified elsewhere in this section.

(16) *Drugs and medicines.* Drugs and medicines that do not meet the requirements of §199.4 or §199.21 are excluded.

(17) *Therapeutic absences.* Therapeutic absences from an inpatient facility or from home for a homebound beneficiary are excluded.

(18) *Custodial care.* Custodial care, as defined in §199.2 is not a stand-alone benefit. Services generally rendered as custodial care may be provided only as specifically set out in this section.

(19) *Domiciliary care.* Domiciliary care, as defined in §199.2, is excluded.

(20) *Respite care.* Respite care for the purpose of covering primary caregiver (as defined in §199.2) absences due to deployment, employment, seeking of employment or to pursue education is

excluded. Authorized respite care covers only the ECHO beneficiary, not siblings or others who may reside in or be visiting in the beneficiary's residence.

(e) *ECHO Home Health Care (EHHC).* The EHHC benefit provides coverage of home health care services and respite care services specified in this section.

(1) *Home health care.* Covered ECHO home health care services are the same as, and provided under the same conditions as those services described in §199.4(e)(21)(i), except that they are not limited to part-time or intermittent services. Custodial care services, as defined in §199.2, may be provided to the extent such services are provided in conjunction with authorized ECHO home health care services, including the EHHC respite care benefit specified in this section. Beneficiaries who are authorized EHHC will receive all home health care services under EHHC and no portion will be provided under the Basic Program. TRICARE-authorized home health agencies are not required to use the Outcome and Assessment Information Set (OASIS) to assess beneficiaries who are authorized EHHC.

(2) *Respite care.* EHHC beneficiaries whose plan of care includes frequent interventions by the primary caregiver(s) are eligible for respite care services in lieu of the ECHO general respite care benefit. For the purpose of this section, the term ''frequent'' means ''more than two interventions during the eight-hour period per day that the primary caregiver would normally be sleeping.'' The services performed by the primary caregiver are those that can be performed safely and effectively by the average non-medical person without direct supervision of a health care provider after the primary caregiver has been trained by appropriate medical personnel. EHHC beneficiaries in this situation are eligible for a maximum of eight hours per day, 5 days per week, of respite care by a TRICARE-authorized home health agency. The home health agency will provide the health care interventions or services for the covered beneficiary so that the primary caregiver is relieved of the responsibility to provide such interventions or services for the duration of that period of respite care. The home health agency will not provide baby-sitting or child care services for other members of the family. The benefit is not cumulative, that is, any respite care hours not used in a given day may not be carried over or banked for use on another occasion. Additionally, the eight-hour respite care periods will not be provided consecutively, that is, a respite care period on one calendar day will not be immediately followed by a respite care period the next calendar day. The Government's cost-share incurred for these services accrue to the maximum yearly ECHO Home Health Care benefit.

(3) *EHHC eligibility.* The EHHC is authorized for beneficiaries who meet all applicable ECHO eligibility requirements and who:

(i) Physically reside within the 50 United States, the District of Columbia, Puerto Rico, the Virgin Islands, or Guam; and

(ii) Are homebound, as defined in §199.2; and

(iii) Require medically necessary skilled services that exceed the level of coverage provided under the Basic Program's home health care benefit; and/or

(iv) Require frequent interventions by the primary caregiver(s) such that respite care services are necessary to allow primary caregiver(s) the opportunity to rest; and

(v) Are case managed to include a reassessment at least every 90 days, and receive services as outlined in a written plan of care; and

(vi) Receive all home health care services from a TRICARE-authorized home health agency, as described in §199.6(b)(4)(xv), in the beneficiary's primary residence.

(4) *EHHC plan of care.* A written plan of care is required prior to authorizing ECHO home health care. The plan must include the type, frequency, scope and duration of the care to be provided and support the professional level of provider. Reimbursement will not be authorized for a level of provider not identified in the plan of care.

(5) *EHHC exclusions*—(i) *General.* ECHO Home Health Care services and supplies are excluded from those who are being provided continuing coverage of home health care as participants of

the former Individual Case Management Program for Persons with Extraordinary Conditions (ICMP-PEC) or previous case management demonstrations.

(ii) *Respite care.* Respite care for the purpose of covering primary caregiver absences due to deployment, employment, seeking of employment or to pursue education is excluded. Authorized respite care covers only the ECHO beneficiary, not siblings or others who may reside in or be visiting in the beneficiary's residence.

(f) *Cost-share liability*—(1) *No deductible.* ECHO benefits are not subject to a deductible amount.

(2) *Sponsor cost-share liability.* (i) Regardless of the number of family members receiving ECHO benefits or ECHO Home Health Care in a given month, the sponsor's cost-share is according to the following table:

TABLE 1—MONTHLY COST-SHARE BY MEMBER'S PAY GRADE

E–1 through E–5	$25
E–6	30
E–7 and O–1	35
E–8 and O–2	40
E–9, W–1, W–2 and O–3	45
W–3, W–4 and O–4	50
W–5 and O–5	65
O–6	75
O–7	100
O–8	150
O–9	200
O–10	250

(ii) The Sponsor's cost-share shown in Table 1 in paragraph (f)(2)(i) of this section will be applied to the first allowed ECHO charges in any given month. The Government's share will be paid, up to the maximum amount specified in paragraph (f)(3) of this section, for allowed charges after the sponsor's cost-share has been applied.

(iii) The provisions of §199.18(d)(1) and (e)(1) regarding elimination of copayments for active duty family members enrolled in TRICARE Prime do not eliminate, reduce, or otherwise affect the sponsor's cost-share shown in Table 1 in paragraph (f)(2)(i) of this section.

(iv) The sponsor's cost-share shown in Table 1 in paragraph (f)(2)(i) of this section does not accrue to the Basic Program's Catastrophic Loss Protection under 10 U.S.C. 1079(b)(5) as shown at §§199.4(f)(10) and 199.18(f).

(3) *Government cost-share liability*—(i) *ECHO.* The total Government share of the cost of all ECHO benefits, except ECHO Home Health Care (EHHC) and EHHC respite care, provided in a given program year to a beneficiary, may not exceed $36,000 after application of the allowable payment methodology.

(ii) *ECHO home health care.* (A) The maximum annual program year Government cost-share per EHHC-eligible beneficiary for ECHO home health care, including EHHC respite care may not exceed the local wage-adjusted highest Medicare Resource Utilization Group (RUG-III) category cost for care in a TRICARE-authorized skilled nursing facility.

(B) When a beneficiary moves to a different locality within the 50 United States, the District of Columbia, Puerto Rico, the Virgin Islands, or Guam, the annual program year cap will be recalculated to reflect the maximum established under paragraph (f)(3)(ii)(A) of this section for the beneficiary's new location and will apply to the EHHC benefit for the remaining portion of that program year.

(g) *Benefit payment*—(1) *Transportation.* The allowable amount for transportation of an ECHO beneficiary is limited to the actual cost of the standard published fare plus any standard surcharge made to accommodate any person with a similar disability or to the actual cost of specialized medical transportation when non-specialized transport cannot accommodate the beneficiary's qualifying condition related needs, or when specialized transport is more economical than non-specialized transport. When transport is by private vehicle, the allowable amount is limited to the Federal government employee mileage reimbursement rate in effect on the date the transportation is provided.

(2) *Equipment.* (i) The TRICARE allowable amount for DE or AT devices shall be calculated in the same manner as DME allowable through section 199.4 of this title, and accrues to the program year benefit limit specified in paragraph (f)(3) of this section.

(ii) Cost-share. A cost-share, as provided by paragraph (f)(2) of this section, is required for each month in which equipment or an AT device is purchased under this section. However, in no month shall a sponsor be required to pay more than one cost-share regardless of the number of benefits the sponsor's dependents received under this section.

(3) *For-profit institutional care provider.* Institutional care provided by a for-profit entry may be allowed only when the care for a specific ECHO beneficiary:

(i) Is contracted for by a public facility as a part of a publicly funded long-term inpatient care program; and

(ii) Is provided based upon the ECHO beneficiary's being eligible for the publicly funded program which has contracted for the care; and

(iii) Is authorized by the public facility as a part of a publicly funded program; and

(iv) Would cause a cost-share liability in the absence of TRICARE eligibility; and

(v) Produces an ECHO beneficiary cost-share liability that does not exceed the maximum charge by the provider to the public facility for the contracted level of care.

(4) *ECHO home health care and EHHC respite care.* (i) TRICARE-authorized home health agencies must provide and bill for all authorized home health care services through established TRICARE claims' mechanisms. No special billing arrangements will be authorized in conjunction with coverage that may be provided by Medicaid or other federal, state, community or private programs.

(ii) For authorized ECHO home health care and respite care, TRICARE will reimburse the allowable charges or negotiated rates.

(iii) The maximum monthly Government reimbursement for EHHC, including EHHC respite care, will be based on the actual number of hours of EHHC services rendered in the month, but in no case will it exceed one-twelfth of the annual maximum Government cost-share as determined in this section and adjusted according to the actual number of days in the month the services were provided.

(h) *Other Requirements*—(1) *Applicable part.* All provisions of this part, except the provisions of §199.4 unless otherwise provided by this section or as directed by the Director, TRICARE Management Activity or designee, apply to the ECHO.

(2) *Registration.* Active duty sponsors must register potential ECHO-eligible beneficiaries through the Director, TRICARE Management Activity, or designee prior to receiving ECHO benefits. The Director, TRICARE Management Activity, or designee will determine ECHO eligibility and update the Defense Enrollment Eligibility Reporting System accordingly. Unless waived by the Director, TRICARE Management Activity or designee, sponsors must provide evidence of enrollment in the Exceptional Family Member Program provided by their branch of Service at the time they register their family member(s) for the ECHO.

(3) *Benefit authorization.* All ECHO benefits require authorization by the Director, TRICARE Management Activity or designee prior to receipt of such benefits.

(i) *Documentation.* The sponsor shall provide such documentation as the Director, TRICARE Management Activity or designee requires as a prerequisite to authorizing ECHO benefits. Such documentation shall describe how the requested benefit will contribute to confirming, arresting, or reducing the disabling effects of the qualifying condition, including maintenance of function or prevention of further deterioration of function, of the beneficiary.

(ii) *Format.* An authorization issued by the Director, TRICARE Management Activity or designee shall specify such description, dates, amounts, requirements, limitations or information as necessary for exact identification of approved benefits and efficient adjudication of resulting claims.

(iii) *Valid period.* An authorization for ECHO benefits shall be valid until such time as the Director, TRICARE Management Activity or designee determines that the authorized services are no longer appropriate or required or the beneficiary is no longer eligible under paragraph (b) of this section.

(iv) *Authorization waiver.* The Director, TRICARE Management Activity or

designee may waive the requirement for a written authorization for rendered ECHO benefits that, except for the absence of the written authorization, would be allowable as an ECHO benefit.

(v) *Public facility use.* (A) An ECHO beneficiary residing within a state must demonstrate that a public facility is not available and adequate to meet the needs of their qualifying condition. Such requirements shall apply to beneficiaries who request authorization for training, rehabilitation, special education, assistive technology, and institutional care in private nonprofit, public, and state institutions and facilities, and if appropriate for beneficiaries receiving institutional care, transportation to and from such institutions and facilities. The maximum Government cost-share for services that require demonstration of public facility non-availability or inadequacy is limited to $36,000 per program year per beneficiary. State-administered plans for medical assistance under Title XIX of the Social Security Act (Medicaid) are not considered available and adequate facilities for the purpose of this section.

(B) The domicile of the beneficiary shall be the basis for the determination of public facility availability when the sponsor and beneficiary are separately domiciled due to the sponsor's move to a new permanent duty station or due to legal custody requirements.

(C) Written certification, in accordance with information requirements, formats, and procedures established by the director, TRICARE Management Activity or designee that requested ECHO services or items cannot be obtained from public facilities because the services or items are not available and adequate, is a prerequisite for ECHO benefit payment for training, rehabilitation, special education, assistive technology, and institutional care in private nonprofit, public, and state institutions and facilities, and if appropriate, transportation to and from such institutions and facilities.

(*1*) An administrator or designee of a public facility may make such certification for a beneficiary residing within the service area of that public facility.

(*2*) The Director, TRICARE Management Activity or designee may determine, on a case-by-case basis, that apparent public facility availability or adequacy for a requested type of service or item cannot be substantiated for a specific beneficiary's request for ECHO benefits and therefore is not available.

(*i*) A case-specific determination shall be based upon a written statement by the beneficiary (or sponsor or guardian acting on behalf of the beneficiary) which details the circumstances wherein a specific individual representing a specific public facility refused to provide a public facility use certification, and such other information as the Director, TRICARE Management Activity or designee determines to be material to the determination.

(*ii*) A case-specific determination of public facility availability by the Director, TRICARE Management Activity or designee is conclusive and is not appealable under § 199.10.

(4) Repair or maintenance of DE owned by the beneficiary or an AT device is exempt from the public facility-use certification requirements.

(5) The requirements of this paragraph (h)(3)(v)(A) notwithstanding, no public facility use certification is required for services and items that are provided under Part C of the Individuals with Disabilities Education Act in accordance with the Individualized Family Services Plan and that are otherwise allowable under the ECHO.

(i) *Implementing instructions.* The Director, TRICARE Management Activity or designee shall issue TRICARE policies, instructions, procedures, guidelines, standards, and criteria as may be necessary to implement the intent of this section.

(j) *Effective date.* All changes to this section are effective as of October 14, 2008, and claims for ECHO benefits provided on or after that date will be reprocessed retroactively to that date as necessary.

[69 FR 51564, Aug. 20, 2004, as amended at 71 FR 47092, Aug. 16, 2006; 72 FR 2447, Jan. 19, 2007; 75 FR 47711, Aug. 9, 2010; 79 FR 78713, Dec. 31, 2014; 81 FR 27329, May 6, 2016; 82 FR 45447, Sept. 29, 2017; 86 FR 36217, July 9, 2021]

§ 199.6 TRICARE—authorized providers.

(a) *General.* This section sets forth general policies and procedures that are the basis for the CHAMPUS cost-sharing of medical services and supplies provided by institutions, individuals, or other types of providers. Providers seeking payment from the Federal Government through programs such as CHAMPUS have a duty to familiarize themselves with, and comply with, the program requirements.

(1) *Listing of provider does not guarantee payment of benefits.* The fact that a type of provider is listed in this section is not to be construed to mean that CHAMPUS will automatically pay a claim for services or supplies provided by such a provider. The provider who actually furnishes the service(s) must, in fact, meet all licensing and other requirements established by this part to be an authorized provider; the provider must not be the subject of sanction under §199.9; and, cost-sharing of the services must not otherwise be prohibited by this part. In addition, the patient must in fact be an eligible beneficiary and the services or supplies billed must be authorized and medically necessary, regardless of the standing of the provider.

(2) *Outside the United States or emergency situations within the United States.* Outside the United States or within the United States and Puerto Rico in emergency situations, the Director, OCHAMPUS, or a designee, after review of the facts, may provide payment to or on behalf of a beneficiary who receives otherwise covered services or supplies from a provider of service that does not meet the standards described in this part.

NOTE: Only the Secretary of Defense, the Secretary of Health and Human Services, or the Secretary of Transportation, or their designees, may authorize (in emergency situations) payment to civilian facilities in the United States that are not in compliance with title VI of the Civil Rights Act of 1964. For the purpose of the Civil Rights Act only, the United States includes the 50 states, the District of Columbia, Puerto Rico, Virgin Islands, American Samoa, Guam, Wake Island, Canal Zone, and the territories and possessions of the United States.

(3) *Dual compensation/Conflict of interest.* Title 5, United States Code, section 5536 prohibits medical personnel who are active duty Uniformed Service members or civilian employees of the Government from receiving additional Government compensation above their normal pay and allowances for medical care furnished. In addition, Uniformed Service members and civilian employees of the Government are generally prohibited by law and agency regulations and policies from participating in apparent or actual conflict of interest situations in which a potential for personal gain exists or in which there is an appearance of impropriety or incompatibility with the performance of their official duties or responsibilities. The Departments of Defense, Health and Human Services, and Transportation have a responsibility, when disbursing appropriated funds in the payment of CHAMPUS benefits, to ensure that the laws and regulations are not violated. Therefore, active duty Uniformed Service members (including a reserve member while on active duty and civilian employees of the United States Government shall not be authorized to be CHAMPUS providers. While individual employees of the Government may be able to demonstrate that the furnishing of care to CHAMPUS beneficiaries may not be incompatible with their official duties and responsibilities, the processing of millions of CHAMPUS claims each year does not enable Program administrators to efficiently review the status of the provider on each claim to ensure that no conflict of interest or dual compensation situation exists. The problem is further complicated given the numerous interagency agreements (for example, resource sharing arrangements between the Department of Defense and the Veterans Administration in the provision of health care) and other unique arrangements which exist at individual treatment facilities around the country. While an individual provider may be prevented from being an authorized CHAMPUS provider even though no conflict of interest or dual compensation situation exists, it is essential for CHAMPUS to have an easily administered, uniform rule which will ensure compliance with

the existing laws and regulations. Therefore, a provider who is an active duty Uniformed Service member or civilian employee of the Government shall not be an authorized CHAMPUS provider. In addition, a provider shall certify on each CHAMPUS claim that he/she is not an active duty Uniformed Service member or civilian employee of the Government.

(4) [Reserved]

(5) *Utilization review and quality assurance.* Providers approved as authorized CHAMPUS providers have certain obligations to provide services and supplies under CHAMPUS which are (i) furnished at the appropriate level and only when and to the extent medically necessary under the criteria of this part; (ii) of a quality that meets professionally recognized standards of health care; and, (iii) supported by adequate medical documentation as may be reasonably required under this part by the Director, OCHAMPUS, or designee, to evidence the medical necessity and quality of services furnished, as well as the appropriateness of the level of care. Therefore, the authorization of CHAMPUS benefits is contingent upon the services and supplies furnished by any provider being subject to pre-payment or post-payment utilization and quality assurance review under professionally recognized standards, norms, and criteria, as well as any standards or criteria issued by the Director, OCHAMPUS, or a designee, pursuant to this part. (Refer to §§199.4, 199.5, and 199.7 of this part.)

(6) *Exclusion of beneficiary liability.* In connection with certain utilization review, quality assurance and preauthorization requirements of section 199.4 of this part, providers may not hold patients liable for payment for certain services for which CHAMPUS payment is disallowed. With respect to such services, providers may not seek payment from the patient or the patient's family. Any such effort to seek payment is a basis for termination of the provider's authorized status.

(7) *Provider required.* In order to be considered for benefits, all services and supplies shall be rendered by, prescribed by, or furnished at the direction of, or on the order of a CHAMPUS-authorized provider practicing within the scope of his or her license.

(8) *Participating providers.* A CHAMPUS-authorized provider is a participating provider, as defined in §199.2 under the following circumstances:

(i) *Mandatory participation.* (A) An institutional provider in §199.6(b), in order to be an authorized provider under TRICARE, must be a participating provider for all claims.

(B) A SNF or a HHA, in order to be an authorized provider under TRICARE, must enter into a participation agreement with TRICARE for all claims.

(C) Corporate services providers authorized as CHAMPUS providers under the provisions of paragraph (f) of this section must enter into a participation agreement as provided by the Director, OCHAMPUS, or designee.

(ii) *Voluntary participation*—(A) *Total claims participation: The participating provider program.* A CHAMPUS-authorized provider that is not required to participate by this part may become a participating provider by entering into an agreement or memorandum of understanding (MOU) with the Director, OCHAMPUS, or designee, which includes, but is not limited to, the provisions of paragraph (a)(13) of this section. The Director, OCHAMPUS, or designee, may include in a participating provider agreement/MOU provisions that establish between CHAMPUS and a class, category, type, or specific provider, uniform procedures and conditions which encourage provider participation while improving beneficiary access to benefits and contributing to CHAMPUS efficiency. Such provisions shall be otherwise allowed by this part or by DoD Directive or DoD Instruction specifically pertaining to CHAMPUS claims participation. Participating provider program provisions may be incorporated into an agreement/MOU to establish a specific CHAMPUS-provider relationship, such as a preferred provider arrangement.

(B) *Claim-specific participation.* A CHAMPUS-authorized provider that is not required to participate and that has not entered into a participation agreement pursuant to paragraph (a)(8)(ii)(A) of this section may elect to

be a participating provider on a claim-by-claim basis by indicating ''accept assignment'' on each claim form for which participation is elected.

(iii) *Claim-by-claim participation.* Individual providers that are not participating providers pursuant to paragraph (a)(8)(ii) of this section may elect to participate on a claim-by-claim basis. They may do so by signing the appropriate space on the claims form and submitting it to the appropriate TRICARE contractor on behalf of the beneficiary.

(9) *Limitation to authorized institutional provider designation.* Authorized institutional provider status granted to a specific institutional provider applicant does not extend to any institution-affiliated provider, as defined in §199.2, of that specific applicant.

(10) *Authorized provider.* A hospital or institutional provider, physician, or other individual professional provider, or other provider of services or supplies specifically authorized in this chapter to provide benefits under CHAMPUS. In addition, to be an authorized CHAMPUS provider, any hospital which is a CHAMPUS participating provider under paragraph (a)(7) of this section, shall be a participating provider for all care, services, or supplies furnished to an active duty member of the uniformed services for which the active duty member is entitled under 10 U.S.C. 1074(c). As a participating provider for active duty members, the CHAMPUS authorized hospital shall provide such care, services, and supplies in accordance with the payment rules of §199.16 of this part. The failure of any CHAMPUS participating hospital to be a participating provider for any active duty member subjects the hospital to termination of the hospital's status as a CHAMPUS authorized provider for failure to meet the qualifications established by this part.

(11) *Balance billing limits*—(i) *In general.* Individual providers including providers salaried or under contract by an institutional provider and other providers who are not participating providers may not balance bill a beneficiary an amount that exceeds the applicable balance billing limit. The balance billing limit shall be the same percentage as the Medicare limiting charge percentage for nonparticipating practitioners and suppliers.

(ii) *Waiver.* The balance billing limit may be waived by the Director, OCHAMPUS on a case-by-case basis if requested by a CHAMPUS beneficiary. A decision by the Director, OCHAMPUS to waive or not waive the limit in any particular case is not subject to the appeal and hearing procedures of §199.10.

(iii) *Compliance.* Failure to comply with the balance billing limit shall be considered abuse and/or fraud and grounds of exclusion or suspension of the provider under §199.9.

(12) *Medical records.* CHAMPUS-authorized provider organizations and individuals providing clinical services shall maintain adequate clinical records to substantiate that specific care was actually furnished, was medically necessary, and appropriate, and identify(ies) the individual(s) who provided the care. This applies whether the care is inpatient or outpatient. The minimum requirements for medical record documentation are set forth by all of the following:

(i) The cognizant state licensing authority;

(ii) The Joint Commission on Accreditation of Healthcare Organizations, or the appropriate Qualified Accreditation Organization as defined in §199.2;

(iii) Standards of practice established by national medical organizations; and

(iv) This part.

(13) *Participation agreements.* A participation agreement otherwise required by this part shall include, in part, all of the following provisions requiring that the provider shall:

(i) Not charge a beneficiary for the following:

(A) Services for which the provider is entitled to payment from CHAMPUS;

(B) Services for which the beneficiary would be entitled to have CHAMPUS payment made had the provider complied with certain procedural requirements.

(C) Services not medically necessary and appropriate for the clinical management of the presenting illness, injury, disorder or maternity;

(D) Services for which a beneficiary would be entitled to payment but for a

reduction or denial in payment as a result of quality review; and

(E) Services rendered during a period in which the provider was not in compliance with one or more conditions of authorization;

(ii) Comply with the applicable provisions of this part and related CHAMPUS administrative policy;

(iii) Accept the CHAMPUS determined allowable payment combined with the cost-share, deductible, and other health insurance amounts payable by, or on behalf of, the beneficiary, as full payment for CHAMPUS allowed services;

(iv) Collect from the CHAMPUS beneficiary those amounts that the beneficiary has a liability to pay for the CHAMPUS deductible and cost-share;

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

(vi) Provide the Director, OCHAMPUS, or designee, prompt written notification of the provider's employment of an individual who, at any time during the twelve months preceding such employment, was employed in a managerial, accounting, auditing, or similar capacity by an agency or organization which is responsible, directly or indirectly for decisions regarding Department of Defense payments to the provider;

(vii) Cooperate fully with a designated utilization and clinical quality management organization which has a contract with the Department of Defense for the geographic area in which the provider renders services;

(viii) Obtain written authorization before rendering designated services or items for which CHAMPUS cost-share may be expected;

(ix) Maintain clinical and other records related to individuals for whom CHAMPUS payment was made for services rendered by the provider, or otherwise under arrangement, for a period of 60 months from the date of service;

(x) Maintain contemporaneous clinical records that substantiate the clinical rationale for each course of treatment, periodic evaluation of the efficacy of treatment, and the outcome at completion or discontinuation of treatment;

(xi) Refer CHAMPUS beneficiaries only to providers with which the referring provider does not have an economic interest, as defined in §199.2; and

(xii) Limit services furnished under arrangement to those for which receipt of payment by the CHAMPUS authorized provider discharges the payment liability of the beneficiary.

(14) *Implementing instructions.* The Director, OCHAMPUS, or a designee, shall issue CHAMPUS policies, instructions, procedures, and guidelines, as may be necessary to implement the intent of this section.

(15) *Exclusion.* Regardless of any provision in this section, a provider who is suspended, excluded, or terminated under §199.9 of this part is specifically excluded as an authorized CHAMPUS provider.

(b) *Institutional providers*—(1) *General.* Institutional providers are those providers who bill for services in the name of an organizational entity (such as hospital and skilled nursing facility), rather than in the name of a person. The term ''institutional provider'' does not include professional corporations or associations qualifying as a domestic corporation under §301.7701–5 of the Internal Revenue Service Regulations nor does it include other corporations that provide principally professional services. Institutional providers may provide medical services and supplies on either an inpatient or outpatient basis.

(i) *Preauthorization.* Preauthorization may be required by the Director, OCHAMPUS for any health care service for which payment is sought under CHAMPUS. (See §§199.4 and 199.15 for further information on preauthorization requirements.)

(ii) Billing practices.

(A) Each institutional billing, including those institutions subject to the CHAMPUS DRG-based reimbursement method or a CHAMPUS-determined all-inclusive rate reimbursement method, must be itemized fully and sufficiently descriptive for the CHAMPUS to make a determination of benefits.

(B) Institutional claims subject to the CHAMPUS DRG-based reimbursement method or a CHAMPUS-determined all-inclusive rate reimbursement method, may be submitted only after the beneficiary has been discharged or transferred from the institutional provider's facility or program.

(C) Institutional claims for Residential Treatment Centers and all other institutional providers, except those listed in (B) above, should be submitted to the appropriate CHAMPUS fiscal intermediary at least every 30 days.

(2) *Nondiscrimination policy.* Except as provided below, payment may not be made for inpatient or outpatient care provided and billed by an institutional provider found by the Federal Government to practice discrimination in the admission of patients to its services on the basis of race, color, or national origin. Reimbursement may not be made to a beneficiary who pays for care provided by such a facility and submits a claim for reimbursement. In the following circumstances, the Secretary of Defense, or a designee, may authorize payment for care obtained in an ineligible facility:

(i) *Emergency care.* Emergency inpatient or outpatient care.

(ii) *Care rendered before finding of a violation.* Care initiated before a finding of a violation and which continues after such violation when it is determined that a change in the treatment facility would be detrimental to the health of the patient, and the attending physician so certifies.

(iii) *Other facility not available.* Care provided in an ineligible facility because an eligible facility is not available within a reasonable distance.

(3) *Procedures for qualifying as a CHAMPUS-approved institutional provider.* General and special hospitals otherwise meeting the qualifications outlined in paragraphs (b)(4) (i), (ii), and (iii), of this section are not required to request CHAMPUS approval formally.

(i) *JCAH accreditation status.* Each CHAMPUS fiscal intermediary shall keep informed as to the current JCAH accreditation status of all hospitals and skilled nursing facilities in its area; and the provider's status under Medicare, particularly with regard to compliance with title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d(1)). The Director, OCHAMPUS, or a designee, shall specifically approve all other authorized institutional providers providing services to CHAMPUS beneficiaries. At the discretion of the Director, OCHAMPUS, any facility that is certified and participating as a provider of services under title XVIII of the Social Security Act (Medicare), may be deemed to meet CHAMPUS requirements. The facility must be providing a type and level of service that is authorized by this part.

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

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

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

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

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

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

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

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

(B) Maintains clinical records on all inpatients (and outpatients if the facility operates an outpatient department or emergency room).

(C) Has bylaws in effect with respect to its operations and medical staff.

(D) Has a requirement that every patient be under the care of a physician.

(E) Provides 24-hour nursing service rendered or supervised by a registered professional nurse, and has a licensed practical nurse or registered professional nurse on duty at all times.

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

(G) In the case of an institution in a state in which state or applicable local law provides for the licensing of hospitals, the hospital:

(*1*) Is licensed pursuant to such law, or

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

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

(I) Is accredited by the JCAH or meets such other requirements as the Secretary of Health and Human Services, the Secretary of Transportation, or the Secretary of Defense finds necessary in the interest of the health and safety of patients who are admitted to and furnished services in the institution.

NOTE TO PARAGRAPH (B)(4)(I)(I): For the duration of Medicare's ''Hospitals Without Walls'' initiative for the coronavirus disease 2019 (COVID–19) outbreak, any entity that temporarily enrolls with Medicare as a hospital may be temporarily exempt from certain institutional requirements for acute care hospitals under TRICARE. To the extent practicable, the Director, Defense Health Agency (DHA), will adopt by administrative policy any process requirement related to Medicare's Hospitals Without Walls initiative.

(ii) *Organ transplant centers.* To obtain TRICARE approval as an organ transplant center, the center must be a Medicare approved transplant center or meet the criteria as established by the Executive Director, TMA, or a designee.

(iii) *Organ transplant consortia.* TRICARE shall approve individual pediatric organ transplant centers that meet the criteria established by the Executive Director, TMA, or a designee.

(iv) *Hospitals, psychiatric.* A psychiatric hospital is an institution which is engaged primarily in providing services to inpatients for the diagnosis and treatment of mental disorders.

(A) There are two major categories of psychiatric hospitals:

(*1*) The private psychiatric hospital category includes both proprietary and the not-for-profit nongovernmental institutions.

(*2*) The second category is those psychiatric hospitals that are controlled, financed, and operated by departments

or agencies of the local, state, or Federal Government and always are operated on a not-for-profit basis.

(B) In order for the services of a psychiatric hospital to be covered, the hospital shall comply with the provisions outlined in paragraph (b)(4)(i) of this section. All psychiatric hospitals shall be accredited under an accrediting organization approved by the Director, in order for their services to be cost-shared under CHAMPUS. In the case of those psychiatric hospitals that are not accredited because they have not been in operation a sufficient period of time to be eligible to request an accreditation survey, the Director, or a designee, may grant temporary approval if the hospital is certified and participating under Title XVIII of the Social Security Act (Medicare, Part A). This temporary approval expires 12 months from the date on which the psychiatric hospital first becomes eligible to request an accreditation survey by an accrediting organization approved by the Director.

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

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

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

(*3*) Are the charges reasonable?

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

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

(v) *Long Term Care Hospital (LTCH).* LTCHs must meet all the criteria for classification as an LTCH under 42 CFR part 412, subpart O, as well as all of the requirements of this part in order to be considered an authorized LTCH under the TRICARE program.

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

(B) Custodial or domiciliary care is not coverable under TRICARE, even if rendered in an otherwise authorized LTCH.

(C) The controlling factor in determining whether a beneficiary's stay in a LTCH is coverable by TRICARE is the level of professional care, supervision, and skilled nursing care that the beneficiary requires, in addition to the diagnosis, type of condition, or degree of functional limitations. The type and level of medical services required or rendered is controlling for purposes of extending TRICARE benefits; not the type of provider or condition of the beneficiary.

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

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

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

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

(D) Maintains clinical records on all patients.

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

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

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

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

(*1*) Is licensed pursuant to such law, or

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

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

(J) Meets such provisions of the most current edition of the Life Safety Code[8] as are applicable to nursing facilities; except that if the Secretary of Health and Human Services has waived, for such periods, as deemed appropriate, specific provisions of such code which, if rigidly applied, would result in unreasonable hardship upon a nursing facility.

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

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

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

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

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

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

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

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

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

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

(*2*) *Eligibility.* (*i*) In order to qualify as a TRICARE authorized provider, every RTC must meet the minimum basic standards set forth in paragraphs

[8] Compiled and published by the National Fire Protection Association, Batterymarch Park, Quincy, Massachusetts 02269.

(b)(4)(vii)(A) through (C) of this section, and as well as such additional elaborative criteria and standards as the Director determines are necessary to implement the basic standards.

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

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

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

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

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

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

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

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

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

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

(*7*) Certify that:

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

(*ii*) It will maintain compliance with the CHAMPUS Standards for Residential Treatment Centers Serving Children and Adolescents with Mental Disorders, as issued by the Director, except for any such standards regarding which the facility notifies the Director that it is not in compliance.

(*8*) Designate an individual who will act as liaison for CHAMPUS inquiries. The RTC shall inform OCHAMPUS in writing of the designated individual;

(*9*) Furnish OCHAMPUS, as requested by OCHAMPUS, with cost data certified by an independent accounting firm or other agency as authorized by the Director, OCHAMPUS;

(*10*) Comply with all requirements of this section applicable to institutional providers generally concerning accreditation requirements, preauthorization, concurrent care review, claims processing, beneficiary liability, double coverage, utilization and quality review, and other matters;

(*11*) Grant the Director, or designee, the right to conduct quality assurance audits or accounting audits with full access to patients and records (including records relating to patients who are not CHAMPUS beneficiaries) to determine the quality and cost-effectiveness of care rendered. The audits may

be conducted on a scheduled or unscheduled (unannounced) basis. This right to audit/review includes, but is not limited to:

(*i*) Examination of fiscal and all other records of the RTC which would confirm compliance with the participation agreement and designation as a TRICARE authorized RTC;

(*ii*) Conducting such audits of RTC records including clinical, financial, and census records, as may be necessary to determine the nature of the services being provided, and the basis for charges and claims against the United States for services provided CHAMPUS beneficiaries;

(*iii*) Examining reports of evaluations and inspections conducted by federal, state and local government, and private agencies and organizations;

(*iv*) Conducting on-site inspections of the facilities of the RTC and interviewing employees, members of the staff, contractors, board members, volunteers, and patients, as required;

(*v*) Audits conducted by the United States Government Accountability Office.

(C) *Other requirements applicable to RTCs.* (*1*) Even though an RTC may qualify as a TRICARE authorized provider and may have entered into a participation agreement with CHAMPUS, payment by CHAMPUS for particular services provided is contingent upon the RTC also meeting all conditions set forth in §199.4 especially all requirements of §199.4(b)(4).

(*2*) The RTC shall provide inpatient services to CHAMPUS beneficiaries in the same manner it provides inpatient services to all other patients. The RTC may not discriminate against CHAMPUS beneficiaries in any manner, including admission practices, placement in special or separate wings or rooms, or provisions of special or limited treatment.

(*3*) The RTC shall assure that all certifications and information provided to the Director, incident to the process of obtaining and retaining authorized provider status is accurate and that it has no material errors or omissions. In the case of any misrepresentations, whether by inaccurate information being provided or material facts withheld, authorized status will be denied or terminated, and the RTC will be ineligible for consideration for authorized provider status for a two year period.

(viii) *Christian Science sanatoriums.* The services obtained in Christian Science sanatoriums are covered by CHAMPUS as inpatient care. To qualify for coverage, the sanatorium either must be operated by, or be listed and certified by the First Church of Christ, Scientist.

(ix) *Infirmaries.* Infirmaries are facilities operated by student health departments of colleges and universities to provide inpatient or outpatient care to enrolled students. Charges for care provided by such facilities will not be cost-shared by CHAMPUS if the student would not be charged in the absence of CHAMPUS, or if student is covered by a mandatory student health insurance plan, in which enrollment is required as a part of the student's school registration and the charges by the college or university include a premium for the student health insurance coverage. CHAMPUS will cost-share only if enrollment in the student health program or health insurance plan is voluntary.

NOTE: An infirmary in a boarding school also may qualify under this provision, subject to review and approval by the Director, OCHAMPUS or a designee.

(x) *Other special institution providers.* (A) *General.* (*1*) Care provided by certain special institutional providers (on either an inpatient or outpatient basis), may be cost-shared by CHAMPUS under specified circumstances and only if the provider is specifically identified in paragraph (b)(4)(x) of this section.

(*i*) The course of treatment is prescribed by a doctor of medicine or osteopathy.

(*ii*) The patient is under the supervision of a physician during the entire course of the inpatient admission or the outpatient treatment.

(*iii*) The type and level of care and service rendered by the institution are otherwise authorized by this part.

(*iv*) The facility meets all licensing or other certification requirements that are extant in the jurisdiction in which the facility is located geographically.

(*v*) Is other than a nursing home, intermediate care facility, home for the aged, halfway house, or other similar institution.

(*vi*) Is accredited by the JCAH or other CHAMPUS-approved accreditation organization, if an appropriate accreditation program for the given type of facility is available. As future accreditation programs are developed to cover emerging specialized treatment programs, such accreditation will be a prerequisite to coverage by CHAMPUS for services provided by such facilities.

(*2*) To ensure that CHAMPUS beneficiaries are provided quality care at a reasonable cost when treated by a special institutional provider, the Director, OCHAMPUS may:

(*i*) Require prior approval of all admissions to special institutional providers.

(*ii*) Set appropriate standards for special institutional providers in addition to or in the absence of JCAHO accreditation.

(*iii*) Monitor facility operations and treatment programs on a continuing basis and conduct onsite inspections on a scheduled and unscheduled basis.

(*iv*) Negotiate agreements of participation.

(*v*) Terminate approval of a case when it is ascertained that a departure from the facts upon which the admission was based originally has occurred.

(*vi*) Declare a special institutional provider not eligible for CHAMPUS payment if that facility has been found to have engaged in fraudulent or deceptive practices.

(*3*) In general, the following disclaimers apply to treatment by special institutional providers:

(*i*) Just because one period or episode of treatment by a facility has been covered by CHAMPUS may not be construed to mean that later episodes of care by the same or similar facility will be covered automatically.

(*ii*) The fact that one case has been authorized for treatment by a specific facility or similar type of facility may not be construed to mean that similar cases or later periods of treatment will be extended CHAMPUS benefits automatically.

(B) *Types of providers.* The following is a list of facilities that have been designated specifically as special institutional providers.

(*1*) *Free-standing ambulatory surgical centers.* Care provided by freestanding ambulatory surgical centers may be cost-shared by CHAMPUS under the following circumstances:

(*i*) The treatment is prescribed and supervised by a physician.

(*ii*) The type and level of care and services rendered by the center are otherwise authorized by this part.

(*iii*) The center meets all licensing or other certification requirements of the jurisdiction in which the facility is located.

(*iv*) The center is accredited by the JCAH, the Accreditation Association for Ambulatory Health Care, Inc. (AAAHC), or such other standards as authorized by the Director, OCHAMPUS.

(*v*) A childbirth procedure provided by a CHAMPUS-approved free-standing ambulatory surgical center shall not be cost-shared by the CHAMPUS unless the surgical center is also a CHAMPUS-approved birthing center institutional provider as established by the birthing center provider certification requirement of this Regulation.

(*2*) [Reserved]

(xi) *Birthing centers.* A birthing center is a freestanding or institution-affiliated outpatient maternity care program which principally provides a planned course of outpatient prenatal care and outpatient childbirth service limited to low-risk pregnancies; excludes care for high-risk pregnancies; limits childbirth to the use of natural childbirth procedures; and provides immediate newborn care.

(A) *Certification requirements.* A birthing center which meets the following criteria may be designated as an authorized CHAMPUS institutional provider:

(*1*) The predominant type of service and level of care rendered by the center is otherwise authorized by this part.

(*2*) The center is licensed to operate as a birthing center where such license is available, or is specifically licensed as a type of ambulatory health care facility where birthing center specific license is not available, and meets all applicable licensing or certification requirements that are extant in the

state, county, municipality, or other political jurisdiction in which the center is located.

(*3*) The center is accredited by a nationally recognized accreditation organization whose standards and procedures have been determined to be acceptable by the Director, OCHAMPUS, or a designee.

(*4*) The center complies with the CHAMPUS birthing center standards set forth in this part.

(*5*) The center has entered into a participation agreement with OCHAMPUS in which the center agrees, in part, to:

(*i*) Participate in CHAMPUS and accept payment for maternity services based upon the reimbursement methodology for birthing centers;

(*ii*) Collect from the CHAMPUS beneficiary only those amounts that represent the beneficiary's liability under the participation agreement and the reimbursement methodology for birthing centers, and the amounts for services and supplies that are not a benefit of the CHAMPUS;

(*iii*) Permit access by the Director, OCHAMPUS, or a designee, to the clinical record of any CHAMPUS beneficiary, to the financial and organizational records of the center, and to reports of evaluations and inspections conducted by state or private agencies or organizations;

(*iv*) Submit claims first to all health benefit and insurance plans primary to the CHAMPUS to which the beneficiary is entitled and to comply with the double coverage provisions of this part;

(*v*) Notify CHAMPUS in writing within 7 days of the emergency transport of any CHAMPUS beneficiary from the center to an acute care hospital or of the death of any CHAMPUS beneficiary in the center.

(*6*) A birthing center shall not be a CHAMPUS-authorized institutional provider and CHAMPUS benefits shall not be paid for any service provided by a birthing center before the date the participation agreement is signed by the Director, OCHAMPUS, or a designee.

(B) *CHAMPUS birthing center standards.* (*1*) *Environment:* The center has a safe and sanitary environment, properly constructed, equipped, and maintained to protect health and safety and meets the applicable provisions of the ''Life Safety Code'' of the National Fire Protection Association.

(*2*) *Policies and procedures:* The center has written administrative, fiscal, personnel and clinical policies and procedures which collectively promote the provision of high-quality maternity care and childbirth services in an orderly, effective, and safe physical and organizational environment.

(*3*) *Informed consent:* Each CHAMPUS beneficiary admitted to the center will be informed in writing at the time of admission of the nature and scope of the center's program and of the possible risks associated with maternity care and childbirth in the center.

(*4*) *Beneficiary care:* Each woman admitted will be cared for by or under the direct supervision of a specific physician or a specific certified nurse-midwife who is otherwise eligible as a CHAMPUS individual professional provider.

(*5*) *Medical direction:* The center has written memoranda of understanding (MOU) for routine consultation and emergency care with an obstetrician-gynecologist who is certified or is eligible for certification by the American Board of Obstetrics and Gynecology or the American Osteopathic Board of Obstetrics and Gynecology and with a pediatrician who is certified or eligible for certification by the American Board of Pediatrics or by the American Osteopathic Board of Pediatrics, each of whom have admitting privileges to at least one backup hospital. In lieu of a required MOU, the center may employ a physician with the required qualifications. Each MOU must be renewed annually.

(*6*) *Admission and emergency care criteria and procedures.* The center has written clinical criteria and administrative procedures, which are reviewed and approved annually by a physician related to the center as required by paragraph (b)(4)(xi)(B)(*5*) above, for the exclusion of a woman with a high-risk pregnancy from center care and for management of maternal and neonatal emergencies.

(*7*) *Emergency treatment.* The center has a written memorandum of understanding (MOU) with at least one

backup hospital which documents that the hospital will accept and treat any woman or newborn transferred from the center who is in need of emergency obstetrical or neonatal medical care. In lieu of this MOU with a hospital, a birthing center may have an MOU with a physician, who otherwise meets the requirements as a CHAMPUS individual professional provider, and who has admitting privileges to a backup hospital capable of providing care for critical maternal and neonatal patients as demonstrated by a letter from that hospital certifying the scope and expected duration of the admitting privileges granted by the hospital to the physician. The MOU must be reviewed annually.

(*8*) *Emergency medical transportation*. The center has a written memorandum of understanding (MOU) with at least one ambulance service which documents that the ambulance service is routinely staffed by qualified personnel who are capable of the management of critical maternal and neonatal patients during transport and which specifies the estimated transport time to each backup hospital with which the center has arranged for emergency treatment as required in paragraph (b)(4)(xi)(B)(*7*) above. Each MOU must be renewed annually.

(*9*) *Professional staff*. The center's professional staff is legally and professionally qualified for the performance of their professional responsibilities.

(*10*) *Medical records*. The center maintains full and complete written documentation of the services rendered to each woman admitted and each newborn delivered. A copy of the informed consent document required by paragraph (b)(4)(xi)(B)(*3*), above, which contains the original signature of the CHAMPUS beneficiary, signed and dated at the time of admission, must be maintained in the medical record of each CHAMPUS beneficiary admitted.

(*11*) *Quality assurance*. The center has an organized program for quality assurance which includes, but is not limited to, written procedures for regularly scheduled evaluation of each type of service provided, of each mother or newborn transferred to a hospital, and of each death within the facility.

(*12*) *Governance and administration*. The center has a governing body legally responsible for overall operation and maintenance of the center and a full-time employee who has authority and responsibility for the day-to-day operation of the center.

(xii) *Psychiatric and substance use disorder partial hospitalization programs*. This paragraph (b)(4)(xii) establishes the definition of and eligibility standards and requirements for psychiatric and substance use disorder partial hospitalization programs.

(A) *Organization and administration*—(*1*) *Definition*. Partial hospitalization is defined as a time-limited, ambulatory, active treatment program that offers therapeutically intensive, coordinated, and structured clinical services within a stable therapeutic milieu. Partial hospitalization programs serve patients who exhibit psychiatric symptoms, disturbances of conduct, and decompensating conditions affecting mental health. Partial hospitalization is appropriate for those whose psychiatric and addiction-related symptoms or concomitant physical and emotional/behavioral problems can be managed outside the hospital for defined periods of time with support in one or more of the major life areas. A partial hospitalization program for the treatment of substance use disorders is an addiction-focused service that provides active treatment to children and adolescents, or adults aged 18 and over.

(*2*) *Eligibility*. (*i*) To qualify as a TRICARE authorized provider, every partial hospitalization program must meet minimum basic standards set forth in paragraphs (b)(4)(xii)(A) through (D) of this section, as well as such additional elaborative criteria and standards as the Director determines are necessary to implement the basic standards. Each partial hospitalization program must be either a distinct part of an otherwise-authorized institutional provider or a free-standing program. Approval of a hospital by TRICARE is sufficient for its partial hospitalization program to be an authorized TRICARE provider. Such hospital-based partial hospitalization programs are not required to be separately authorized by TRICARE.

(*ii*) To be approved as a TRICARE authorized provider, the facility is required to be licensed and operate in substantial compliance with state and federal regulations.

(*iii*) The facility is required to be currently accredited by an accrediting organization approved by the Director. Each PHP authorized to treat substance use disorder must be accredited to provide the level of required treatment by an accreditation body approved by the Director.

(*iv*) The facility is required to have a written participation agreement with OCHAMPUS. The PHP is not a CHAMPUS-authorized provider and CHAMPUS benefits are not paid for services provided until the date upon which a participation agreement is signed by the Director.

(B) *Participation agreement requirements.* In addition to other requirements set forth in this paragraph (b)(4)(xii), in order for the services of a PHP to be authorized, the PHP shall have entered into a Participation Agreement with OCHAMPUS. A single consolidated participation agreement is acceptable for all units of the TRICARE authorized facility granted that all programs meet the requirements of this part. The period of a Participation Agreement shall be specified in the agreement, and will generally be for not more than five years. The PHP shall not be considered to be a CHAMPUS authorized provider and CHAMPUS payments shall not be made for services provided by the PHP until the date the participation agreement is signed by the Director. In addition to review of a facility's application and supporting documentation, an on-site inspection by OCHAMPUS authorized personnel may be required prior to signing a participation agreement. The Participation Agreement shall include at least the following requirements:

(*1*) Render partial hospitalization program services to eligible CHAMPUS beneficiaries in need of such services, in accordance with the participation agreement and CHAMPUS regulation.

(*2*) Accept payment for its services based upon the methodology provided in §199.14, or such other method as determined by the Director;

(*3*) Accept the CHAMPUS all-inclusive per diem rate as payment in full and collect from the CHAMPUS beneficiary or the family of the CHAMPUS beneficiary only those amounts that represent the beneficiary's liability, as defined in §199.4, and charges for services and supplies that are not a benefit of CHAMPUS;

(*4*) Make all reasonable efforts acceptable to the Director to collect those amounts, which represent the beneficiary's liability, as defined in §199.4;

(*5*) Comply with the provisions of §199.8, and submit claims first to all health insurance coverage to which the beneficiary is entitled that is primary to CHAMPUS;

(*6*) Submit claims for services provided to CHAMPUS beneficiaries at least every 30 days (except to the extent a delay is necessitated by efforts to first collect from other health insurance). If claims are not submitted at least every 30 days, the PHP agrees not to bill the beneficiary or the beneficiary's family for any amounts disallowed by CHAMPUS;

(*7*) Certify that:

(*i*) It is and will remain in compliance with the TRICARE standards and provisions of paragraph (b)(4)(xii) of this section establishing standards for psychiatric and substance use disorder partial hospitalization programs; and

(*ii*) It will maintain compliance with the CHAMPUS Standards for Psychiatric Substance Use Disorder Partial Hospitalization Programs, as issued by the Director, except for any such standards regarding which the facility notifies the Director, or designee, that it is not in compliance.

(*8*) Designate an individual who will act as liaison for CHAMPUS inquiries. The PHP shall inform the Director, or designee, in writing of the designated individual;

(*9*) Furnish OCHAMPUS, as requested by OCHAMPUS, with cost data certified by an independent accounting firm or other agency as authorized by the Director;

(*10*) Comply with all requirements of this section applicable to institutional providers generally concerning accreditation requirements, preauthorization,

concurrent care review, claims processing, beneficiary liability, double coverage, utilization and quality review, and other matters;

(*11*) Grant the Director, or designee, the right to conduct quality assurance audits or accounting audits with full access to patients and records (including records relating to patients who are not CHAMPUS beneficiaries) to determine the quality and cost-effectiveness of care rendered. The audits may be conducted on a scheduled or unscheduled (unannounced) basis. This right to audit/review includes, but is not limited to:

(*i*) Examination of fiscal and all other records of the PHP which would confirm compliance with the participation agreement and designation as a TRICARE authorized PHP provider;

(*ii*) Conducting such audits of PHP records including clinical, financial, and census records, as may be necessary to determine the nature of the services being provided, and the basis for charges and claims against the United States for services provided CHAMPUS beneficiaries;

(*iii*) Examining reports of evaluations and inspections conducted by federal, state and local government, and private agencies and organizations;

(*iv*) Conducting on-site inspections of the facilities of the PHP and interviewing employees, members of the staff, contractors, board members, volunteers, and patients, as required;

(*v*) Audits conducted by the United States General Account Office.

(C) *Other requirements applicable to PHPs.* (*1*) Even though a PHP may qualify as a TRICARE authorized provider and may have entered into a participation agreement with CHAMPUS, payment by CHAMPUS for particular services provided is contingent upon the PHP also meeting all conditions set forth in §199.4.

(*2*) The PHP may not discriminate against CHAMPUS beneficiaries in any manner, including admission practices, placement in special or separate wings or rooms, or provisions of special or limited treatment.

(*3*) The PHP shall assure that all certifications and information provided to the Director incident to the process of obtaining and retaining authorized provider status is accurate and that is has no material errors or omissions. In the case of any misrepresentations, whether by inaccurate information being provided or material facts withheld, authorized provider status will be denied or terminated, and the PHP will be ineligible for consideration for authorized provider status for a two year period.

(xiii) *Hospice programs.* Hospice programs must be Medicare approved and meet all Medicare conditions of participation (42 CFR part 418) in relation to CHAMPUS patients in order to receive payment under the CHAMPUS program. A hospice program may be found to be out of compliance with a particular Medicare condition of participation and still participate in the CHAMPUS as long as the hospice is allowed continued participation in Medicare while the condition of noncompliance is being corrected. The hospice program can be either a public agency or private organization (or a subdivision thereof) which:

(A) Is primarily engaged in providing the care and services described under §199.4(e)(19) and makes such services available on a 24-hour basis.

(B) Provides bereavement counseling for the immediate family or terminally ill individuals.

(C) Provides for such care and services in individuals' homes, on an outpatient basis, and on a short-term inpatient basis, directly or under arrangements made by the hospice program, except that the agency or organization must:

(*1*) Ensure that substantially all the core services are routinely provided directly by hospice employees.

(*2*) Maintain professional management responsibility for all services which are not directly furnished to the patient, regardless of the location or facility in which the services are rendered.

(*3*) Provide assurances that the aggregate number of days of inpatient care provided in any 12-month period does not exceed 20 percent of the aggregate number of days of hospice care during the same period.

(*4*) Have an interdisciplinary group composed of the following personnel

who provide the care and services described under §199.4(e)(19) and who establish the policies governing the provision of such care/services:

(*i*) A physician;

(*ii*) A registered professional nurse;

(*iii*) A social worker; and

(*iv*) A pastoral or other counselor.

(*5*) Maintain central clinical records on all patients.

(*6*) Utilize volunteers.

(*7*) The hospice and all hospice employees must be licensed in accordance with applicable Federal, State and local laws and regulations.

(*8*) The hospice must enter into an agreement with CHAMPUS in order to be qualified to participate and to be eligible for payment under the program. In this agreement the hospice and CHAMPUS agree that the hospice will:

(*i*) Not charge the beneficiary or any other person for items or services for which the beneficiary is entitled to have payment made under the CHAMPUS hospice benefit.

(*ii*) Be allowed to charge the beneficiary for items or services requested by the beneficiary in addition to those that are covered under the CHAMPUS hospice benefit.

(*9*) Meet such other requirements as the Secretary of Defense may find necessary in the interest of the health and safety of the individuals who are provided care and services by such agency or organization.

(xiv) *Substance use disorder rehabilitation facilities.* This paragraph (b)(4)(xiv) establishes the definition of eligibility standards and requirements for residential substance use disorder rehabilitation facilities (SUDRF).

(A) *Organization and administration*—(*1*) *Definition.* A SUDRF is a residential or rehabilitation facility, or distinct part of a facility, that provides medically monitored, interdisciplinary addiction-focused treatment to beneficiaries who have psychoactive substance use disorders. Qualified health care professionals provide 24-hour, seven-day-per-week, assessment, treatment, and evaluation. A SUDRF is appropriate for patients whose addiction-related symptoms, or concomitant physical and emotional/behavioral problems reflect persistent dysfunction in several major life areas. Residential or inpatient rehabilitation is differentiated from:

(*i*) Acute psychoactive substance use treatment and from treatment of acute biomedical/emotional/behavioral problems; which problems are either life-threatening and/or severely incapacitating and often occur within the context of a discrete episode of addiction-related biomedical or psychiatric dysfunction;

(*ii*) A partial hospitalization center, which serves patients who exhibit emotional/behavioral dysfunction but who can function in the community for defined periods of time with support in one or more of the major life areas;

(*iii*) A group home, sober-living environment, halfway house, or three-quarter way house;

(*iv*) Therapeutic schools, which are educational programs supplemented by addiction-focused services;

(*v*) Facilities that treat patients with primary psychiatric diagnoses other than psychoactive substance use or dependence; and

(*vi*) Facilities that care for patients with the primary diagnosis of mental retardation or developmental disability.

(*2*) *Eligibility.* (*i*) In order to become a TRICARE authorized provider, every SUDRF must meet minimum basic standards set forth in paragraphs (b)(4)(xiv)(A) through (C) of this section, as well as such additional elaborative criteria and standards as the Director determines are necessary to implement the basic standards.

(*ii*) To be approved as a TRICARE authorized provider, the SUDRF is required to be licensed and operate in substantial compliance with state and federal regulations.

(*iii*) The SUDRF is currently accredited by an accrediting organization approved by the Director. Each SUDRF must be accredited to provide the level of required treatment by an accreditation body approved by the Director.

(*iv*) The SUDRF has a written participation agreement with OCHAMPUS. The SUDRF is not considered a TRICARE authorized provider, and CHAMPUS benefits are not paid for services provided until the date upon which a participation agreement is signed by the Director.

(B) *Participation agreement requirements.* In addition to other requirements set forth in this paragraph (b)(4)(xiv), in order for the services of an inpatient rehabilitation center for the treatment of substance use disorders to be authorized, the center shall have entered into a Participation Agreement with OCHAMPUS. A single consolidated participation agreement is acceptable for all units of the TRICARE authorized facility. The period of a Participation Agreement shall be specified in the agreement, and will generally be for not more than five years. The SUDRF shall not be considered to be a CHAMPUS authorized provider and CHAMPUS payments shall not be made for services provided by the SUDRF until the date the participation agreement is signed by the Director. In addition to review of the SUDRF's application and supporting documentation, an on-site visit by OCHAMPUS representatives may be part of the authorization process. The Participation Agreement shall include at least the following requirements:

(*1*) Render applicable services to eligible CHAMPUS beneficiaries in need of such services, in accordance with the participation agreement and CHAMPUS regulation;

(*2*) Accept payment for its services based upon the methodology provided in §199.14, or such other method as determined by the Director;

(*3*) Accept the CHAMPUS-determined rate as payment in full and collect from the CHAMPUS beneficiary or the family of the CHAMPUS beneficiary only those amounts that represent the beneficiary's liability, as defined in §199.4, and charges for services and supplies that are not a benefit of CHAMPUS;

(*4*) Make all reasonable efforts acceptable to the Director to collect those amounts which represent the beneficiary's liability, as defined in §199.4;

(*5*) Comply with the provisions of §199.8, and submit claims first to all health insurance coverage to which the beneficiary is entitled that is primary to CHAMPUS;

(*6*) Furnish OCHAMPUS with cost data, as requested by OCHAMPUS, certified to by an independent accounting firm or other agency as authorized by the Director;

(*7*) Certify that:

(*i*) It is and will remain in compliance with the provisions of paragraph (b)(4)(xiv) of the section establishing standards for substance use disorder rehabilitation facilities; and

(*ii*) It has conducted a self-assessment of the facility's compliance with the CHAMPUS Standards for Substance Use Disorder Rehabilitation Facilities, as issued by the Director and notified the Director of any matter regarding which the facility is not in compliance with such standards; and

(*iii*) It will maintain compliance with the CHAMPUS Standards for Substance Use Disorder Rehabilitation Facilities, as issued by the Director, except for any such standards regarding which the facility notifies the Director that it is not in compliance.

(*8*) Designate an individual who will act as liaison for CHAMPUS inquiries. The SUDRF shall inform OCHAMPUS in writing of the designated individual;

(*9*) Furnish OCHAMPUS, as requested by OCHAMPUS, with cost data certified by an independent accounting firm or other agency as authorized by the Director;

(*10*) Comply with all requirements of this section applicable to institutional providers generally concerning accreditation requirements, preauthorization, concurrent care review, claims processing, beneficiary liability, double coverage, utilization and quality review, and other matters;

(*11*) Grant the Director, or designee, the right to conduct quality assurance audits or accounting audits with full access to patients and records (including records relating to patients who are not CHAMPUS beneficiaries) to determine the quality and cost effectiveness of carerendered. The audits may be conducted on a scheduled or unscheduled (unannounced) basis. This right to audit/review included, but is not limited to:

(*i*) Examination of fiscal and all other records of the center which would confirm compliance with the participation agreement and designation as an authorized TRICARE provider;

(*ii*) Conducting such audits of center records including clinical, financial,

and census records, as may be necessary to determine the nature of the services being provided, and the basis for charges and claims against the United States for services provided CHAMPUS beneficiaries;

(*iii*) Examining reports of evaluations and inspection conducted by federal, state and local government, and private agencies and organizations;

(*iv*) Conducting on-site inspections of the facilities of the SUDRF and interviewing employees, members of the staff, contractors, board members, volunteers, and patients, as required.

(*v*) Audits conducted by the United States Government Accountability Office.

(C) Other requirements applicable to substance use disorder rehabilitation facilities.

(*1*) Even though a SUDRF may qualify as a TRICARE authorized provider and may have entered into a participation agreement with CHAMPUS, payment by CHAMPUS for particular services provided is contingent upon the SUDRF also meeting all conditions set forth in §199.4.

(*2*) The center shall provide inpatient services to CHAMPUS beneficiaries in the same manner it provides services to all other patients. The center may not discriminate against CHAMPUS beneficiaries in any manner, including admission practices, placement in special or separate wings or rooms, or provisions of special or limited treatment.

(*3*) The substance use disorder facility shall assure that all certifications and information provided to the Director, incident to the process of obtaining and retaining authorized provider status, is accurate and that it has no material errors or omissions. In the case of any misrepresentations, whether by inaccurate information being provided or material facts withheld, authorized provider status will be denied or terminated, and the facility will be ineligible for consideration for authorized provider status for a two year period.

(xv) *Home health agencies (HHAs).* HHAs must be Medicare approved and meet all Medicare conditions of participation under sections 1861(o) and 1891 of the Social Security Act (42 U.S.C. 1395x(o) and 1395bbb) and 42 CFR part 484 in relation to TRICARE beneficiaries in order to receive payment under the TRICARE program. An HHA may be found to be out of compliance with a particular Medicare condition of participation and still participate in the TRICARE program as long as the HHA is allowed continued participation in Medicare while the condition of noncompliance is being corrected. An HHA is a public or private organization, or a subdivision of such an agency or organization, that meets the following requirements:

(A) Engaged in providing skilled nursing services and other therapeutic services, such as physical therapy, speech-language pathology services, or occupational therapy, medical services, and home health aide services.

(*1*) Makes available part-time or intermittent skilled nursing services and at least one other therapeutic service on a visiting basis in place of residence used as a patient's home.

(*2*) Furnishes at least one of the qualifying services directly through agency employees, but may furnish the second qualifying service and additional services under arrangement with another HHA or organization.

(B) Policies established by a professional group associated with the agency or organization (including at least one physician and one registered nurse) to govern the services and provides for supervision of such services by a physician or a registered nurse.

(C) Maintains clinical records for all patients.

(D) Licensed in accordance with State and local law or is approved by the State or local licensing agency as meeting the licensing standards, where applicable.

(E) Enters into an agreement with TRICARE in order to participate and to be eligible for payment under the program. In this agreement the HHA and TRICARE agree that the HHA will:

(*1*) Not charge the beneficiary or any other person for items or services for which the beneficiary is entitled to have payment under the TRICARE HHA prospective payment system.

(*2*) Be allowed to charge the beneficiary for items or services requested by the beneficiary in addition to those

that are covered under the TRICARE HHA prospective payment system.

(F) Abide by the following consolidated billing requirements:

(*1*) The HHA must submit all TRICARE claims for all home health services, excluding durable medical equipment (DME), while the beneficiary is under the home health plan without regard to whether or not the item or service was furnished by the HHA, by others under arrangement with the HHA, or under any other contracting or consulting arrangement.

(*2*) Separate payment will be made for DME items and services provided under the home health benefit which are under the DME fee schedule. DME is excluded from the consolidated billing requirements.

(*3*) Home health services included in consolidated billing are:

(*i*) Part-time or intermittent skilled nursing;

(*ii*) Part-time or intermittent home health aide services;

(*iii*) Physical therapy, occupational therapy and speech-language pathology;

(*iv*) Medical social services;

(*v*) Routine and non-routine medical supplies;

(*vi*) A covered osteoporosis drug (not paid under PPS rate) but excluding other drugs and biologicals;

(*vii*) Medical services provided by an intern or resident-in-training of a hospital, under an approved teaching program of the hospital in the case of an HHA that is affiliated or under common control of a hospital;

(*viii*) Services at hospitals, SNFs or rehabilitation centers when they involve equipment too cumbersome to bring home.

(G) Meet such other requirements as the Secretary of Health and Human Services and/or Secretary of Defense may find necessary in the interest of the health and safety of the individuals who are provided care and services by such agency or organization.

(xvi) *Critical Access Hospitals (CAHs).* CAHs must meet all conditions of participation under 42 CFR 485.601 through 485.645 in relation to TRICARE beneficiaries in order to receive payment under the TRICARE program. If a CAH provides inpatient psychiatric services or inpatient rehabilitation services in a distinct part unit, the distinct part unit must meet the conditions of participation in 42 CFR 485.647, with the exception of being paid under the inpatient prospective payment system for psychiatric facilities as specified in 42 CFR 412.1(a)(2) or the inpatient prospective payment system for rehabilitation hospitals or rehabilitation units as specified in 42 CFR 412.1(a)(3). Upon implementation of TRICARE's IRF PPS in §199.14(a)(10), if a CAH provides inpatient rehabilitation services in a distinct part unit, the distinct part unit shall be paid under TRICARE's IRF PPS.

(xvii) *Sole community hospitals (SCHs).* SCHs must meet all the criteria for classification as an SCH under 42 CFR 412.92, in order to be considered an SCH under the TRICARE program.

(xviii) *Intensive outpatient programs.* This paragraph (b)(4)(xviii) establishes standards and requirements for intensive outpatient treatment programs for psychiatric and substance use disorder.

(A) *Organization and administration—*(*1*) *Definition.* Intensive outpatient treatment (IOP) programs are defined in §199.2. IOP services consist of a comprehensive and complimentary schedule of recognized treatment approaches that may include day, evening, night, and weekend services consisting of individual and group counseling or therapy, and family counseling or therapy as clinically indicated for children and adolescents, or adults aged 18 and over, and may include case management to link patients and their families with community based support systems.

(*2*) *Eligibility.* (*i*) In order to qualify as a TRICARE authorized provider, every intensive outpatient program must meet the minimum basic standards set forth in paragraphs (b)(4)(xviii)(A) through (C) of this section, as well as additional elaborative criteria and standards as the Director determines are necessary to implement the basic standards. Each intensive outpatient program must be either a distinct part of an otherwise-authorized institutional provider or a free-standing psychiatric or substance use disorder intensive outpatient program. Approval of a hospital by TRICARE is sufficient for its IOP to be an authorized

TRICARE provider. Such hospital-based intensive outpatient programs are not required to be separately authorized by TRICARE.

(*ii*) To qualify as a TRICARE authorized provider, the IOP is required to be licensed and operate in substantial compliance with state and federal regulations.

(*iii*) The IOP is currently accredited by an accrediting organization approved by the Director. Each IOP authorized to treat substance use disorder must be accredited to provide the level of required treatment by an accreditation body approved by the Director.

(*iv*) The facility has a written participation agreement with TRICARE. The IOP is not considered a TRICARE authorized provider and TRICARE benefits are not paid for services provided until the date upon which a participation agreement is signed by the Director.

(B) *Participation agreement requirements*. In addition to other requirements set forth in paragraph (b)(4)(xii) of this section, in order for the services of an IOP to be authorized, the IOP shall have entered into a Participation Agreement with TRICARE. A single consolidated participation agreement is acceptable for all units of the TRICARE authorized facility granted that all programs meet the requirements of this part. The period of a Participation Agreement shall be specified in the agreement, and will generally be for not more than five years. In addition to review of a facility's application and supporting documentation, an on-site inspection by DHA authorized personnel may be required prior to signing a participation agreement. The Participation Agreement shall include at least the following requirements:

(*1*) Render intensive outpatient program services to eligible TRICARE beneficiaries in need of such services, in accordance with the participation agreement and TRICARE regulation.

(*2*) Accept payment for its services based upon the methodology provided in §199.14, or such other method as determined by the Director;

(*3*) Collect from the TRICARE beneficiary or the family of the TRICARE beneficiary only those amounts that represent the beneficiary's liability, as defined in §199.4, and charges for services and supplies that are not a benefit of TRICARE;

(*4*) Make all reasonable efforts acceptable to the Director to collect those amounts, which represent the beneficiary's liability, as defined in §199.4;

(*5*) Comply with the provisions of §199.8, and submit claims first to all health insurance coverage to which the beneficiary is entitled that is primary to TRICARE;

(*6*) Submit claims for services provided to TRICARE beneficiaries at least every 30 days (except to the extent a delay is necessitated by efforts to first collect from other health insurance). If claims are not submitted at least every 30 days, the IOP agrees not to bill the beneficiary or the beneficiary's family for any amounts disallowed by TRICARE;

(*7*) Free-standing intensive outpatient programs shall certify that:

(*i*) It is and will remain in compliance with the provisions of paragraph (b)(4)(xii) of this section establishing standards for psychiatric and SUD IOPs;

(*ii*) It has conducted a self-assessment of the facility's compliance with the CHAMPUS Standards for Intensive Outpatient Programs, as issued by the Director, and notified the Director of any matter regarding which the facility is not in compliance with such standards; and

(*iii*) It will maintain compliance with the TRICARE standards for IOPs, as issued by the Director, except for any such standards regarding which the facility notifies the Director, or a designee that it is not in compliance.

(*8*) Designate an individual who will act as liaison for TRICARE inquiries. The IOP shall inform TRICARE, or a designee in writing of the designated individual;

(*9*) Furnish OCHAMPUS with cost data, as requested by OCHAMPUS, certified by an independent accounting firm or other agency as authorized by the Director.

(*10*) Comply with all requirements of this section applicable to institutional providers generally concerning accreditation requirements, preauthorization,

concurrent care review, claims processing, beneficiary liability, double coverage, utilization and quality review, and other matters;

(*11*) Grant the Director, or designee, the right to conduct quality assurance audits or accounting audits with full access to patients and records (including records relating to patients who are not CHAMPUS beneficiaries) to determine the quality and cost effectiveness of care rendered. The audits may be conducted on a scheduled or unscheduled (unannounced) basis. This right to audit/review included, but is not limited to:

(*i*) Examination of fiscal and all other records of the center which would confirm compliance with the participation agreement and designation as an authorized TRICARE provider;

(*ii*) Conducting such audits of center records including clinical, financial, and census records, as may be necessary to determine the nature of the services being provided, and the basis for charges and claims against the United States for services provided CHAMPUS beneficiaries;

(*iii*) Examining reports of evaluations and inspection conducted by federal, state and local government, and private agencies and organizations;

(*iv*) Conducting on-site inspections of the facilities of the IOP and interviewing employees, members of the staff, contractors, board members, volunteers, and patients, as required.

(*v*) Audits conducted by the United States Government Accountability Office.

(C) *Other requirements applicable to Intensive Outpatient Programs (IOP).* (*1*) Even though an IOP may qualify as a TRICARE authorized provider and may have entered into a participation agreement with CHAMPUS, payment by CHAMPUS for particular services provided is contingent upon the IOP also meeting all conditions set forth in §199.4.

(*2*) The IOP may not discriminate against CHAMPUS beneficiaries in any manner, including admission practices, placement in special or separate wings or rooms, or provisions of special or limited treatment.

(*3*) The IOP shall assure that all certifications and information provided to the Director incident to the process of obtaining and retaining authorized provider status is accurate and that is has no material errors or omissions. In the case of any misrepresentations, whether by inaccurate information being provided or material facts withheld, authorized provider status will be denied or terminated, and the IOP will be ineligible for consideration for authorized provider status for a two year period.

(xix) *Opioid Treatment Programs (OTPs).* This paragraph (b)(4)(xix) establishes standards and requirements for Opioid Treatment Programs.

(A) *Organization and administration.* (*1*) *Definition.* Opioid Treatment Programs (OTPs) are defined in §199.2. Opioid Treatment Programs (OTPs) are organized, ambulatory, addiction treatment services for patients with an opioid use disorder. OTPs have the capacity to provide daily direct administration of medications without the prescribing of medications. Medication supplies for patients to take outside of OTPs originate from within OTPs. OTPs offer medication assisted treatment, patient-centered, recovery-oriented individualized treatment through addiction counseling, mental health therapy, case management, and health education.

(*2*) *Eligibility.* (*i*) Every free-standing Opioid Treatment Program must be accredited by an accrediting organization recognized by Director, under the current standards of an accrediting organization, as well as meet additional elaborative criteria and standards as the Director determines are necessary to implement the basic standards. OTPs adhere to requirements of the Department of Health and Human Services' 42 CFR part 8, the Substance Abuse and Mental Health Services Administration's Center for Substance Abuse Treatment, and the Drug Enforcement Agency. OTPs must be either a distinct part of an otherwise authorized institutional provider or a free-standing program. Approval of hospitals by TRICARE is sufficient for their OTPs to be authorized TRICARE providers. Such hospital-based OTPs, if certified under 42 CFR 8, are not required to be separately authorized by TRICARE.

(*ii*) To qualify as a TRICARE authorized provider, OTPs are required to be licensed and operate in substantial compliance with state and federal regulations.

(*iii*) OTPs have a written participation agreement with OCHAMPUS. OTPs are not considered a TRICARE authorized provider, and CHAMPUS benefits are not paid for services provided until the date upon which a participation agreement is signed by the Director.

(B) Participation agreement requirements. In addition to other requirements set forth in this paragraph (b)(4)(xix), in order for the services of OTPs to be authorized, OTPs shall have entered into a Participation Agreement with TRICARE. A single consolidated participation agreement is acceptable for all units of a TRICARE authorized facility. The period of a Participation Agreement shall be specified in the agreement, and will generally be for not more than five years. In addition to review of a facility's application and supporting documentation, an on-site inspection by DHA authorized personnel may be required prior to signing a participation agreement. The Participation Agreement shall include at least the following requirements:

(*1*) Render services from OTPs to eligible TRICARE beneficiaries in need of such services, in accordance with the participation agreement and TRICARE regulation.

(*2*) Accept payment for its services based upon the methodology provided in §199.14, or such other method as determined by the Director;

(*3*) Collect from the TRICARE beneficiary or the family of the TRICARE beneficiary only those amounts that represent the beneficiary's liability, as defined in §199.4, and charges for services and supplies that are not a benefit of TRICARE;

(*4*) Make all reasonable efforts acceptable to the Director to collect those amounts, which represent the beneficiary's liability, as defined in §199.4;

(*5*) Comply with the provisions of §199.8, and submit claims first to all health insurance coverage to which the beneficiary is entitled that is primary to TRICARE;

(*6*) Submit claims for services provided to TRICARE beneficiaries at least every 30 days (except to the extent a delay is necessitated by efforts to first collect from other health insurance). If claims are not submitted at least every 30 days, OTPs agree not to bill the beneficiary or the beneficiary's family for any amounts disallowed by TRICARE;

(*7*) Free-standing opioid treatment programs shall certify that:

(*i*) It is and will remain in compliance with the provisions of paragraph (b)(4)(xii) of this section establishing standards for opioid treatment programs;

(*ii*) It will maintain compliance with the TRICARE standards for OTPs, as issued by the Director, except for any such standards regarding which the facility notifies the Director, or a designee, that it is not in compliance.

(*8*) Designate an individual who will act as liaison for TRICARE inquiries. OTPs shall inform TRICARE, or a designee, in writing of the designated individual;

(*9*) Furnish TRICARE, or a designee, with cost data, as requested by TRICARE, certified by an independent accounting firm or other agency as authorized by the Director;

(*10*) Comply with all requirements of this section applicable to institutional providers generally concerning accreditation requirements, claims processing, beneficiary liability, double coverage, utilization and quality review, and other matters;

(*11*) Grant the Director, or designee, the right to conduct quality assurance audits or accounting audits with full access to patients and records (including records relating to patients who are not TRICARE beneficiaries) to determine the quality and cost effectiveness of care rendered. The audits may be conducted on a scheduled or unscheduled (unannounced) basis. This right to audit/review includes, but is not limited to:

(*i*) Examination of fiscal and all other records of OTPs which would confirm compliance with the participation agreement and designation as an authorized TRICARE provider;

(*ii*) Conducting such audits of OTPs' records including clinical, financial,

and census records, as may be necessary to determine the nature of the services being provided, and the basis for charges and claims against the United States for services provided TRICARE beneficiaries;

(*iii*) Examining reports of evaluations and inspections conducted by federal, state and local government, and private agencies and organizations.

(C) *Other requirements applicable to OTPs.* (*1*) Even though OTPs may qualify as a TRICARE authorized provider and may have entered into a participation agreement with CHAMPUS, payment by CHAMPUS for particular services provided is contingent upon OTPs also meeting all conditions set forth in §199.4.

(*2*) OTPs may not discriminate against CHAMPUS beneficiaries in any manner, including admission practices or provisions of special or limited treatment.

(*3*) OTPs shall assure that all certifications and information provided to the Director incident to the process of obtaining and retaining authorized provider status is accurate and that is has no material errors or omissions. In the case of any misrepresentations, whether by inaccurate information being provided or material facts withheld, authorized provider status will be denied or terminated, and OTPs will be ineligible for consideration for authorized provider status for a two year period.

(xx) *Inpatient Rehabilitation Facility (IRF).* IRFs must meet all the criteria for classification as an IRF under 42 CFR part 412, subpart B, and meet all applicable requirements established in this part in order to be considered an authorized IRF under the TRICARE program.

(A) In order for the services of inpatient rehabilitation facilities to be covered, the facility must comply with the provisions outlined in paragraph (b)(4)(i) of this section. In addition, in order for services provided by these facilities to be covered by TRICARE, they must be primarily for the treatment of the presenting illness.

(B) Custodial or domiciliary care is not coverable under TRICARE, even if rendered in an otherwise authorized inpatient rehabilitation facility.

(C) The controlling factor in determining whether a beneficiary's stay in an inpatient rehabilitation facility is coverable by TRICARE is the level of professional care, supervision, and skilled nursing care that the beneficiary requires, in addition to the diagnosis, type of condition, or degree of functional limitations. The type and level of medical services required or rendered is controlling for purposes of extending TRICARE benefits; not the type of provider or condition of the beneficiary.

(xxi) *Freestanding End Stage Renal Disease (ESRD) facilities.* Freestanding ESRD facilities must be Medicare certified and meet all Medicare conditions for coverage as provided in 42 CFR part 494, and be classified as freestanding ESRD facilities by Medicare, in order to be approved as TRICARE-authorized institutional providers and receive payment under the TRICARE program. State licensing are not required in cases of a freestanding ESRD facility located in a State that does not license such facilities. Freestanding ESRD facilities are not hospital-affiliated nor hospital-based and are reimbursed based on the payment methodology established in §199.14(c). Freestanding ESRD facilities render outpatient hemodialysis or peritoneal dialysis services in the ESRD facility or in a patient's home for the treatment of ESRD and acute kidney injury (AKI).

(c) *Individual professional providers of care*—(1) *General*—(i) *Purpose.* This individual professional provider class is established to accommodate individuals who are recognized by 10 U.S.C. 1079(a) as authorized to assess or diagnose illness, injury, or bodily malfunction as a prerequisite for CHAMPUS cost-share of otherwise allowable related preventive or treatment services or supplies, and to accommodate such other qualified individuals who the Director, OCHAMPUS, or designee, may authorize to render otherwise allowable services essential to the efficient implementation of a plan-of-care established and managed by a 10 U.S.C. 1079(a) authorized professional.

(ii) *Professional corporation affiliation or association membership permitted.* Paragraph (c) of this section applies to

those individual health care professionals who have formed a professional corporation or association pursuant to applicable state laws. Such a professional corporation or association may file claims on behalf of a CHAMPUS-authorized individual professional provider and be the payee for any payment resulting from such claims when the CHAMPUS-authorized individual certifies to the Director, OCHAMPUS, or designee, in writing that the professional corporation or association is acting on the authorized individual's behalf.

(iii) *Scope of practice limitation.* For CHAMPUS cost-sharing to be authorized, otherwise allowable services provided by a CHAMPUS-authorized individual professional provider shall be within the scope of the individual's license as regulated by the applicable state practice act of the state where the individual rendered the service to the CHAMPUS beneficiary or shall be within the scope of the test which was the basis for the individual's qualifying certification.

(iv) *Employee status exclusion.* An individual employed directly, or indirectly by contract, by an individual or entity to render professional services otherwise allowable by this part is excluded from provider status as established by this paragraph (c) for the duration of each employment.

(v) *Training status exclusion.* Individual health care professionals who are allowed to render health care services only under direct and ongoing supervision as training to be credited towards earning a clinical academic degree or other clinical credential required for the individual to practice independently are excluded from provider status as established by this paragraph (c) for the duration of such training.

(2) *Conditions of authorization*—(i) *Professional license requirement.* The individual must be currently licensed to render professional health care services in each state in which the individual renders services to CHAMPUS beneficiaries. Such license is required when a specific state provides, but does not require, license for a specific category of individual professional provider. The license must be at full clinical practice level to meet this requirement. A temporary license at the full clinical practice level is acceptable. During the period of national emergency for the global coronavirus 2019 (COVID–19) pandemic, a license is not required in the United States for each state in which the provider practices, so long as the provider holds an equivalent license in another state, the state in which the provider is practicing permits such practice under its interstate licensing requirements or the state licensing requirements have been preempted by Federal law, and the provider is not affirmatively barred or restricted from practicing in any state. During the COVID–19 pandemic, providers overseas are not required to be licensed in each nation in which the provider operates, so long as the provider holds an equivalent license in another nation, the host nation permits such practice under its licensing requirements, and the provider is not on the Department of Health and Human Services sanction list.

(ii) *Professional certification requirement.* When a state does not license a specific category of individual professional, certification by a Qualified Accreditation Organization, as defined in §199.2, is required. Certification must be at full clinical practice level. A temporary certification at the full clinical practice level is acceptable.

(iii) *Education, training and experience requirement.* The Director, OCHAMPUS, or designee, may establish for each category or type of provider allowed by this paragraph (c) specific education, training, and experience requirements as necessary to promote the delivery of services by fully qualified individuals.

(iv) *Physician referral and supervision.* When physician referral and supervision is a prerequisite for CHAMPUS cost-sharing of the services of a provider authorized under this paragraph (c), such referral and supervision means that the physicians must actually see the patient to evaluate and diagnose the condition to be treated prior to referring the beneficiary to another provider and that the referring physician provides ongoing oversight of the course of referral related treatment throughout the period during which

the beneficiary is being treated in response to the referral. Written contemporaneous documentation of the referring physician's basis for referral and ongoing communication between the referring and treating provider regarding the oversight of the treatment rendered as a result of the referral must meet all requirements for medical records established by this part. Referring physician supervision does not require physical location on the premises of the treating provider or at the site of treatment.

(v) Subject to section 1079(a) of title 10, U.S.C., chapter 55, a physician or other health care practitioner who is eligible to receive reimbursement for services provided under Medicare (as defined in section 1086(d)(3)(C) of title 10 U.S.C., chapter 55) shall be considered approved to provide medical care authorized under section 1079 and section 1086 of title 10, U.S.C., chapter 55 unless the administering Secretaries have information indicating Medicare, TRICARE, or other Federal health care program integrity violations by the physician or other health care practitioner. Approval is limited to those classes of provider currently considered TRICARE authorized providers as outlined in 32 CFR 199.6. Services and supplies rendered by those providers who are not currently considered authorized providers shall be denied.

(3) *Types of providers.* Subject to the standards of participation provisions of this part, the following individual professional providers of medical care are authorized to provide services to CHAMPUS beneficiaries:

(i) *Physicians.* (A) Doctors of Medicine (M.D.).

(B) Doctors of Osteopathy (D.O.).

(ii) *Dentists.* Except for covered oral surgery as specified in §199.4(e) of this part, all otherwise covered services rendered by dentists require preauthorization.

(A) Doctors of Dental Medicine (D.M.D.).

(B) Doctors of Dental Surgery (D.D.S.).

(iii) *Other allied health professionals.* The services of the following individual professional providers of care are coverable on a fee-for-service basis provided such services are otherwise authorized in this or other sections of this part.

(A) *Clinical psychologist.* For purposes of CHAMPUS, a clinical psychologist is an individual who is licensed or certified by the state for the independent practice of psychology and:

(*1*) Possesses a doctoral degree in psychology from a regionally accredited university; and

(*2*) Has had 2 years of supervised clinical experience in psychological health services of which at least 1 year is post-doctoral and 1 year (may be the post-doctoral year) is in an organized psychological health service training program; or

(*3*) As an alternative to paragraphs (c)(3)(iii)(A)(*1*) and (*2*) of this section is listed in the National Register of Health Service Providers in Psychology.

(B) *Doctors of Optometry.*

(C) *Doctors of Podiatric Medicine or Podiatrists.*

(D) *Certified nurse midwives.*

(*1*) A certified nurse midwife may provide covered care independent of physician referral and supervision, provided the nurse midwife is:

(*i*) Licensed, when required, by the local licensing agency for the jurisdiction in which the care is provided; and

(*ii*) Certified by the American College of Nurse Midwives. To receive certification, a candidate must be a registered nurse who has completed successfully an educational program approved by the American College of Nurse Midwives, and passed the American College of Nurse Midwives National Certification Examination.

(*2*) The services of a registered nurse who is not a certified nurse midwife may be authorized only when the patient has been referred for care by a licensed physician and a licensed physician provides continuing supervision of the course of care. A lay midwife who is neither a certified nurse midwife nor a registered nurse is not a CHAMPUS-authorized provider, regardless of whether the services rendered may otherwise be covered.

(E) *Certified nurse practitioner.* Within the scope of applicable licensure or certification requirements, a certified nurse practitioner may provide covered care independent of physician referral

and supervision, provided the nurse practitioner is:

(*1*) A licensed, registered nurse; and

(*2*) Specifically licensed or certified as a nurse practitioner by the state in which the care was provided, if the state offers such specific licensure or certification; or

(*3*) Certified as a nurse practitioner (certified nurse) by a professional organization offering certification in the specialty of practice, if the state does not offer specific licensure or certification for nurse practitioners.

(F) *Certified Clinical Social Worker*. A clinical social worker may provide covered services independent of physician referral and supervision, provided the clinical social worker:

(*1*) Is licensed or certified as a clinical social worker by the jurisdiction where practicing; or, if the jurisdiction does not provide for licensure or certification of clinical social workers, is certified by a national professional organization offering certification of clinical social workers; and

(*2*) Has at least a master's degree in social work from a graduate school of social work accredited by the Council on Social Work Education; and

(*3*) Has had a minimum of 2 years or 3,000 hours of post-master's degree supervised clinical social work practice under the supervision of a master's level social worker in an appropriate clinical setting, as determined by the Director, OCHAMPUS, or a designee.

NOTE: Patients' organic medical problems must receive appropriate concurrent management by a physician.

(G) *Certified psychiatric nurse specialist*. A certified psychiatric nurse specialist may provide covered care independent of physician referral and supervision. For purposes of CHAMPUS, a certified psychiatric nurse specialist is an individual who:

(*1*) Is a licensed, registered nurse; and

(*2*) Has at least a master's degree in nursing from a regionally accredited institution with a specialization in psychiatric and mental health nursing; and

(*3*) Has had at least 2 years of post-master's degree practice in the field of psychiatric and mental health nursing, including an average of 8 hours of direct patient contact per week; or

(*4*) Is listed in a CHAMPUS-recognized, professionally sanctioned listing of clinical specialists in psychiatric and mental health nursing.

(H) *Certified physician assistant*. A physician assistant may provide care under general supervision of a physician (see §199.14(j)(1)(ix) of this part for limitations on reimbursement). For purposes of CHAMPUS, a physician assistant must meet the applicable state requirements governing the qualifications of physician assistants and at least one of the following conditions:

(*1*) Is currently certified by the National Commission on Certification of Physician Assistants to assist primary care physicians, or

(*2*) Has satisfactorily completed a program for preparing physician assistants that:

(*i*) Was at least 1 academic year in length;

(*ii*) Consisted of supervised clinical practice and at least 4 months (in the aggregate) of classroom instruction directed toward preparing students to deliver health care; and

(*iii*) Was accredited by the American Medical Association's Committee on Allied Health Education and Accreditation; or

(*3*) Has satisfactorily completed a formal educational program for preparing program physician assistants that does not meet the requirement of paragraph (c)(3)(iii)(H)(*2*) of this section and had been assisting primary care physicians for a minimum of 12 months during the 18-month period immediately preceding January 1, 1987.

(I) *Anesthesiologist Assistant*. An anesthesiologist assistant may provide covered anesthesia services, if the anesthesiologist assistant:

(*1*) Works under the direct supervision of an anesthesiologist who bills for the services and for each patient;

(*i*) The anesthesiologist performs a pre-anesthetic examination and evaluation;

(*ii*) The anesthesiologist prescribes the anesthesia plan;

(*iii*) The anesthesiologist personally participates in the most demanding aspects of the anesthesia plan including, if applicable, induction and emergence;

(*iv*) The anesthesiologist ensures that any procedures in the anesthesia plan

that he or she does not perform are performed by a qualified anesthesiologist assistant;

(*v*) The anesthesiologist monitors the course of anesthesia administration at frequent intervals;

(*vi*) The anesthesiologist remains physically present and available for immediate personal diagnosis and treatment of emergencies;

(*vii*) The anesthesiologist provides indicated post-anesthesia care; and

(*viii*) The anesthesiologist performs no other services while he or she supervises no more than four anesthesiologist assistants concurrently or a lesser number if so limited by the state in which the procedure is performed.

(*2*) Is in compliance with all applicable requirements of state law, including any licensure requirements the state imposes on nonphysician anesthetists; and

(*3*) Is a graduate of a Master's level anesthesiologist assistant educational program that is established under the auspices of an accredited medical school and that:

(*i*) Is accredited by the Committee on Allied Health Education and Accreditation, or its successor organization; and

(*ii*) Includes approximately two years of specialized basic science and clinical education in anesthesia at a level that builds on a premedical undergraduate science background.

(*4*) The Director, TMA, or a designee, shall issue TRICARE policies, instructions, procedures, guidelines, standards, and criteria as may be necessary to implement the intent of this section.

(J) *Certified Registered Nurse Anesthetist (CRNA).* A certified registered nurse anesthetist may provide covered care independent of physician referral and supervision as specified by state licensure. For purposes of CHAMPUS, a certified registered nurse anesthetist is an individual who:

(*1*) Is a licensed, registered nurse; and

(*2*) Is certified by the Council on Certification of Nurse Anesthetists, or its successor organization.

(K) *Other individual paramedical providers.* (*1*) The services of the following individual professional providers of care to be considered for benefits on a fee-for-service basis may be provided only if the beneficiary is referred by a physician for the treatment of a medically diagnosed condition and a physician must also provide continuing and ongoing oversight and supervision of the program or episode of treatment provided by these individual paramedical providers.

(*i*) Licensed registered nurses.

(*ii*) Audiologists.

(*2*) The services of the following individual paramedical providers of care to be considered for benefits on a fee-for-service basis may be provided only if: The beneficiary is referred by a physician, certified physician assistant, certified nurse practitioner, or podiatrist; and a physician, certified physician assistant, certified nurse practitioner, or podiatrist must also provide continuing and ongoing oversight and supervision of the program or episode of treatment provided by these individual paramedical providers.

(*i*) Licensed registered physical therapist (PT), including a licensed or certified physical therapist assistant (PTA) performing under the supervision of a TRICARE-authorized PT. PTAs shall meet the qualifications specified by Medicare (42 CFR 484.115, or successor regulation) and the Director, DHA, shall issue policy adopting, to the extent practicable, Medicare's requirements for PTA supervision.

(*ii*) Licensed registered occupational therapist (OT), including a licensed or certified occupational therapy assistant (OTA) performing under the supervision of a TRICARE authorized OT. OTAs shall meet the qualifications specified by Medicare (42 CFR 484.115, or successor regulation) and the Director, DHA, shall issue policy adopting, to the extent practicable, Medicare's requirements for OTA supervision.

(*3*) Licensed registered speech therapists (speech pathologists). In order to be considered for benefits on a fee-for-service basis, the services of a licensed registered speech therapist as an individual paramedical provider of care may be provided only if: (1) The beneficiary is referred by a physician, a certified physician assistant, or a certified nurse practitioner; and (2) a physician, a certified physician assistant, or a certified nurse practitioner must also

provide continuing and ongoing oversight and supervision of the program or episode of treatment provided by these individual paramedical providers.

(L) *Nutritionist.* The nutritionist must be licensed by the State in which the care is provided and must be under the supervision of a physician who is overseeing the episode of treatment or the covered program of services.

(M) *Registered dietician.* The dietician must be licensed by the State in which the care is provided and must be under the supervision of a physician who is overseeing the episode of treatment or the covered program of services.

(N) *TRICARE certified mental health counselor.* For the purposes of CHAMPUS, a TRICARE certified mental health counselor (TCMHC) must be licensed for independent practice in mental health counseling by the jurisdiction where practicing. In jurisdictions with two or more licenses allowing for differing scopes of independent practice, the licensed mental health counselor may only practice within the scope of the license he or she possesses. In addition, a TCMHC must meet the requirements of either paragraph (c)(3)(iii)(N)(*1*) or the requirements of paragraph (c)(3)(iii)(N)(*2*) of this section.

(*1*) The requirements of this paragraph are that the TCMHC:

(*i*) Must have passed the National Clinical Mental Health Counselor Examination (NCMHCE) or its successor as determined by the Director, TMA; and

(*ii*) Must possess a master's or higher-level degree from a mental health counseling program of education and training accredited by the Council for Accreditation of Counseling and Related Educational Programs (CACREP); and

(*iii*) Must have a minimum of two (2) years of post-master's degree supervised mental health counseling practice which includes a minimum of 3,000 hours of supervised clinical practice and 100 hours of face-to-face supervision. Supervision must be provided by mental health counselors at the highest level of state licensure, psychiatrists, clinical psychologists, certified clinical social workers, or certified psychiatric nurse specialists who are licensed for independent practice in the jurisdiction where practicing and who are practicing within the scope of their licenses. Supervised clinical practice must be received in a manner that is consistent with the guidelines regarding knowledge, skills, and practice standards for supervision of the American Mental Health Counselors Association; and

(*iv*) Is licensed or certified for independent practice in mental health counseling by the jurisdiction where practicing (see paragraph (c)(2)(ii) of this section for more specific information).

(*2*) The requirements of this paragraph are that the TCMHC, prior to January 1, 2017:

(*i*) Possess a master's or higher-level degree from a mental health counseling program of education and training accredited by CACREP and must have passed the National Counselor Examination (NCE); or

(*ii*) Possess a master's or higher-level degree from a mental health counseling program of education and training from either a CACREP or regionally accredited institution and have passed the NCMHCE; and

(*iii*) Must have a minimum of two (2) years of post-master's degree supervised mental health counseling practice which includes a minimum of 3,000 hours of supervised clinical practice and 100 hours of face-to-face supervision. Supervision must be provided by mental health counselors at the highest level of state licensure, psychiatrists, clinical psychologists, certified clinical social workers, or certified psychiatric nurse specialists who are licensed for independent practice in the jurisdiction where practicing and who are practicing within the scope of their licenses. Supervised clinical practice must be received in a manner that is consistent with the guidelines regarding knowledge, skills, and practice standards for supervision of the American Mental Health Counselors Association; and

(*iv*) Is licensed or certified for independent practice in mental health counseling by the jurisdiction where practicing (see paragraph (c)(2)(ii) of this section for more specific information).

(*3*) The Director, TRICARE Management Activity may amend or modify existing or specify additional certification requirements as needed to accommodate future practice and licensing standards and to ensure that all TCMHCs continue to meet educational, licensing, and clinical training requirements considered appropriate.

(iv) *Extramedical individual providers.* Extramedical individual providers are those who do counseling or nonmedical therapy and whose training and therapeutic concepts are outside the medical field. The services of extramedical individual professionals are coverable following the CHAMPUS determined allowable charge methodology provided such services are otherwise authorized in this or other sections of the regulation.

(A) *Certified marriage and family therapists.* For the purposes of CHAMPUS, a certified marriage and family therapist is an individual who meets the following requirements:

(*1*) Recognized graduate professional education with the minimum of an earned master's degree from a regionally accredited educational institution in an appropriate behavioral science field, mental health discipline; and

(*2*) The following experience:

(*i*) Either 200 hours of approved supervision in the practice of marriage and family counseling, ordinarily to be completed in a 2- to 3-year period, of which at least 100 hours must be in individual supervision. This supervision will occur preferably with more than one supervisor and should include a continuous process of supervision with at least three cases; and

(*ii*) 1,000 hours of clinical experience in the practice of marriage and family counseling under approved supervision, involving at least 50 different cases; or

(*iii*) 150 hours of approved supervision in the practice of psychotherapy, ordinarily to be completed in a 2- to 3-year period, of which at least 50 hours must be individual supervision; plus at least 50 hours of approved individual supervision in the practice of marriage and family counseling, ordinarily to be completed within a period of not less than 1 nor more than 2 years; and

(*iv*) 750 hours of clinical experience in the practice of psychotherapy under approved supervision involving at least 30 cases; plus at least 250 hours of clinical practice in marriage and family counseling under approved supervision, involving at least 20 cases; and

(*3*) Is licensed or certified to practice as a marriage and family therapist by the jurisdiction where practicing (see paragraph (c)(3)(iv)(D) of this section for more specific information regarding licensure); and

(*4*) Agrees that a patients' organic medical problems must receive appropriate concurrent management by a physician.

(*5*) Agrees to accept the CHAMPUS determined allowable charge as payment in full, except for applicable deductibles and cost-shares, and hold CHAMPUS beneficiaries harmless for noncovered care (i.e., may not bill a beneficiary for noncovered care, and may not balance bill a beneficiary for amounts above the allowable charge). The certified marriage and family therapist must enter into a participation agreement with the Office of CHAMPUS within which the certified marriage and family therapist agrees to all provisions specified above.

(*6*) As of the effective date of termination, the certified marriage and family therapist will no longer be recognized as an authorized provider under CHAMPUS. Subsequent to termination, the certified marriage and family therapist may only be reinstated as an authorized CHAMPUS extramedical provider by entering into a new participation agreement as a certified marriage and family therapist.

(B) *Pastoral counselors.* For the purposes of CHAMPUS, a pastoral counselor is an individual who meets the following requirements:

(*1*) Recognized graduate professional education with the minimum of an earned master's degree from a regionally accredited educational institution in an appropriate behavioral science field, mental health discipline; and

(*2*) The following experience:

(*i*) Either 200 hours of approved supervision in the practice of pastoral counseling, ordinarily to be completed in a 2- to 3-year period, of which at least 100 hours must be in individual supervision. This supervision will occur preferably with more than one supervisor

and should include a continuous process of supervision with at least three cases; and

(*ii*) 1,000 hours of clinical experience in the practice of pastoral counseling under approved supervision, involving at least 50 different cases; or

(*iii*) 150 hours of approved supervision in the practice of psychotherapy, ordinarily to be completed in a 2- to 3-year period, of which at least 50 hours must be individual supervision; plus at least 50 hours of approved individual supervision in the practice of pastoral counseling, ordinarily to be completed within a period of not less than 1 nor more than 2 years; and

(*iv*) 750 hours of clinical experience in the practice of psychotherapy under approved supervision involving at least 30 cases; plus at least 250 hours of clinical practice in pastoral counseling under approved supervision, involving at least 20 cases; and

(*3*) Is licensed or certified to practice as a pastoral counselor by the jurisdiction where practicing (see paragraph (c)(3)(iv)(D) of this section for more specific information regarding licensure); and

(*4*) The services of a pastoral counselor meeting the above requirements are coverable following the CHAMPUS determined allowable charge methodology, under the following specified conditions:

(*i*) The CHAMPUS beneficiary must be referred for therapy by a physician; and

(*ii*) A physician is providing ongoing oversight and supervision of the therapy being provided; and

(*iii*) The pastoral counselor must certify on each claim for reimbursement that a written communication has been made or will be made to the referring physician of the results of the treatment. Such communication will be made at the end of the treatment, or more frequently, as required by the referring physician (refer to §199.7).

(*5*) Because of the similarity of the requirements for licensure, certification, experience, and education, a pastoral counselor may elect to be authorized under CHAMPUS as a certified marriage and family therapist, and as such, be subject to all previously defined criteria for the certified marriage and family therapist category, to include acceptance of the CHAMPUS determined allowable charge as payment in full, except for applicable deductibles and cost-shares (i.e., balance billing of a beneficiary above the allowable charge is prohibited; may not bill beneficiary for noncovered care). The pastoral counselor must also agree to enter into the same participation agreement as a certified marriage and family therapist with the Office of CHAMPUS within which the pastoral counselor agrees to all provisions including licensure, national association membership and conditions upon termination, outlined above for certified marriage and family therapist.

NOTE: No dual status will be recognized by the Office of CHAMPUS. Pastoral counselors must elect to become one of the categories of extramedical CHAMPUS provides specified above. Once authorized as either a pastoral counselor, or a certified marriage and family therapist, claims review and reimbursement will be in accordance with the criteria established for the elected provider category.

(C) *Supervised mental health counselor.* For the purposes of TRICARE, a supervised mental health counselor is an individual who does not meet the requirements of a TRICARE certified mental health counselor in paragraph (c)(3)(iii)(N) of this section, but meets all of the following requirements and conditions of practice:

(*1*) Minimum of a master's degree in mental health counseling or allied mental health field from a regionally accredited institution; and

(*2*) Two years of post-masters experience which includes 3,000 hours of clinical work and 100 hours of face-to-face supervision; and

(*3*) Is licensed or certified to practice as a mental health counselor by the jurisdiction where practicing (see paragraph (c)(3)(iv)(D) of this section for more specific information); and

(*4*) May only be reimbursed when:

(*i*) The TRICARE beneficiary is referred for therapy by a physician; and

(*ii*) A physician is providing ongoing oversight and supervision of the therapy being provided; and

(*iii*) The mental health counselor certifies on each claim for reimbursement that a written communication has been made or will be made to the referring

physician of the results of the treatment. Such communication will be made at the end of the treatment, or more frequently, as required by the referring physician (refer to §199.7).

(D) The following additional information applies to each of the above categories of extramedical individual providers:

(*1*) These providers must also be licensed or certified to practice as a certified marriage and family therapist, pastoral counselor or mental health counselor by the jurisdiction where practicing. In jurisdictions that do not provide for licensure or certification, the provider must be certified by or eligible for full clinical membership in the appropriate national professional association that sets standards for the specific profession.

(*2*) Grace period for therapists or counselors in states where licensure/certification is optional. CHAMPUS is providing a grace period for those therapists or counselors who did not obtain optional licensure/certification in their jurisdiction, not realizing it was a CHAMPUS requirement for authorization. The exemption by state law for pastoral counselors may have misled this group into thinking licensure was not required. The same situation may have occurred with the other therapist or counselor categories where licensure was either not mandated by the state or was provided under a more general category such as ''professional counselors.'' This grace period pertains only to the licensure/certification requirement, applies only to therapists or counselors who are already approved as of October 29, 1990, and only in those areas where the licensure/certification is optional. Any therapist or counselor who is not licensed/certified in the state in which he/she is practicing by August 1, 1991, will be terminated under the provisions of §199.9. This grace period does not change any of the other existing requirements which remain in effect. During this grace period, membership or proof of eligibility for full clinical membership in a recognized professional association is required for those therapists or counselors who are not licensed or certified by the state. The following organizations are recognized for therapists or counselors at the level indicated: Full clinical member of the American Association of Marriage and Family Therapy; membership at the fellow or diplomate level of the American Association of Pastoral Counselors; and membership in the National Academy of Certified Clinical Mental Health Counselors. Acceptable proof of eligibility for membership is a letter from the appropriate certifying organization. This opportunity for delayed certification/licensure is limited to the counselor or therapist category only as the language in all of the other provider categories has been consistent and unmodified from the time each of the other provider categories were added. The grace period does not apply in those states where licensure is mandatory.

(E) *Christian Science practitioners and Christian Science nurses.* CHAMPUS cost-shares the services of Christian Science practitioners and nurses. In order to bill as such, practitioners or nurses must be listed or be eligible for listing in the Christian Science Journal[1] at the time the service is provided.

(d) *Other providers.* Certain medical supplies and services of an ancillary or supplemental nature are coverable by CHAMPUS, subject to certain controls. This category of provider includes the following:

(1) *Independent laboratory.* Laboratory services of independent laboratories may be cost-shared if the laboratory is approved for participation under Medicare and certified by the Medicare Bureau, Health Care Financing Administration.

(2) *Suppliers of portable x-ray services.* Such suppliers must meet the conditions of coverage of the Medicare program, set forth in the Medicare regulations, or the Medicaid program in that state in which the covered service is provided.

(3) *Pharmacies.* Pharmacies must meet the applicable requirements of state law in the state in which the

[1] Copies of this journal can be obtained through the Christian Science Publishing Company, 1 Norway Street, Boston, MA 02115–3122 or the Christian Science Publishing Society, P.O. Box 11369, Des Moines, IA 50340.

pharmacy is located. In addition to being subject to the policies and procedures for authorized providers established by this section, additional policies and procedures may be established for authorized pharmacies under § 199.21 of this part implementing the Pharmacy Benefits Program.

(4) *Ambulance companies.* Such companies must meet the requirements of state and local laws in the jurisdiction in which the ambulance firm is licensed.

(5) *Medical equipment firms, medical supply firms, and Durable Medical Equipment, Prosthetic, Orthotic, Supplies providers/suppliers.* Any firm, supplier, or provider that is an authorized provider under Medicare or is otherwise designated an authorized provider by the Director, TRICARE Management Activity.

(6) *Mammography suppliers.* Mammography services may be cost-shared only if the supplier is certified by Medicare for participation as a mammography supplier, or is certified by the American College of Radiology as having met its mammography supplier standards.

(e) *Extended Care Health Option Providers*—(1) *General.* (i) Services and items cost-shared through § 199.5 must be rendered by a CHAMPUS-authorized provider.

(ii) A Program for Persons with Disabilities (PFPWD) provider with TRICARE-authorized status on the effective date for the Extended Care Health Option (ECHO) Program shall be deemed to be a TRICARE-authorized provider until the expiration of all outstanding PFPWD benefit authorizations for services or items being rendered by the provider.

(2) *ECHO provider categories*—(i) *ECHO inpatient care provider.* A provider of residential institutional care, which is otherwise an ECHO benefit, shall be:

(A) A not-for-profit entity or a public facility; and

(B) Located within a state; and

(C) Be certified as eligible for Medicaid payment in accordance with a state plan for medical assistance under Title XIX of the Social Security Act (Medicaid) as a Medicaid Nursing Facility, or Intermediate Care Facility for the Mentally Retarded, or be a TRICARE-authorized institutional provider as defined in paragraph (b) of this section, or be approved by a state educational agency as a training institution.

(ii) *ECHO outpatient care provider.* A provider of ECHO outpatient, ambulatory, or in-home services shall be:

(A) A TRICARE-authorized provider of services as defined in this section; or

(B) An individual, corporation, foundation, or public entity that predominantly renders services of a type uniquely allowable as an ECHO benefit and not otherwise allowable as a benefit of § 199.4, that meets all applicable licensing or other regulatory requirements of the state, county, municipality, or other political jurisdiction in which the ECHO service is rendered, or in the absence of such licensing or regulatory requirements, as determined by the Director, TRICARE Management Activity or designee.

(iii) *ECHO vendor.* A provider of an allowable ECHO item, such as supplies or equipment, shall be deemed to be a TRICARE-authorized vendor for the provision of the specific item, supply or equipment when the vendor supplies such information as the Director, TRICARE Management Activity or designee determines necessary to adjudicate a specific claim.

(3) *ECHO provider exclusion or suspension.* A provider of ECHO services or items may be excluded or suspended for a pattern of discrimination on the basis of disability. Such exclusion or suspension shall be accomplished according to the provisions of § 199.9.

(f) *Corporate services providers*—(1) *General.* (i) This corporate services provider class is established to accommodate individuals who would meet the criteria for status as a CHAMPUS authorized individual professional provider as established by paragraph (c) of this section but for the fact that they are employed directly or contractually by a corporation or foundation that provides principally professional services which are within the scope of the CHAMPUS benefit. With authorization of freestanding end stage renal disease (ESRD) facilities as TRICARE institutional providers under paragraph (b)(4)(xxi) of this section, corporate

service provider status will not be authorized for the provision of ESRD services.

(ii) Payment for otherwise allowable services may be made to a CHAMPUS-authorized corporate services provider subject to the applicable requirements, exclusions and limitations of this part.

(iii) The Director, OCHAMPUS, or designee, may create discrete types within any allowable category of provider established by this paragraph (f) to improve the efficiency of CHAMPUS management.

(iv) The Director, OCHAMPUS, or designee, may require, as a condition of authorization, that a specific category or type of provider established by this paragraph (f):

(A) Maintain certain accreditation in addition to or in lieu of the requirement of paragraph (f)(2)(v) of this section;

(B) Cooperate fully with a designated utilization and clinical quality management organization which has a contract with the Department of Defense for the geographic area in which the provider does business;

(C) Render services for which direct or indirect payment is expected to be made by CHAMPUS only after obtaining CHAMPUS written authorization; and

(D) Maintain Medicare approval for payment when the Director, OCHAMPUS, or designee, determines that a category, or type, of provider established by this paragraph (f) is substantially comparable to a provider or supplier for which Medicare has regulatory conditions of participation or conditions of coverage.

(v) Otherwise allowable services may be rendered at the authorized corporate services provider's place of business, or in the beneficiary's home under such circumstances as the Director, OCHAMPUS, or designee, determines to be necessary for the efficient delivery of such in-home services.

(vi) The Director, OCHAMPUS, or designee, may limit the term of a participation agreement for any category or type of provider established by this paragraph (f).

(vii) Corporate services providers shall be assigned to only one of the following allowable categories based upon the predominate type of procedure rendered by the organization;

(A) Medical treatment procedures;

(B) Surgical treatment procedures;

(C) Maternity management procedures;

(D) Rehabilitation and/or habilitation procedures; or

(E) Diagnostic technical procedures.

(viii) The Director, OCHAMPUS, or designee, shall determine the appropriate procedural category of a qualified organization and may change the category based upon the provider's CHAMPUS claim characteristics. The category determination of the Director, OCHAMPUS, designee, is conclusive and may not be appealed.

(2) *Conditions of authorization.* An applicant must meet the following conditions to be eligible for authorization as a CHAMPUS corporate services provider:

(i) Be a corporation or a foundation, but not a professional corporation or professional association; and

(ii) Be institution-affiliated or free-standing as defined in §199.2; and

(iii) Provide:

(A) Services and related supplies of a type rendered by CHAMPUS individual professional providers or diagnostic technical services and related supplies of a type which requires direct patient contact and a technologist who is licensed by the state in which the procedure is rendered or who is certified by a Qualified Accreditation Organization as defined in §199.2; and

(B) A level of care which does not necessitate that the beneficiary be provided with on-site sleeping accommodations and food in conjunction with the delivery of services; and

(iv) Complies with all applicable organizational and individual licensing or certification requirements that are extant in the state, county, municipality, or other political jurisdiction in which the provider renders services; and

(v) Be approved for Medicare payment when determined to be substantially comparable under the provisions of paragraph (f)(1)(iv)(D) of this section or, when Medicare approved status is not required, be accredited by a qualified accreditation organization, as defined in §199.2; and

(vi) Has entered into a participation agreement approved by the Director, OCHAMPUS, or designee, which at least complies with the minimum participation agreement requirements of this section.

(3) *Transfer of participation agreement.* In order to provide continuity of care for beneficiaries when there is a change of provider ownership, the provider agreement is automatically assigned to the new owner, subject to all the terms and conditions under which the original agreement was made.

(i) The merger of the provider corporation or foundation into another corporation or foundation, or the consolidation of two or more corporations or foundations resulting in the creation of a new corporation or foundation, constitutes a change of ownership.

(ii) Transfer of corporate stock or the merger of another corporation or foundation into the provider corporation or foundation does not constitute change of ownership.

(iii) The surviving corporation or foundation shall notify the Director, OCHAMPUS, or designee, in writing of the change of ownership promptly after the effective date of the transfer or change in ownership.

(4) *Pricing and payment methodology:* The pricing and payment of procedures rendered by a provider authorized under this paragraph (f) shall be limited to those methods for pricing and payment allowed by this part which the Director, OCHAMPUS, or designee, determines contribute to the efficient management of CHAMPUS.

(5) *Termination of participation agreement.* A provider may terminate a participation agreement upon 45 days written notice to the Director, OCHAMPUS, or designee, and to the public.

[51 FR 24008, July 1, 1986]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §199.6, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

EFFECTIVE DATE NOTE: At 88 FR 19855, Apr. 4, 2023, §199.6 was amended by revising paragraph (b)(4)(x)(B)(*1*), effective Oct. 1, 2023. For the convenience of the user, the added and revised text is set forth as follows:

§ 199.6 TRICARE-authorized providers.

* * * * *

(b) * * *

(4) * * *

(x) * * *

(B) * * *

(*1*) *Ambulatory surgical centers (ASC).* ASCs must meet all criteria for classification as an Ambulatory Surgical Center under 42 CFR part 416, as well as all of the requirements of this part, in order to be considered an authorized ASC under the TRICARE program. Care provided by an authorized TRICARE ASC may be cost-shared under the following circumstances:

(*i*) A childbirth procedure provided by a CHAMPUS-approved ASC shall not be cost-shared by CHAMPUS unless the surgical center is also a CHAMPUS-approved birthing center institutional provider as established by the birthing center provider certification requirement of this part, and then reimbursement of covered maternity care and childbirth services shall be subject to §199.14(e).

(*ii*) ASCs must demonstrate they have a valid participation agreement with Medicare, except as provided under paragraph (b)(4)(x)(B)(*1*)(*i*) of this section. In addition, in order to be considered an authorized TRICARE provider, ASCs must accept the requirements for a participating provider under paragraph (a)(13) of this section and must also enter into a participation agreement with TRICARE which includes a specific ''hold harmless'' provision under which the facility will agree not to bill the patient for services not on the Medicare ASC procedures list unless, the patient is advised in writing that the non-listed procedure is not covered by TRICARE and the patient agrees, in advance in writing, to be financially liable for the non-covered procedure.

(*iii*) ASCs that do not have an agreement with Medicare due to the nature of the patients they treat (*e.g.*, pediatric patients) shall be accredited by the Joint Commission, the Accreditation Association for Ambulatory Health Care, Inc. (AAAHC), or such other accreditation as authorized by the Director, DHA and published in the implementing instructions. Additionally, these facilities must enter into participation agreements with TRICARE, including the hold harmless provisions under paragraph (b)(4)(x)(B)(*1*)(*ii*) of this section, and accept the requirements for a participating provider under paragraph (a)(13) of this section in order to be an authorized TRICARE provider.

* * * * *

§ 199.7 Claims submission, review, and payment.

(a) *General.* The Director, OCHAMPUS, or a designee, is responsible for ensuring that benefits under CHAMPUS are paid only to the extent described in this part. Before benefits can be paid, an appropriate claim must be submitted that includes sufficient information as to beneficiary identification, the medical services and supplies provided, and double coverage information, to permit proper, accurate, and timely adjudication of the claim by the CHAMPUS contractor or OCHAMPUS. Providers must be able to document that the care or service shown on the claim was rendered. This section sets forth minimum medical record requirements for verification of services. Subject to such definitions, conditions, limitations, exclusions, and requirements as may be set forth in this part, the following are the CHAMPUS claim filing requirements:

(1) *CHAMPUS identification card required.* A patient shall present his or her applicable CHAMPUS identification card (that is, Uniformed Services identification card) to the authorized provider of care that identifies the patient as an eligible CHAMPUS beneficiary (refer to § 199.3 of this part).

(2) *Claim required.* No benefit may be extended under the Basic Program or Extended Care Health Option (ECHO) without submission of an appropriate, complete and properly executed claim form.

(3) *Responsibility for perfecting claim.* It is the responsibility of the CHAMPUS beneficiary or sponsor or the authorized provider acting on behalf of the CHAMPUS beneficiary to perfect a claim for submission to the appropriate CHAMPUS fiscal intermediary. Neither a CHAMPUS fiscal intermediary nor OCHAMPUS is authorized to prepare a claim on behalf of a CHAMPUS beneficiary.

(4) *Obtaining appropriate claim form.* CHAMPUS provides specific CHAMPUS forms appropriate for making a claim for benefits for various types of medical services and supplies (such as hospital, physician, or prescription drugs). Claim forms may be obtained from the appropriate CHAMPUS fiscal intermediary who processes claims for the beneficiary's state of residence, from the Director, OCHAMPUS, or a designee, or from CHAMPUS health benefits advisors (HBAs) located at all Uniformed Services medical facilities.

(5) *Prepayment not required.* A CHAMPUS beneficiary or sponsor is not required to pay for the medical services or supplies before submitting a claim for benefits.

(6) *Deductible certificate.* If the calendar year outpatient deductible, as defined in § 199.4(f)(2) has been met by a beneficiary or a family through the submission of a claim or claims to a CHAMPUS fiscal intermediary in a geographic location different 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 individual or family calendar 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 individual or family calendar year deductible being applied. However, this second deductible may be reimbursed once appropriate documentation, as described in this paragraph is supplied to the CHAMPUS fiscal intermediary applying the second deductible (refer to § 199.4 (f)(2)(i)(F)).

(7) *Nonavailability Statement (DD Form 1251).* In some geographic locations or under certain circumstances, it is necessary for a CHAMPUS beneficiary to determine whether the required medical care can be provided through a Uniformed Services facility. If the required medical care cannot be provided by the Uniformed Services facility, a Nonavailability Statement will be issued. When required (except for emergencies), this Nonavailability Statement must be issued before medical care is obtained from civilian sources. Failure to secure such a statement will waive the beneficiary's rights to benefits under CHAMPUS, subject to appeal to the appropriate hospital commander (or higher medical authority).

(i) *Rules applicable to issuance of Nonavailability Statement.* Appropriate policy guidance may be issued as necessary to prescribe the conditions for

issuance and use of a Nonavailability Statement.

(ii) *Beneficiary responsibility*. The beneficiary shall ascertain whether or not he or she resides in a geographic area that requires obtaining a Nonavailability Statement. Information concerning current rules may be obtained from the CHAMPUS fiscal intermediary concerned, a CHAMPUS HBA or the Director, OCHAMPUS, or a designee.

(iii) *Rules in effect at time civilian care is provided apply*. The applicable rules regarding Nonavailability Statements in effect at the time the civilian care is rendered apply in determining whether a Nonavailability Statement is required.

(iv) *Nonavailability Statement must be filed with applicable claim*. When a claim is submitted for CHAMPUS benefits that includes services for which a Nonavailability Statement is required, such statement must be submitted along with the claim form.

(b) *Information required to adjudicate a CHAMPUS claim*. Claims received that are not completed fully and that do not provide the following minimum information may be returned. If enough space is not available on the appropriate claim form, the required information must be attached separately and include the patient's name and address, be dated, and signed.

(1) *Patient's identification information*. The following patient identification information must be completed on every CHAMPUS claim form submitted for benefits before a claim will be adjudicated and processed:

(i) *Patient's full name*.

(ii) *Patient's residence address*.

(iii) *Patient's date of birth*.

(iv) *Patient's relationship to sponsor*.

NOTE: If name of patient is different from sponsor, explain (for example, stepchild or illegitimate child).

(v) *Patient's identification number (from DD Form 1173)*.

(vi) *Patient's identification card effective date and expiration date (from DD Form 1173)*.

(vii) *Sponsor's full name*.

(viii) *Sponsor's service or social security number*.

(ix) *Sponsor's grade*.

(x) *Sponsor's organization and duty station*. Home port for ships; home address for retiree.

(xi) *Sponsor's branch of service or deceased or retiree's former branch of service*.

(xii) *Sponsor's current status*. Active duty, retired, or deceased.

(2) *Patient treatment information*. The following patient treatment information routinely is required relative to the medical services and supplies for which a claim for benefits is being made before a claim will be adjudicated and processed:

(i) *Diagnosis*. All applicable diagnoses are required; standard nomenclature is acceptable. In the absence of a diagnosis, a narrative description of the definitive set of symptoms for which the medical care was rendered must be provided.

(ii) *Source of care*. Full name of source of care (such as hospital or physician) providing the specific medical services being claimed.

(iii) *Full address of source of care*. This address must be where the care actually was provided, not a billing address.

(iv) *Attending physician*. Name of attending physician (or other authorized individual professional provider).

(v) *Referring physician*. Name and address of ordering, prescribing, or referring physician.

(vi) *Status of patient*. Status of patient at the time the medical services and supplies were rendered (that is, inpatient or outpatient).

(vii) *Dates of service*. Specific and inclusive dates of service.

(viii) *Inpatient stay*. Source and dates of related inpatient stay (if applicable).

(ix) *Physicians or other authorized individual professional providers*. The claims must give the name of the individual actually rendering the care, along with the individual's professional status (e.g., M.D., Ph.D., R.N., etc.) and provider number, if the individual signing the claim is not the provider who actually rendered the service. The following information must also be included:

(A) Date each service was rendered.

(B) Procedure code or narrative description of each procedure or service for each date of service.

(C) Individual charge for each item of service or each supply for each date.

(D) Detailed description of any unusual complicating circumstances related to the medical care provided that the physician or other individual professional provider may choose to submit separately.

(x) *Hospitals or other authorized institutional providers.* For care provided by hospitals (or other authorized institutional providers), the following information also must be provided before a claim will be adjudicated and processed:

(A) An itemized billing showing each item of service or supply provided for each day covered by the claim.

NOTE: The Director, OCHAMPUS, or a designee, may approve, in writing, an alternative billing procedure for RTCs or other special institutions, in which case the itemized billing requirement may be waived. The particular facility will be aware of such approved alternate billing procedure.

(B) Any absences from a hospital or other authorized institution during a period for which inpatient benefits are being claimed must be identified specifically as to date or dates and provide details on the purpose of the absence. Failure to provide such information will result in denial of benefits and, in an ongoing case, termination of benefits for the inpatient stay at least back to the date of the absence.

(C) For hospitals subject to the CHAMPUS DRG-based payment system (see paragraph (a)(1)(ii)(D) of §199.14), the following information is also required:

(*1*) The principal diagnosis (the diagnosis established, after study, to be chiefly responsible for causing the patient's admission to the hospital).

(*2*) All secondary diagnoses.

(*3*) All significant procedures performed.

(*4*) The discharge status of the beneficiary.

(*5*) The hospital's Medicare provider number.

(*6*) The source of the admission.

(D) Claims submitted by hospitals (or other authorized institutional providers) must include the name of the individual actually rendering the care, along with the individual's professional status (e.g., M.D., Ph.D., R.N., etc.).

(xi) *Prescription drugs and medicines (and insulin).* For prescription drugs and medicines (and insulin, whether or not a prescription is required) receipted bills must be attached and the following additional information provided:

(A) Name of drug.

NOTE: When the physician or pharmacist so requests, the name of the drugs may be submitted to the CHAMPUS fiscal intermediary directly by the physician or pharmacist.

(B) Strength of drug.

(C) Name and address of pharmacy where drug was purchased.

(D) Prescription number of drug being claimed.

(xii) *Other authorized providers.* For items from other authorized providers (such as medical supplies), an explanation as to the medical need must be attached to the appropriate claim form. For purchases of durable equipment under the ECHO it is necessary also to attach a copy of the authorization.

(xiii) *Nonparticipating providers.* When the beneficiary or sponsor submits the claim to the CHAMPUS fiscal intermediary (that is, the provider elects not to participate), an itemized bill from the provider to the beneficiary or sponsor must be attached to the CHAMPUS claim form.

(3) *Medical records/medical documentation.* Medical records are of vital importance in the care and treatment of the patient. Medical records serve as a basis for planning of patient care and for the ongoing evaluation of the patient's treatment and progress. Accurate and timely completion of orders, notes, etc., enable different members of a health care team and subsequent health care providers to have access to relevant data concerning the patient. Appropriate medical records must be maintained in order to accommodate utilization review and to substantiate that billed services were actually rendered.

(i) All care rendered and billed must be appropriately documented in writing. Failure to document the care billed will result in the claim or specific services on the claim being denied CHAMPUS cost-sharing.

(ii) A pattern of failure to adequately document medical care will result in

episodes of care being denied CHAMPUS cost-sharing.

(iii) Cursory notes of a generalized nature that do not identify the specific treatment and the patient's response to the treatment are not acceptable.

(iv) The documentation of medical records must be legible and prepared as soon as possible after the care is rendered. Entries should be made when the treatment described is given or the observations to be documented are made. The following are documentation requirements and specific time frames for entry into the medical records:

(A) General requirements for acute medical/surgical services:

(*1*) Admission evaluation report within 24 hours of admission.

(*2*) Completed history and physical examination report within 72 hours of admission.

(*3*) Registered nursing notes at the end of each shift.

(*4*) Daily physician notes.

(B) Requirements specific to mental health services:

(*1*) Psychiatric admission evaluation report within 24 hours of admission.

(*2*) History and physical examination within 24 hours of admission; complete report documented within 72 hours for acute and residential programs and within 3 working days for partial programs.

(*3*) Individual and family therapy notes within 24 hours of procedure for acute, detoxification and Residential Treatment Center (RTC) programs and within 48 hours for partial programs.

(*4*) Preliminary treatment plan within 24 hours of admission.

(*5*) Master treatment plan within 5 calendar days of admission for acute care, 10 days for RTC care, 5 days for full-day partial programs and within 7 days for half-day partial programs.

(*6*) Family assessment report within 72 hours of admission for acute care and 7 days for RTC and partial programs.

(*7*) Nursing assessment report within 24 hours of admission.

(*8*) Nursing notes at the end of each shift for acute and detoxification programs; every ten visits for partial hospitalization; and at least once a week for RTCs.

(*9*) Daily physician notes for intensive treatment, detoxification, and rapid stabilization programs; twice per week for acute programs; and once per week for RTC and partial programs.

(*10*) Group therapy notes once per week.

(*11*) Ancillary service notes once per week.

NOTE: A pattern of failure to meet the above criteria may result in provider sanctions prescribed under §199.9.

(4) *Double coverage information.* When the CHAMPUS beneficiary is eligible for medical benefits coverage through another plan, insurance, or program, either private or Government, the following information must be provided:

(i) *Name of other coverage.* Full name and address of double coverage plan, insurance, or program (such as Blue Cross, Medicare, commercial insurance, and state program).

(ii) *Source of double coverage.* Source of double coverage (such as employment, including retirement, private purchase, membership in a group, and law).

(iii) *Employer information.* If source of double coverage is employment, give name and address of employer.

(iv) *Identification number.* Identification number or group number of other coverage.

(5) *Right to additional information.* (i) As a condition precedent to the cost-sharing of benefits under this part or pursuant to a review or audit, whether the review or audit is prospective, concurrent, or retroactive, OCHAMPUS or CHAMPUS contractors may request, and shall be entitled to receive, information from a physician or hospital or other person, institution, or organization (including a local, state, or Federal Government agency) providing services or supplies to the beneficiary for whom claims or requests for approval for benefits are submitted. Such information and records may relate to the attendance, testing, monitoring, examination, diagnosis, treatment, or services and supplies furnished to a beneficiary and, as such, shall be necessary for the accurate and efficient administration of CHAMPUS benefits. This may include requests for copies of all medical records or documentation

related to the episode of care. In addition, before a determination on a request for preauthorization or claim of benefits is made, a beneficiary, or sponsor, shall provide additional information relevant to the requested determination, when necessary. The recipient of such information shall hold such records confidential except when:

(A) Disclosure of such information is authorized specifically by the beneficiary;

(B) Disclosure is necessary to permit authorized governmental officials to investigate and prosecute criminal actions; or

(C) Disclosure is authorized or required specifically under the terms of DoD Directive 5400.7 and 5400.11, the Freedom of Information Act, and the Privacy Act (refer to paragraph (m) of §199.1 of this part).

(ii) For the purposes of determining the applicability of and implementing the provisions of §§199.8 and 199.9, or any provision of similar purpose of any other medical benefits coverage or entitlement, OCHAMPUS or CHAMPUS fiscal intermediaries, without consent or notice to any beneficiary or sponsor, may release to or obtain from any insurance company or other organization, governmental agency, provider, or person, any information with respect to any beneficiary when such release constitutes a routine use duly published in the FEDERAL REGISTER in accordance with the Privacy Act.

(iii) Before a beneficiary's claim of benefits is adjudicated, the beneficiary or the provider(s) must furnish to CHAMPUS that information which is necessary to make the benefit determination. Failure to provide the requested information will result in denial of the claim. A beneficiary, by submitting a CHAMPUS claim(s) (either a participating or nonparticipating claim), is deemed to have given consent to the release of any and all medical records or documentation pertaining to the claims and the episode of care.

(c) *Signature on CHAMPUS Claim Form*—(1) *Beneficiary signature.* CHAMPUS claim forms must be signed by the beneficiary except under the conditions identified in paragraph (c)(1)(v) of this section. The parent or guardian may sign for any beneficiary under 18 years.

(i) *Certification of identity.* This signature certifies that the patient identification information provided is correct.

(ii) *Certification of medical care provided.* This signature certifies that the specific medical care for which benefits are being claimed actually were rendered to the beneficiary on the dates indicated.

(iii) *Authorization to obtain or release information.* Before requesting additional information necessary to process a claim or releasing medical information, the signature of the beneficiary who is 18 years old or older must be recorded on or obtained on the CHAMPUS claim form or on a separate release form. The signature of the beneficiary, parent, or guardian will be requested when the beneficiary is under 18 years.

NOTE: If the care was rendered to a minor and a custodial parent or legal guardian requests information prior to the minor turning 18 years of age, medical records may still be released pursuant to the signature of the parent or guardian, and claims information may still be released to the parent or guardian in response to the request, even though the beneficiary has turned 18 between the time of the request and the response. However, any follow-up request or subsequent request from the parent or guardian, after the beneficiary turns 18 years of age, will necessitate the authorization of the beneficiary (or the beneficiary's legal guardian as appointed by a cognizant court), before records and information can be released to the parent or guardian.

(iv) *Certification of accuracy and authorization to release double coverage information.* This signature certifies to the accuracy of the double coverage information and authorizes the release of any information related to double coverage. (Refer to §199.8 of this part).

(v) *Exceptions to beneficiary signature requirement.* (A) Except as required by paragraph (c)(1)(iii) of this section, the signature of a spouse, parent, or guardian will be accepted on a claim submitted for a beneficiary who is 18 years old or older.

(B) When the institutional provider obtains the signature of the beneficiary (or the signature of the parent or guardian when the beneficiary is under

18 years) on a CHAMPUS claim form at admission, the following participating claims may be submitted without the beneficiary's signature.

(*1*) Claims for laboratory and diagnostic tests and test interpretations from radiologists, pathologists, neurologists, and cardiologists.

(*2*) Claims from anesthesiologists.

(C) Claims filed by providers using CHAMPUS-approved signature-on-file and claims submission procedures.

(2) *Provider's signature.* A participating provider (see paragraph (a)(8) of §199.6) is required to sign the CHAMPUS claim form.

(i) *Certification.* A participating provider's signature on a CHAMPUS claim form:

(A) Certifies that the specific medical care listed on the claim form was, in fact, rendered to the specific beneficiary for which benefits are being claimed, on the specific date or dates indicated, at the level indicated and by the provider signing the claim unless the claim otherwise indicates another individual provided the care. For example, if the claim is signed by a psychiatrist and the care billed was rendered by a psychologist or licensed social worker, the claim must indicate both the name and profession of the individual who rendered the care.

(B) Certifies that the provider has agreed to participate (providing this agreement has been indicated on the claim form) and that the CHAMPUS-determined allowable charge or cost will constitute the full charge or cost for the medical care listed on the specific claim form; and further agrees to accept the amount paid by CHAMPUS or the CHAMPUS payment combined with the cost-shared amount paid by, or on behalf of the beneficiary, as full payment for the covered medical services or supplies.

(*1*) Thus, neither CHAMPUS nor the sponsor is responsible for any additional charges, whether or not the CHAMPUS-determined charge or cost is less than the billed amount.

(*2*) Any provider who signs and submits a CHAMPUS claim form and then violates this agreement by billing the beneficiary or sponsor for any difference between the CHAMPUS-determined charge or cost and the amount billed is acting in bad faith and is subject to penalties including withdrawal of CHAMPUS approval as a CHAMPUS provider by administrative action of the Director, OCHAMPUS, or a designee, and possible legal action on the part of CHAMPUS, either directly or as a part of a beneficiary action, to recover monies improperly obtained from CHAMPUS beneficiaries or sponsors (refer to §199.6 of this part.)

(ii) *Physician or other authorized individual professional provider.* A physician or other authorized individual professional provider is liable for any signature submitted on his or her behalf. Further, a facsimile signature is not acceptable unless such facsimile signature is on file with, and has been authorized specifically by, the CHAMPUS fiscal intermediary serving the state where the physician or other authorized individual professional provider practices.

(iii) *Hospital or other authorized institutional provider.* The provider signature on a claim form for institutional services must be that of an authorized representative of the hospital or other authorized institutional provider, whose signature is on file with and approved by the appropriate CHAMPUS fiscal intermediary.

(d) *Claims filing deadline.* For all services provided on or after January 1, 1993, to be considered for benefits, all claims submitted for benefits must, except as provided in paragraph (d)(2) of this section, be filed with the appropriate CHAMPUS contractor no later than one year after the services are provided. Unless the requirement is waived, failure to file a claim within this deadline waives all rights to benefits for such services or supplies.

(1) *Claims returned for additional information.* When a claim is submitted initially within the claim filing time limit, but is returned in whole or in part for additional information to be considered for benefits, the returned claim, along with the requested information, must be resubmitted and received by the appropriate CHAMPUS contractor no later than the later of:

(i) One year after the services are provided; or

(ii) 90 days from the date the claim was returned to the provider or beneficiary.

(2) *Exception to claims filing deadline.* The Director, OCHAMPUS, or a designee, may grant exceptions to the claims filing deadline requirements.

(i) *Types of exception.* (A) *Retroactive eligibility.* Retroactive CHAMPUS eligibility determinations.

(B) *Administrative error.* Administrative error (that is, misrepresentation, mistake, or other accountable action) of an officer or employee of OCHAMPUS (including OCHAMPUSEUR) or a CHAMPUS fiscal intermediary, performing functions under CHAMPUS and acting within the scope of that official's authority.

(C) *Mental incompetency.* Mental incompetency of the beneficiary or guardian or sponsor, in the case of a minor child (which includes inability to communicate, even if it is the result of a physical disability).

(D) *Delays by other health insurance.* When not attributable to the beneficiary, delays in adjudication by other health insurance companies when double coverage coordination is required before the CHAMPUS benefit determination.

(E) *Other waiver authority.* The Director, OCHAMPUS may waive the claims filing deadline in other circumstances in which the Director determines that the waiver is necessary in order to ensure adequate access for CHAMPUS beneficiaries to health care services.

(ii) *Request for exception to claims filing deadline.* Beneficiaries who wish to request an exception to the claims filing deadline may submit such a request to the CHAMPUS fiscal intermediary having jurisdiction over the location in which the service was rendered, or as otherwise designated by the Director, OCHAMPUS.

(A) Such requests for an exception must include a complete explanation of the circumstances of the late filing, together with all available documentation supporting the request, and the specific claim denied for late filing.

(B) Each request for an exception to the claims filing deadline is reviewed individually and considered on its own merits.

(e) *Other claims filing requirements.* Notwithstanding the claims filing deadline described in paragraph (d) of this section, to lessen any potential adverse impact on a CHAMPUS beneficiary or sponsor that could result from a retroactive denial, the following additional claims filing procedures are recommended or required.

(1) *Continuing care.* Except for claims subject to the CHAMPUS DRG-based payment system, whenever medical services and supplies are being rendered on a continuing basis, an appropriate claim or claims should be submitted every 30 days (monthly) whether submitted directly by the beneficiary or sponsor or by the provider on behalf of the beneficiary. Such claims may be submitted more frequently if the beneficiary or provider so elects. The Director, OCHAMPUS, or a designee, also may require more frequent claims submission based on dollars. Examples of care that may be rendered on a continuing basis are outpatient physical therapy, private duty (special) nursing, or inpatient stays. For claims subject to the CHAMPUS DRG-based payment system, claims may be submitted only after the beneficiary has been discharged or transferred from the hospital.

(2) [Reserved]

(3) Claims involving the services of marriage and family counselors, pastoral counselors, and supervised mental health counselors. CHAMPUS requires that marriage and family counselors, pastoral counselors, and supervised mental health counselors make a written report to the referring physician concerning the CHAMPUS beneficiary's progress. Therefore, each claim for reimbursement for services of marriage and family counselors, pastoral counselors, and supervised mental health counselors must include certification to the effect that a written communication has been made or will be made to the referring physician at the end of treatment, or more frequently, as required by the referring physician.

(f) *Preauthorization.* When specifically required in other sections of this part, preauthorization requires the following:

(1) *Preauthorization must be granted before benefits can be extended.* In those situations requiring preauthorization, the request for such preauthorization shall be submitted and approved before benefits may be extended, except as provided in §199.4(a)(11). If a claim for services or supplies is submitted without the required preauthorization, no benefits shall be paid, unless the Director, OCHAMPUS, or a designee, has granted an exception to the requirement for preauthorization.

(i) *Specifically preauthorized services.* An approved preauthorization specifies the exact services or supplies for which authorization is being given. In a preauthorization situation, benefits cannot be extended for services or supplies provided beyond the specific authorization.

(ii) *Time limit on preauthorization.* Approved preauthorizations are valid for specific periods of time, appropriate for the circumstances presented and specified at the time the preauthorization is approved. In general, preauthorizations are valid for 30 days. If the preauthorized service or supplies are not obtained or commenced within the specified time limit, a new preauthorization is required before benefits may be extended. For organ and stem cell transplants, the preauthorization shall remain in effect as long as the beneficiary continues to meet the specific transplant criteria set forth in the TRICARE/CHAMPUS Policy Manual, or until the approved transplant occurs.

(2) *Treatment plan.* Each preauthorization request shall be accompanied by a proposed medical treatment plan (for inpatient stays under the Basic Program) which shall include generally a diagnosis; a detailed summary of complete history and physical; a detailed statement of the problem; the proposed treatment modality, including anticipated length of time the proposed modality will be required; any available test results; consultant's reports; and the prognosis. When the preauthorization request involves transfer from a hospital to another inpatient facility, medical records related to the inpatient stay also must be provided.

(3) *Claims for services and supplies that have been preauthorized.* Whenever a claim is submitted for benefits under CHAMPUS involving preauthorized services and supplies, the date of the approved preauthorization must be indicated on the claim form and a copy of the written preauthorization must be attached to the appropriate CHAMPUS claim.

(4) *Advance payment prohibited.* No CHAMPUS payment shall be made for otherwise authorized services or items not yet rendered or delivered to the beneficiary.

(g) *Claims review.* It is the responsibility of the CHAMPUS fiscal intermediary (or OCHAMPUS, including OCHAMPUSEUR) to review each CHAMPUS claim submitted for benefit consideration to ensure compliance with all applicable definitions, conditions, limitations, or exclusions specified or enumerated in this part. It is also required that before any CHAMPUS benefits may be extended, claims for medical services and supplies will be subject to utilization review and quality assurance standards, norms, and criteria issued by the Director, OCHAMPUS, or a designee (see paragraph (a)(1)(v) of §199.14 for review standards for claims subject to the CHAMPUS DRG-based payment system).

(h) *Benefit payments.* CHAMPUS benefit payments are made either directly to the beneficiary or sponsor or to the provider, depending on the manner in which the CHAMPUS claim is submitted.

(1) *Benefit payments made to beneficiary or sponsor.* When the CHAMPUS beneficiary or sponsor signs and submits a specific claim form directly to the appropriate CHAMPUS fiscal intermediary (or OCHAMPUS, including OCHAMPUSEUR), any CHAMPUS benefit payments due as a result of that specific claim submission will be made in the name of, and mailed to, the beneficiary or sponsor. In such circumstances, the beneficiary or sponsor is responsible to the provider for any amounts billed.

(2) *Benefit payments made to participating provider.* When the authorized provider elects to participate by signing a CHAMPUS claim form, indicating

participation in the appropriate space on the claim form, and submitting a specific claim on behalf of the beneficiary to the appropriate CHAMPUS fiscal intermediary, any CHAMPUS benefit payments due as a result of that claim submission will be made in the name of and mailed to the participating provider. Thus, by signing the claim form, the authorized provider agrees to abide by the CHAMPUS-determined allowable charge or cost, whether or not lower than the amount billed. Therefore, the beneficiary or sponsor is responsible only for any required deductible amount and any cost-sharing portion of the CHAMPUS-determined allowable charge or cost as may be required under the terms and conditions set forth in §§ 199.4 and 199.5 of this part.

(3) *CEOB.* When a CHAMPUS claim is adjudicated, a CEOB is sent to the beneficiary or sponsor. A copy of the CEOB also is sent to the provider if the claim was submitted on a participating basis. The CEOB form provides, at a minimum, the following information:

(i) Name and address of beneficiary.

(ii) Name and address of provider.

(iii) Services or supplies covered by claim for which CEOB applies.

(iv) Dates services or supplies provided.

(v) Amount billed; CHAMPUS-determined allowable charge or cost; and amount of CHAMPUS payment.

(vi) To whom payment, if any, was made.

(vii) Reasons for any denial.

(viii) Recourse available to beneficiary for review of claim decision (refer to § 199.10 of this part).

NOTE: The Director, OCHAMPUS, or a designee, may authorize a CHAMPUS fiscal intermediary to waive a CEOB to protect the privacy of a CHAMPUS beneficiary.

(4) *Benefit under $1.* If the CHAMPUS benefit is determined to be under $1, payment is waived.

(i) *Extension of the Active Duty Dependents Dental Plan to areas outside the United States.* The Assistant Secretary of Defense (Health Affairs) (ASD(HA) may, under the authority of 10 U.S.C. 1076a(h), extend the Active Duty Dependents Dental Plan to areas other than those areas specified in paragraph (a)(2)(i) of this section for the eligible beneficiaries of members of the Uniformed Services. In extending the program outside the Continental United States, the ASD(HA), or designee, is authorized to establish program elements, methods of administration and payment rates and procedures to providers that are different from those in effect under this section in the Continental United States to the extent the ASD(HA), or designee, determines necessary for the effective and efficient operation of the plan outside the Continental United States. This includes provisions for preauthorization of care if the needed services are not available in a Uniformed Service overseas dental treatment facility and payment by the Department of certain cost-shares and other portions of a provider's billed charges. Other differences may occur based on limitations in the availability and capabilities of the Uniformed Services overseas dental treatment facility and a particular nation's civilian sector providers in certain areas. Otherwise, rules pertaining to services covered under the plan and quality of care standards for providers shall be comparable to those in effect under this section in the Continental United States and available military guidelines. In addition, all provisions of 10 U.S.C. 1076a shall remain in effect.

(j) *General assignment of benefits not recognized.* CHAMPUS does not recognize any general assignment of CHAMPUS benefits to another person. All CHAMPUS benefits are payable as described in this and other Sections of this part.

[51 FR 24008, July 1, 1986]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 199.7, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§ 199.8 Double coverage.

(a) *Introduction.* (1) In enacting TRICARE legislation, Congress clearly has intended that TRICARE be the secondary payer to all health benefit, insurance and third-party payer plans. 10 U.S.C. 1079(j)(1) specifically provides that a benefit may not be paid under a plan (CHAMPUS) covered by this section in the case of a person enrolled in, or covered by, any other insurance,

medical service, or health plan, including any plan offered by a third-party payer (as defined in 10 U.S.C. 1095(h)(1)) to the extent that the benefit is also a benefit under the other plan, except in the case of a plan administered under title XIX of the Social Security Act (42 U.S.C. 1396 *et seq.*).

(2) The provision in paragraph (a)(1) of this section is made applicable specifically to retired members, dependents, and survivors by 10 U.S.C. 1086(g). The underlying intent, in addition to preventing waste of Federal resources, is to ensure that TRICARE beneficiaries receive maximum benefits while ensuring that the combined payments of TRICARE and other health and insurance plans do not exceed the total charges.

(b) *Double coverage plan.* A double coverage plan is one of the following:

(1) *Insurance plan.* An insurance plan is any plan or program that is designed to provide compensation or coverage for expenses incurred by a beneficiary for medical services and supplies. It includes plans or programs for which the beneficiary pays a premium to an issuing agent as well as those plans or programs to which the beneficiary is entitled as a result of employment or membership in, or association with, an organization or group.

(2) *Medical service or health plan.* A medical service or health plan is any plan or program of an organized health care group, corporation, or other entity for the provision of health care to an individual from plan providers, both professional and institutional. It includes plans or programs for which the beneficiary pays a premium to an issuing agent as well as those plans or programs to which the beneficiary is entitled as a result of employment or membership in, or association with, an organization or group.

(3) *Third-party payer.* A third-party payer means an entity that provides an insurance, medical service, or health plan by contract or agreement, including an automobile liability insurance or no-fault insurance carrier and a workers' compensation program or plan, and any other plan or program (e.g., homeowners insurance, etc.) that is designed to provide compensation or coverage for expenses incurred by a beneficiary for medical services or supplies. For purposes of the definition of ''third-party payer,'' an insurance, medical service or health plan includes a preferred provider organization, an insurance plan described as Medicare supplemental insurance, and a personal injury protection plan or medical payments benefit plan for personal injuries resulting from the operation of a motor vehicle.

(4) *Exceptions.* Double coverage plans do not include:

(i) Plans administered under title XIX of the Social Security Act (Medicaid);

(ii) Coverage specifically designed to supplement CHAMPUS benefits (a health insurance policy or other health benefit plan that meets the definition and criteria under supplemental insurance plan as set forth in §199.2(b));

(iii) Entitlement to receive care from Uniformed Services medical care facilities;

(iv) Certain Federal Government programs, as prescribed by the Director, OCHAMPUS, that are designed to provide benefits to a distinct beneficiary population and for which entitlement does not derive from either premium payment of monetary contribution (for example, the Indian Health Service); or

(v) State Victims of Crime Compensation Programs.

(c) *Application of double coverage provisions.* CHAMPUS claims submitted for otherwise covered services or supplies and which involve double coverage shall be adjudicated as follows:

(1) *TRICARE last pay.* For any claim that involves a double coverage plan as defined in paragraph (b) of this section, TRICARE shall be last pay *except* as may be authorized by the Director, TRICARE Management Activity, or a designee, pursuant to paragraph (c)(2) of this section. That is, TRICARE benefits may not be extended until all other double coverage plans have adjudicated the claim.

(2) *TRICARE advance payment.* The Director, TRICARE Management Activity, or a designee, may authorize payment of a claim in advance of adjudication of the claim by a double coverage plan and recover, under §199.12,

the TRICARE costs of health care incurred on behalf of the covered beneficiary under the following conditions:

(i) The claim is submitted for health care services furnished to a covered beneficiary; and,

(ii) The claim is identified as involving services for which a third-party payer, other than a primary medical insurer, may be liable.

(3) *Primary medical insurer*. For purposes of paragraph (c)(2) of this section, a ''primary medical insurer'' is an insurance plan, medical service or health plan, or a third-party payer under this section, the primary or sole purpose of which is to provide or pay for health care services, supplies, or equipment. The term ''primary medical insurer'' does not include automobile liability insurance, no-fault insurance, workers' compensation program or plan, homeowners insurance, or any other similar third-party payer as may be designated by the Director, TRICARE Management Activity, or a designee, in any policy guidance or instructions issued in implementation of this Part.

(4) *Waiver of benefits*. A CHAMPUS beneficiary may not elect to waive benefits under a double coverage plan and use CHAMPUS. Whenever double coverage exists, the provisions of this Section shall be applied.

(5) *Lack of payment by double coverage plan*. Amounts that have been denied by a double coverage plan simply because a claim was not filed timely or because the beneficiary failed to meet some other requirement of coverage cannot be paid. If a statement from the double coverage plan as to how much that plan would have paid had the claim met the plan's requirements is provided to the CHAMPUS contractor, the claim can be processed as if the double coverage plan actually paid the amount shown on the statement. If no such statement is received, no payment from CHAMPUS is authorized.

(d) *Special considerations*—(1) *CHAMPUS and Medicare*—(i) *General rule*. In any case in which a beneficiary is eligible for both Medicare and CHAMPUS received medical or dental care for which payment may be made under Medicare and CHAMPUS, Medicare is always the primary payer except in the case of retroactive determinations of disability as provided in paragraph (d)(1)(v) of this section. For dependents of active duty members, payment will be determined in accordance to paragraph (c) of this section. For all other beneficiaries eligible for Medicare, the amount payable under CHAMPUS shall be the amount of actual out-of-pocket costs incurred by the beneficiary for that care over the sum of the amount paid for that care under Medicare and the total of all amounts paid or payable by third party payers other than Medicare.

(ii) *Payment limit*. The total CHAMPUS amount payable for care under paragraph (d)(1)(i) of this section may not exceed the total amount that would be paid under CHAMPUS if payment for that care was made solely under CHAMPUS.

(iii) *Application of general rule*. In applying the general rule under paragraph (d)(1)(i) of this section, the first determination will be whether payment may be made under Medicare. For this purpose, Medicare exclusions, conditions, and limitations will be based for the determination.

(A) For items or services or portions or segments of items or services for which payment may be made under Medicare, the CHAMPUS payment will be the amount of the beneficiary's actual out of pocket liability, minus the amount payable by Medicare, also minus amount payable by other third party payers, subject to the limit under paragraph (d)(1)(ii) of this section.

(B) For items or services or segments of items or services for which no payment may be made under Medicare, the CHAMPUS payment will be the same as it would be for a CHAMPUS eligible retiree, dependent, or survivor beneficiary who is not Medicare eligible.

(C) For Medicare beneficiaries who enroll in Medicare Part D, the Part D plan is primary and TRICARE is secondary payer. TRICARE will pay the beneficiary's out-of-pocket costs for Medicare and TRICARE covered medications, including the initial deductible and Medicare Part D cost-sharing amounts up to the initial coverage limit of the Medicare Part D plan. The Medicare Part D plan, although the primary plan, pays nothing during any

coverage gap period. When the beneficiary becomes responsible for 100 percent of the drug costs under a Part D coverage gap period, the beneficiary may use the TRICARE pharmacy benefit as the secondary payer. TRICARE will cost share during the coverage gap to the same extent as it does under Section 199.21 for beneficiaries not enrolled in Medicare Part D plan. The beneficiary is responsible for the applicable TRICARE pharmacy cost-sharing amounts (and deductible if using a retail non-network pharmacy). Part D plan sponsors may offer a defined standard benefit, or an actuarially equivalent standard benefit. Part D plan sponsors may also offer alternative prescription drug coverage, which may consist of basic alternative coverage or enhanced alternative coverage. Therefore depending on the Part D plan that a beneficiary chooses, monthly premiums, coinsurances, copays, deductibles and benefit design may vary from plan to plan. TRICARE payment of the beneficiary's initial deductible, if any, along with payment of any beneficiary cost share count towards total spending on drugs, and may have the effect of moving the beneficiary more quickly through the initial phase of coverage to the coverage gap. Irrespective of the phase of the benefit in which a beneficiary may be, if a beneficiary is accessing a pharmacy under contract with his or her Part D plan, the provider will bill the Part D plan first, then TRICARE. If the beneficiary chooses to use his or her TRICARE pharmacy benefit during a coverage gap under Part D, the beneficiary may do so, but the beneficiary is responsible for the TRICARE cost-shares.

(iv) *Examples of applications of general rule.* The following examples are illustrative. They are not all-inclusive.

(A) In the case of a Medicare-eligible beneficiary receiving typical physician office visit services, Medicare payment generally will be made. CHAMPUS payment will be determined consistent with paragraph (d)(1)(iii)(A) of this section.

(B) In the case of a Medicare-eligible beneficiary residing and receiving medical care overseas, Medicare payment generally may not be made. CHAMPUS payment will be determined consistent with paragraph (d)(1)(iii)(B) of this section.

(C) In the case of a Medicare-eligible beneficiary receiving skilled nursing facility services a portion of which is payable by Medicare (such as during the first 100 days) and a portion of which is not payable by Medicare (such as after 100 days), CHAMPUS payment for the first portion will be determined consistent with paragraph (d)(1)(iii)(A) of this section and for the second portion consistent with paragraph (d)(1)(iii)(B) of this section.

(v) *Application of catastrophic cap.* Only in cases in which CHAMPUS payment is determined consistent with paragraph (d)(1)(iii)(B) of this section, actual beneficiary out of pocket liability remaining after CHAMPUS payments will be counted for purposes of the annual catastrophic loss protection, set forth under §199.4(f)(10). When a family has met the cap, CHAMPUS will pay allowable amounts for remaining covered services through the end of that calendar year.

(vi) *Retroactive determinations of disability.* In circumstances involving determinations of retroactive Medicare Part A entitlement for persons under 65 years of age, Medicare becomes the primary payer effective as of the date of issuance of the retroactive determination by the Social Security Administration. For care and services rendered prior to issuance of the retroactive determination, the CHAMPUS payment will be determined consistent with paragraph (d)(1)(iii)(B) of this section notwithstanding the beneficiary's retroactive entitlement for Medicare Part A during that period.

(vii) *Effect on enrollment in Medicare Advantage Prescription Drug (MA–PD) plan.* In the case of a beneficiary enrolled in a MA–PD plan who receives items or services for which payment may be made under both the MA–PD plan and CHAMPUS/TRICARE, a claim for the beneficiary's normal out-of-pocket costs under the MA–PD plan may be submitted for CHAMPUS/TRICARE payment. However, consistent with paragraph (c)(4) of this

section, out-of-pocket costs do not include costs associated with unauthorized out-of-system care or care otherwise obtained under circumstances that result in a denial or limitation of coverage for care that would have been covered or fully covered had the beneficiary met applicable requirements and procedures. In such cases, the CHAMPUS/TRICARE amount payable is limited to the amount that would have been paid if the beneficiary had received care covered by the Medicare Advantage plan. If the TRICARE-Medicare beneficiary enrolls in a MA–PD drug plan, it generally will be governed by Medicare Part C, although plans that offer a prescription drug benefit must comply with Medicare Part D rules. The beneficiary has to pay the plan's monthly premiums and obtain all medical care and prescription drugs through the Medicare Advantage plan before seeking CHAMPUS/TRICARE payment. CHAMPUS/TRICARE payment for such beneficiaries may not exceed that which would be payable for a beneficiary under paragraph (d)(1)(iii)(C) of this section.

(viii) *Effect of other double coverage plans, including medigap plans.* CHAMPUS is second payer to other third-party payers of health insurance, including Medicare supplemental plans.

(ix) *Effect of employer-provided insurance.* In the case of individuals with health insurance due to their current employment status, the employer insurance plan shall be first payer, Medicare shall be the second payer, and CHAMPUS shall be the tertiary payer.

(2) *CHAMPUS and Medicaid.* Medicaid is not a double coverage plan. In any double coverage situation involving Medicaid, CHAMPUS is always the primary payer.

(3) *TRICARE and Workers' Compensation.* TRICARE benefits are not payable for a work-related illness or injury that is covered under a workers' compensation program. Pursuant to paragraph (c)(2) of this section, however, the Director, TRICARE Management Activity, or a designee, may authorize payment of a claim involving a work-related illness or injury covered under a workers' compensation program in advance of adjudication and payment of the workers' compensation claim and then recover, under §199.12, the TRICARE costs of health care incurred on behalf of the covered beneficiary.

(4) *Extended Care Health Option (ECHO).* For those services or supplies that require use of public facilities, an ECHO eligible beneficiary (or sponsor or guardian acting on behalf of the beneficiary) does not have the option of waiving the full use of public facilities which are determined by the Director, TRICARE Management Activity or designee to be available and adequate to meet a disability related need for which an ECHO benefit was requested. Benefits eligible for payment under a state plan for medical assistance under Title XIX of the Social Security Act (Medicaid) are never considered to be available in the adjudication of ECHO benefits.

(5) *Primary payer.* The requirements of paragraph (d)(4) of this section notwithstanding, TRICARE is primary payer for services and items that are provided in accordance with the Individualized Family Service Plan as required by Part C of the Individuals with Disabilities Education Act and that are medically or psychologically necessary and otherwise allowable under the TRICARE Basic Program or the Extended Care Health Option.

(6) *Prohibition against financial and other incentives not to enroll in a group health plan*—(i) *General rule.* Under 10 U.S.C. 1097c, an employer or other entity is prohibited from offering TRICARE beneficiaries financial or other benefits as incentives not to enroll in, or to terminate enrollment in, a group health plan that is or would be primary to TRICARE. This prohibition applies in the same manner as section 1862(b)(3)(C) of the Social Security Act applies to incentives for a Medicare-eligible employee not to enroll in a group health plan that is or would be primary to Medicare.

(ii) *Application of general rule.* The prohibition in paragraph (d)(6)(i) of this section precludes offering to TRICARE beneficiaries an alternative to the employer primary plan unless:

(A) The beneficiary has primary coverage other than TRICARE; or

(B) The benefit is offered under a cafeteria plan under section 125 of the Internal Revenue Code and is offered to all similarly situated employees, including non-TRICARE eligible employees; or

(C) The benefit is offered under a cafeteria plan under section 125 of the Internal Revenue Code and, although offered only to TRICARE-eligible employees, the employer does not provide any payment for the benefit nor receive any direct or indirect consideration or compensation for offering the benefit; the employer's only involvement is providing the administrative support for the benefits under the cafeteria plan, and the employee's participation in the plan is completely voluntary.

(iii) *Documentation.* In the case of a benefit excluded by paragraph (d)(6)(ii)(C) of this section from the prohibition in paragraph (d)(6)(i) of this section, the exclusion is dependent on the employer maintaining in the employer's files a certification signed by the employer that the conditions described in paragraph (d)(6)(ii)(C) of this section are met, and, upon request of the Department of Defense, providing a copy of that certification to the Department of Defense.

(iv) *Remedies and penalties.* (A) Remedies for violation of this paragraph (d)(6) include but are not limited to remedies under the Federal Claims Collection Act, 31 U.S.C. 3701 *et seq.*

(B) Penalties for violation of this paragraph (d)(6) include a civil monetary penalty of up to $5,000 for each violation. The provisions of section 1128A of the Social Security Act, 42 U.S.C. 1320a–7a, (other than subsections (a) and (b)) apply to the civil monetary penalty in the same manner as the provisions apply to a penalty or proceeding under section 1128A.

(v) *Definitions.* For the purposes of this paragraph (d)(6):

(A) The term ''employer'' includes any State or unit of local government and any employer that employs at least 20 employees.

(B) The term ''group health plan'' means a group health plan as that term is defined in section 5000(b)(1) of the Internal Revenue Code of 1986 without regard to section 5000(d) of the Internal Revenue Code of 1986.

(C) The term ''similarly situated'' means sharing common attributes, such as part-time employees, or other bona fide employment-based classifications consistent with the employer's usual business practice. (Internal Revenue Service regulations at 26 CFR 54.9802–1(d) may be used as a reference for this purpose). However, in no event shall eligibility for or entitlement to TRICARE (or ineligibility or non-entitlement to TRICARE) be considered a bona fide employment-based classification.

(D) The term ''TRICARE-eligible employee'' means a covered beneficiary under section 1086 of title 10, United States Code, Chapter 55, entitled to health care benefits under the TRICARE program.

(vi) *Procedures.* The Departments of Defense and Health and Human Services are authorized to enter into agreements to further carry out this section.

(e) *Implementing instructions.* The Director, OCHAMPUS, or a designee, shall issue such instructions, procedures, or guidelines, as necessary, to implement the intent of this section.

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§ 199.9 Administrative remedies for fraud, abuse, and conflict of interest.

(a) *General.* (1) This section sets forth provisions for invoking administrative remedies under CHAMPUS in situations involving fraud, abuse, or conflict of interest. The remedies impact institutional providers, professional providers, and beneficiaries (including parents, guardians, or other representatives of beneficiaries), and cover situations involving criminal fraud, civil fraud, administrative determinations of conflicts of interest or dual compensation, and administrative determinations of fraud or abuse. The administrative actions, remedies, and

procedures may differ based upon whether the initial findings were made by a court of law, another agency, or the Director, OCHAMPUS (or designee).

(2) This section also sets forth provisions for invoking administrative remedies in situations requiring administrative action to enforce provisions of law, regulation, and policy in the administration of CHAMPUS and to ensure quality of care for CHAMPUS beneficiaries. Examples of such situations may include a case in which it is discovered that a provider fails to meet requirements under this part to be an authorized CHAMPUS provider; a case in which the provider ceases to be qualified as a CHAMPUS provider because of suspension or revocation of the provider's license by a local licensing authority; or a case in which a provider meets the minimum requirements under this part but, nonetheless, it is determined that it is in the best interest of the CHAMPUS or CHAMPUS beneficiaries that the provider should not be an authorized CHAMPUS provider.

(3) The administrative remedies set forth in this section are in addition to, and not in lieu of, any other remedies or sanctions authorized by law or regulation. For example, administrative action under this section may be taken in a particular case even if the same case will be or has been processed under the administrative procedures established by the Department of Defense to implement the Program Fraud Civil Remedies Act.

(4) Providers seeking payment from the Federal Government through programs such as CHAMPUS have a duty to familiarize themselves with, and comply with, the program requirements.

(5) CHAMPUS contractors and peer review organizations have a responsibility to apply provisions of this regulation in the discharge of their duties, and to report all known situations involving fraud, abuse, or conflict of interest. Failure to report known situations involving fraud, abuse, or conflict of interest will result in the withholding of administrative payments or other contractual remedies as determined by the Director, OCHAMPUS, or a designee.

(b) *Abuse.* The term ''abuse'' generally describes incidents and practices which may directly or indirectly cause financial loss to the Government under CHAMPUS or to CHAMPUS beneficiaries. For the definition of abuse, see §199.2 of this part. The type of abuse to which CHAMPUS is most vulnerable is the CHAMPUS claim involving the overutilization of medical and health care services. To avoid abuse situations, providers have certain obligations to provide services and supplies under CHAMPUS which are: Furnished at the appropriate level and only when and to the extent medically necessary as determined under the provisions of this part; of a quality that meets professionally recognized standards of health care; and, supported by adequate medical documentation as may reasonably be required under this part by the Director, OCHAMPUS, or a designee, to evidence the medical necessity and quality of services furnished, as well as the appropriateness of the level of care. A provider's failure to comply with these obligations can result in sanctions being imposed by the Director, OCHAMPUS, or a designee, under this section. Even when administrative remedies are not initiated under this section, abuse situations under CHAMPUS are a sufficient basis for denying all or any part of CHAMPUS cost-sharing of individual claims. The types of abuse or possible abuse situations under CHAMPUS include, but are not limited, to the following:

(1) A pattern of waiver of beneficiary (patient) cost-share or deductible.

NOTE: In a case of a legitimate bad debt write-off of patient cost-share or deductible, the provider's record should include documentation as to what efforts were made to collect the debt, when the debt was written off, why the debt was written off, and the amount of the debt written off.

(2) Improper billing practices. Examples include, charging CHAMPUS beneficiaries rates for services and supplies that are in excess of those charges routinely charged by the provider to the general public, commercial health insurance carriers, or other federal health benefit entitlement programs

for the same or similar services. (This includes dual fee schedules—one for CHAMPUS beneficiaries and one for other patients or third-party payers. This also includes billing other third-party payers the same as CHAMPUS is billed but accepting less than the billed amount as reimbursement. However, a formal discount arrangement such as through a preferred provider organization, may not necessarily constitute an improper billing practice.)

(3) A pattern of claims for services which are not medically necessary or, if medically necessary, not to the extent rendered. For example, a battery of diagnostic tests are given when, based on the diagnosis, fewer tests were needed.

(4) Care of inferior quality. For example, consistently furnishing medical or mental health services that do not meet accepted standards of care.

(5) Failure to maintain adequate medical or financial records.

(6) Refusal to furnish or allow the Government (for example, OCHAMPUS) or Government contractors access to records related to CHAMPUS claims.

(7) Billing substantially in excess of customary or reasonable charges unless it is determined by OCHAMPUS that the excess charges are justified by unusual circumstances or medical complications requiring additional time, effort, or expense in localities when it is accepted medical practice to make an extra charge in such cases.

(8) Unauthorized use of the term ''Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)'' in private business. While the use of the term ''CHAMPUS'' is not prohibited by federal statute, misrepresentation or deception by use of the term ''CHAMPUS'' to imply an official connection with the Government or to defraud CHAMPUS beneficiaries may be a violation of federal statute. Regardless of whether the actual use of the term ''CHAMPUS'' may be actionable under federal statute, the unauthorized or deceptive use of the term ''CHAMPUS'' in private business will be considered abuse for purposes of this Section.

(c) *Fraud.* For the definition of fraud, see §199.2 of this part. Examples of situations which, for the purpose of this part, are presumed to be fraud include, but are not limited to:

(1) Submitting CHAMPUS claims (including billings by providers when the claim is submitted by the beneficiary) for services, supplies, or equipment not furnished to, or used by, CHAMPUS beneficiaries. For example, billing or claiming services when the provider was on call (other than an authorized standby charge) and did not provide any specific medical care to the beneficiary; providing services to an ineligible person and billing or submitting a claim for the services in the name of an eligible CHAMPUS beneficiary; billing or submitting a CHAMPUS claim for an office visit for a missed appointment; or billing or submitting a CHAMPUS claim for individual psychotherapy when a medical visit was the only service provided.

(2) Billing or submitting a CHAMPUS claim for costs for noncovered or nonchargeable services, supplies, or equipment disguised as covered items. Some examples are: (i) Billings or CHAMPUS claims for services which would be covered except for the frequency or duration of the services, such as billing or submitting a claim for two one-hour psychotherapy sessions furnished on separate days when the actual service furnished was a two-hour therapy session on a single day, (ii) spreading the billing or claims for services over a time period that reduces the apparent frequency to a level that may be cost-shared by CHAMPUS, (iii) charging to CHAMPUS, directly or indirectly, costs not incurred or not reasonably allowable to the services billed or claimed under CHAMPUS, for example, costs attributable to nonprogram activities, other enterprises, or the personal expenses of principals, or (iv) billing or submitting claim on a fee-for-service basis when in fact a personal service to a specific patient was not performed and the service rendered is part of the overall management of, for example, the laboratory or x-ray department.

(3) Breach of a provider participation agreement which results in the beneficiary (including parent, guardian, or other representative) being billed for amounts which exceed the CHAMPUS-determined allowable charge or cost.

(4) Billings or CHAMPUS claims for supplies or equipment which are clearly unsuitable for the patient's needs or are so lacking in quality or sufficiency for the purpose as to be virtually worthless.

(5) Billings or CHAMPUS claims which involve flagrant and persistent overutilization of services without proper regard for results, the patient's ailments, condition, medical needs, or the physician's orders.

(6) Misrepresentations of dates, frequency, duration, or description of services rendered, or of the identity of the recipient of the services or the individual who rendered the services.

(7) Submitting falsified or altered CHAMPUS claims or medical or mental health patient records which misrepresent the type, frequency, or duration of services or supplies or misrepresent the name(s) of the individual(s) who provided the services or supplies.

(8) Duplicate billings or CHAMPUS claims. This includes billing or submitting CHAMPUS claims more than once for the same services, billing or submitting claims both to CHAMPUS and the beneficiary for the same services, or billing or submitting claims both to CHAMPUS and other third-parties (such as other health insurance or government agencies) for the same services, without making full disclosure of material facts or immediate, voluntary repayment or notification to CHAMPUS upon receipt of payments which combined exceed the CHAMPUS-determined allowable charge of the services involved.

(9) Misrepresentation by a provider of his or her credentials or concealing information or business practices which bear on the provider's qualifications for authorized CHAMPUS provider status. For example, a provider representing that he or she has a qualifying doctorate in clinical psychology when the degree is not from a regionally accredited university.

(10) Reciprocal billing. Billing or claiming services which were furnished by another provider or furnished by the billing provider in a capacity other than as billed or claimed. For example, practices such as the following: (i) One provider performing services for another provider and the latter bills as though he had actually performed the services (e.g., a weekend fill-in); (ii) providing service as an institutional employee and billing as a professional provider for the services; (iii) billing for professional services when the services were provided by another individual who was an institutional employee; (iv) billing for professional services at a higher provider profile than would be paid for the person actually furnishing the services, (for example, bills reflecting that an M.D. or Ph.D. performed the services when services were actually furnished by a licensed social worker, psychiatric nurse, or marriage and family counselor); or (v) an authorized provider billing for services which were actually furnished by an unauthorized or sanctioned provider.

(11) Submitting CHAMPUS claims at a rate higher than a rate established between CHAMPUS and the provider, if such a rate has been established. For example, billing or claiming a rate in excess of the provider's most favored rate limitation specified in a residential treatment center agreement.

(12) Arrangements by providers with employees, independent contractors, suppliers, or others which appear to be designed primarily to overcharge the CHAMPUS through various means (such as commissions, fee-splitting, and kickbacks) used to divert or conceal improper or unnecessary costs or profits.

(13) Agreements or arrangements between the supplier and recipient (recipient could be either a provider or beneficiary, including the parent, guardian, or other representative of the beneficiary) that result in billings or claims which include unnecessary costs or charges to CHAMPUS.

(d) *Conflict of Interest.* (1) Conflict of interest includes any situation where an active duty member of the Uniformed Services (including a reserve member while on active duty, active duty for training, or inactive duty training) or civilian employee of the United States Government, through an official federal position has the apparent or actual opportunity to exert, directly or indirectly, any influence on the referral of CHAMPUS beneficiaries to himself/herself or others with some

potential for personal gain or the appearance of impropriety. Although individuals under contract to the Uniformed Services are not considered ''employees,'' such individuals are subject to conflict of interest provisions by express terms of their contracts and, for purposes of this part, may be considered to be involved in conflict of interest situations as a result of their contract positions. In any situation involving potential conflict of interest of a Uniformed Service employee, the Director, OCHAMPUS, or a designee, may refer the case to the Uniformed Service concerned for appropriate review and action. If such a referral is made, a report of the results of findings and action taken shall be made to the Director, OCHAMPUS, by the Uniformed Service having jurisdiction within 90 days of receiving the referral.

(2) CHAMPUS cost-sharing shall be denied on any claim where a conflict of interest situation is found to exist. This denial of cost-sharing applies whether the claim is submitted by the individual who provided the care, the institutional provider in which the care was furnished, or the beneficiary.

(e) *Dual Compensation.* (1) Federal law (5 U.S.C. 5536) prohibits active duty members of the Uniformed Services or employees (including part-time or intermittent) appointed in the civil service of the United States Government from receiving additional compensation from the Government above their normal pay and allowances. This prohibition applies to CHAMPUS payments for care furnished to CHAMPUS beneficiaries by active duty members of the Uniformed Services or civilian employees of the Government.

(2) CHAMPUS cost-sharing of a claim shall be denied where the services or supplies were provided by an active duty member of the Uniformed Services or a civilian employee of the Government. This denial of CHAMPUS payment applies whether the claim for reimbursement is filed by the individual who provided the care, the institutional provider in which the care was furnished, or by the beneficiary.

NOTE: Physicians of the National Health Service Corps (NHSC) may be assigned to areas where there is a shortage of medical providers. Although these physicians would be prohibited from accepting CHAMPUS payments as individuals if they are employees of the United States Government, the private organizations to which they may be assigned may be eligible for payment, as determined by the Director, OCHAMPUS, or a designee.

(3) The prohibition against dual compensation does not apply to individuals under contract to the Uniformed Services or the Government.

(f) *Administrative Remedies.* Administrative remedies available under CHAMPUS in this section are set forth below.

(1) *Provider exclusion or suspension.* The Director, OCHAMPUS, or a designee, shall have the authority to exclude or suspend an otherwise authorized CHAMPUS provider from the program based on any criminal conviction or civil judgment involving fraud by the provider; fraud or abuse under CHAMPUS by the provider; exclusion or suspension of the provider by another agency of the Federal Government, a state, or local licensing authority; participation in a conflict of interest situation by the provider; or, when it is in the best interests of the program or CHAMPUS beneficiaries to exclude or suspend a provider under CHAMPUS. In all cases, the exclusion or suspension of a provider shall be effective 15 calendar days from the date on the written initial determination issued under paragraph (h)(2) of this section.

(i) *Criminal conviction or civil judgment involving fraud by a provider*—(A) *Criminal conviction involving CHAMPUS fraud.* A provider convicted by a Federal, state, foreign, or other court of competent jurisdiction of a crime involving CHAMPUS fraud, whether the crime is a felony or misdemeanor, shall be excluded or suspended from CHAMPUS for a period of time as determined by the Director, OCHAMPUS, or a designee. The CHAMPUS exclusion or suspension applies whether or not the provider, as a result of the conviction, receives probation or the sentence is suspended or deferred, and whether or not the conviction or sentence is under appeal.

NOTE: Under the above paragraph (f)(1)(i)(A) of this section, an entity may be excluded or suspended from CHAMPUS

whenever the entity is found to have a person, convicted of a crime involving CHAMPUS fraud, who has a direct or indirect ownership or control interest (see §199.2) of 5 percent or more in the entity, or is an officer, director, agent or managing employee of the entity. The entity will have an opportunity to provide evidence to show that the ownership or control relationship has ceased. While an entity will not be excluded or suspended from CHAMPUS for employing a provider who has been sanctioned under this Section, the entity will be denied CHAMPUS payment for any services furnished by the sanctioned employee. As an authorized CHAMPUS provider, the entity is responsible for ensuring that all CHAMPUS claims involve services furnished to CHAMPUS beneficiaries by employees who meet all requirements under CHAMPUS for provider status.

(B) *Criminal conviction involving fraud of other Federal programs.* Any provider convicted by a Federal, state, or other court of competent jurisdiction of a crime involving another Federal health care or benefit program (such as plans administered under titles XVIII and XIX of the Social Security Act, Federal Workmen's Compensation, and the Federal Employees Program (FEP) for employee health insurance), whether the crime is a felony or misdemeanor, shall be excluded from CHAMPUS for a period of time as determined by the Director, OCHAMPUS, or a designee. The CHAMPUS exclusion or suspension applies whether or not the provider, as a result of the conviction, receives probation or the sentence is suspended or deferred, and whether or not the conviction or sentence is under appeal.

(C) *Criminal conviction involving fraud of non-Federal programs.* Any provider convicted by a Federal, state, foreign, or other court of competent jurisdiction of a crime involving any non-Federal health benefit program or private insurance involving health benefits may be excluded or suspended from CHAMPUS for a period of time as determined by the Director, OCHAMPUS, or a designee.

(D) *Civil fraud involving CHAMPUS.* If a judgment involving civil fraud has been entered (whether or not it is appealed) against a provider in a civil action involving CHAMPUS benefits (whether or not other Federal programs are involved), the provider shall be excluded or suspended from CHAMPUS for a period determined by the Director, OCHAMPUS, or a designee.

(E) *Civil fraud involving other programs.* If a judgment involving civil fraud has been entered against a provider (whether or not it has been appealed) in a civil action involving other public or private health care programs or health insurance, the provider may be excluded or suspended for a period of time determined by the Director, OCHAMPUS, or a designee.

(ii) *Administrative determination of fraud or abuse under CHAMPUS.* If the Director of the Defense Health Agency determines a provider committed fraud or abuse as defined in this part, the provider shall be excluded or suspended from CHAMPUS/TRICARE for a period of time determined by the Director. A final determination of an imposition of a civil money penalty (CMP) under 32 CFR part 200 shall constitute an administrative determination of fraud and abuse.

(iii) *Administrative determination that the provider has been excluded or suspended by another agency of the Federal Government, a state, or local licensing authority.* Any provider who is excluded or suspended by any other Federal health care program (for example, Medicare), shall be excluded or suspended under CHAMPUS. A provider who has his/her credentials revoked through a Veterans Administration or Military Department credentials review process and who is excluded, suspended, terminated, retired, or separated, shall also be excluded or suspended under CHAMPUS. The period of time of exclusion or suspension shall be determined by the Director, OCHAMPUS, or a designee, pursuant to paragraph (g) of this section.

(iv) *Administrative determination that the provider has participated in a conflict of interest situation.* The Director, OCHAMPUS, or a designee, may exclude or suspend any provider who has knowingly been involved in a conflict of interest situation under CHAMPUS. The period of time of exclusion or suspension shall be determined by the Director, OCHAMPUS, or a designee, pursuant to paragraph (g) of this section. For purposes of this administrative determination, it will be presumed that a

CHAMPUS provider knowingly participated in a conflict of interest situation if the provider employs, in the treatment of a CHAMPUS beneficiary (resulting in a CHAMPUS claim), any medical personnel who are active duty members of the Uniformed Services or civilian employees of the Government. The burden of proof to rebut this presumption rests with the CHAMPUS provider. Two exceptions will be recognized to the presumption that a conflict of interest exists. First, indirect CHAMPUS payments may be made to private organizations to which physicians of the National Health Service Corps (NHSC) are assigned. Second, any off-duty Government medical personnel employed in an emergency room of an acute care hospital will be presumed not to have had the opportunity to exert, directly or indirectly, any influence on the referral of CHAMPUS beneficiaries; therefore, CHAMPUS payments may be made to the employing hospital *provided* the medical care was not furnished directly by the off-duty Government medical personnel in violation of dual compensation provisions.

(v) *Administrative determination that it is in the best interests of the CHAMPUS or CHAMPUS beneficiaries to exclude or suspend a provider*—(A) *Unethical or improper practices or unprofessional conduct.* (*1*) In most instances, unethical or improper practices or unprofessional conduct by a provider will be program abuse and subject the provider to exclusion or suspension for abuse. However, in some cases such practices and conduct may provide an independent basis for exclusion or suspension of the provider by the Director, OCHAMPUS, or a designee.

(*2*) Such exclusions or suspensions may be based on findings or recommendations of state licensure boards, boards of quality assurance, other regulatory agencies, state medical societies, peer review organizations, or other professional associations.

(B) *In any other case in which the Director, OCHAMPUS (or designee), determines that exclusion or suspension of a provider is in the best interests of CHAMPUS or CHAMPUS beneficiaries.* The Director, OCHAMPUS, or a designee, may exclude or suspend any provider if it is determined that the authorization of that particular provider under CHAMPUS poses an unreasonable potential for fraud, abuse, or professional misconduct. Any documented misconduct by the provider reflecting on the business or professional competence or integrity of the provider may be considered. Situations in which the Director, OCHAMPUS, or a designee, may take administrative action under this Section to protect CHAMPUS or CHAMPUS beneficiaries include, but are not limited to, a case in which it is determined that a provider poses an unreasonable potential cost to the Government to monitor the provider for fraud or abuse and to avoid the issuance of erroneous payments; or that the provider poses an unreasonable potential harm to the financial or health status of CHAMPUS beneficiaries; or that the provider poses any other unreasonable threat to the interests of CHAMPUS or CHAMPUS beneficiaries. One example of such circumstances involves a provider who, for his/her entire practice or for most of his/her practice, provides or bills for treatment that is not a CHAMPUS benefit, resulting in CHAMPUS frequently and repeatedly denying claims as noncovered services. This may occur when a professional provider furnishes sex therapy (a therapy which may be recognized by the provider's licensing authority but which is excluded from CHAMPUS coverage) and repeatedly submits CHAMPUS claims for the services.

(2) *Provider termination.* The Director, OCHAMPUS, or a designee, shall terminate the provider status of any provider determined not to meet the qualifications established by this part to be an authorized CHAMPUS provider.

(i) *Effective date of termination.* Except as provided in paragraph (g)(2)(ii) of this section, the termination shall be retroactive to the date on which the provider did not meet the requirements of this part.

(A) The retroactive effective date of termination shall not be limited due to the passage of time, erroneous payment of claims, or any other events which may be cited as a basis for CHAMPUS recognition of the provider

notwithstanding the fact that the provider does not meet program qualifications. Unless specific provision is made in this part to ''grandfather'' or authorize a provider who does not otherwise meet the qualifications established by this part, all unqualified providers shall be terminated.

(B) Any claims cost-shared or paid under CHAMPUS for services or supplies furnished by the provider on or after the effective date of termination, even when the effective date is retroactive, shall be deemed an erroneous payment unless specific exception is provided in this part. All erroneous payments are subject to collection under §199.11 of this part.

(C) If an institution is terminated as an authorized CHAMPUS provider, the institution shall immediately give written notice of the termination to any CHAMPUS beneficiary (or their parent, guardian, or other representative) admitted to, or receiving care at, the institution on or after the effective date of the termination. In addition, when an institution is terminated with an effective date of termination after the date of the initial determination terminating the provider, any beneficiary admitted to the institution prior to the effective date of termination (or their parent, guardian, or other representative) shall be notified by the Director, OCHAMPUS, or a designee, by certified mail of the termination, and that CHAMPUS cost-sharing of the beneficiary's care in the institution will cease as of the effective date of the termination. However, any beneficiary admitted to the institution prior to any grace period extended to the institution under paragraph (f)(2)(ii)(A) of this section shall be advised that, if the beneficiary's care otherwise qualifies for CHAMPUS coverage, CHAMPUS cost-sharing of the care in the institution will continue in order to provide a reasonable period of transition of care; however the transitional period of CHAMPUS cost-sharing shall not exceed the last day of the month following the month in which the institution's status as a CHAMPUS provider is terminated. (This authorized CHAMPUS cost-sharing of the inpatient care received during the transition period is an exception to the general rule that CHAMPUS payment for care furnished after the effective date of termination of the provider's status shall be deemed to be an erroneous payment.) If a major violation under paragraph (f)(2)(ii)(B) of this section is involved, in order to ensure immediate action is taken to transfer beneficiaries to an approved provider, CHAMPUS cost-sharing shall not be authorized after the effective date of termination of the provider's status.

(ii) *Institutions not in compliance with CHAMPUS standards.* If it is determined that an institution is not in compliance with one or more of the standards applicable to its specific category of institution under this part, the Director, OCHAMPUS, or a designee, shall take immediate steps to bring about compliance or terminate the status of the provider as an authorized CHAMPUS provider.

(A) *Minor violations.* An institution determined to be in violation of one or more of the standards shall be advised by certified mail of the nature of the discrepancy or discrepancies and will be given a grace period of 30 days to effect appropriate corrections. The grace period may be extended at the discretion of the Director, OCHAMPUS, or a designee, but in no event shall the extension exceed 90 days.

(*1*) CHAMPUS will not cost-share a claim for any beneficiary admitted during the grace period.

(*2*) Any beneficiary admitted to the institution prior to the grace period (or the beneficiary's parent, guardian, or other representative) will be notified by the Director, OCHAMPUS, or a designee, in writing, of the minor violations and the grace period granted the institution to correct the violations. The beneficiary will also be advised that, if the beneficiary's care otherwise meets all requirements for CHAMPUS coverage, CHAMPUS cost-sharing will continue during the grace period.

(*3*) If the institution submits written notice before the end of the grace period that corrective action has been taken *and* if the Director, OCHAMPUS, or a designee, determines that the corrective action has eliminated the minor violations, the provider will be advised that the institution is restored to full status as an authorized

CHAMPUS provider as of 12:01 a.m. on the day written notice of correction was received by the Director, OCHAMPUS, or a designee, or the day on which acceptable corrective action was completed in the judgment of the Director, OCHAMPUS, or a designee. Any beneficiary admitted to the institution prior to the grace period will be notified by the Director, OCHAMPUS, or a designee, of the corrective action and that the provider continues to be an authorized CHAMPUS provider. CHAMPUS cost-sharing for any beneficiary admitted to the institution during the grace period shall be allowed only for care received after 12:01 a.m. on the day written notice of correction was received by the Director, OCHAMPUS, or a designee, or the day on which acceptable corrective action was completed in the judgment of the Director, OCHAMPUS, or a designee.

(*4*) If the institution has failed to give notification in writing before the end of the grace period that corrective action has been completed *or,* in the judgment of the Director, OCHAMPUS, or a designee, the institution has not completed acceptable corrective action during the grace period, the Director, OCHAMPUS, or a designee, may initiate action to terminate the provider as an authorized CHAMPUS provider.

(B) *Major violations.* If the Director, OCHAMPUS, or a designee, determines that an institution is in violation of standards detrimental to life, safety, or health, or substantially in violation of approved treatment programs, immediate action shall be taken to terminate the institution as an authorized CHAMPUS provider. The institution shall be notified by telegram, certified mail, or express mail of the termination under this subparagraph, effective on receipt of the notice. The notice shall include a brief statement of the nature of violations resulting in the termination and advise the institution that an initial determination formalizing the administrative action of termination will be issued pursuant to paragraph (h)(3)(ii) of this section within 15 days.

(3) *Beneficiary sanctions.* (i) With entitlement to CHAMPUS benefits based on public law, an eligible beneficiary will not be suspended or excluded from CHAMPUS. However, the Director, OCHAMPUS, or a designee, may take action deemed appropriate and reasonable to protect the Government from those beneficiaries (including sponsors, parents, guardians, or representatives of beneficiaries) who have submitted false claims.

(ii) Pursuant to §199.11 of this part, the Director, OCHAMPUS, or a designee, may recover erroneous payments on claims involving fraud or false or misleading statements. Remedies for recovery of the erroneous payments include the use of offset against future CHAMPUS payments.

(iii) Under policies adopted by the Director, OCHAMPUS, or a designee, individuals who, based on reliable information, have previously submitted fraudulent or false CHAMPUS claims, may be required to comply with any procedures (e.g., partial or total prepayment audit or review, restriction to a designated primary care provider, etc.) which the Director, OCHAMPUS, or a designee, deems appropriate to ensure that their future medical care and CHAMPUS claims (including the medical care and CHAMPUS claims submitted by or for members of their family) are valid.

(g) *Period of exclusion, suspension, or termination*—(1) *Exclusions or suspensions.* Except as otherwise required by paragraph (g)(1)(i) of this section, the Director, OCHAMPUS, or a designee, shall determine the period of exclusion or suspension for a provider using the factors set forth in paragraph (g)(1)(ii) of this section.

(i) *Exclusion or suspension of a provider based on the provider's exclusion or suspension by another agency of the Federal Government, a state, or a local licensing authority.* If the administrative action under CHAMPUS is based *solely* on the provider's exclusion or suspension by another agency, state, or local licensing authority, the period of exclusion or suspension under CHAMPUS shall be for the same length of time of exclusion or suspension imposed by the other agency, state, or local licensing authority. The provider may request reinstatement as an authorized CHAMPUS provider if reinstatement is achieved under the other program prior to the end of the period of exclusion or

suspension. If the administrative action under CHAMPUS is not based *solely* on the provider's exclusion or suspension by another agency, state, or local licensing authority, the minimum period of exclusion or suspension shall be for the same period of exclusion or suspension imposed by the other agency, state, or local licensing authority.

(ii) *Factors to be considered in determining the period of exclusion or suspension of providers under CHAMPUS.* In determining the period of exclusion or suspension of a provider, the Director, OCHAMPUS, or a designee, may consider any or all of the following:

(A) When the case concerns all or any part of the same issues which have been the subject of criminal conviction or civil judgment involving fraud by a provider:

(*1*) The period(s) of sentence, probation, and other sanction imposed by court order against the provider may be presumed reasonable and adopted as the administrative period of exclusion or suspension under CHAMPUS, unless aggravating or mitigating factors exist.

(*2*) If any aggravating factors exist, then cause exists for the Director, OCHAMPUS, or a designee, to consider the factors set forth in paragraph (g)(1)(ii)(B) of this section, in imposing a period of administrative exclusion or suspension in excess of the period(s) of sentence, probation, and/or other sanctions imposed by court order. Examples of aggravating factors include, but are not limited to:

(*i*) An administrative determination by the Director, OCHAMPUS, or a designee, that the basis for administrative exclusion or suspension includes an act(s) of fraud or abuse under CHAMPUS in addition to, or unrelated to, an act(s) of fraud included in the court conviction or civil judgment.

(*ii*) The fraudulent act(s) involved in the criminal conviction or civil judgment, or similar acts, were committed over a significant period of time; that is, one year or more.

(*iii*) The act(s) of fraud or abuse had an adverse physical, mental, or financial impact on one or more CHAMPUS beneficiaries.

(*iv*) The loss or potential loss to CHAMPUS is over $5,000. The entire amount of loss or potential loss to CHAMPUS due to acts of fraud and abuse will be considered, in addition to the amount of loss involved in the court conviction or civil judgment, regardless of whether full or partial restitution has been made to CHAMPUS.

(*v*) The provider has a prior court record, criminal or civil, or administrative record or finding of fraud or abuse.

(*3*) If any mitigating factors exist, then cause may exist for the Director, OCHAMPUS, or a designee, to reduce a period of administrative exclusion or suspension from any period(s) imposed by court conviction or civil judgment. Only the existence of either of the following two factors may be considered in mitigation:

(*i*) The criminal conviction or civil judgment only involved three or fewer misdemeanor offenses, and the total of the estimated losses incurred (including any loss from act(s) not involved in the conviction or judgment) is less than $1,000, regardless of whether full or partial restitution has been made.

(*ii*) The criminal or civil court proceedings establish that the provider had a mental, emotional or physical condition, prior to or contemporaneous with the commission of the act(s), that reduced the provider's criminal or civil culpability.

(B) The Director, OCHAMPUS, or a designee, may consider the following factors in determining a reasonable period of exclusion or suspension of a provider under CHAMPUS:

(*1*) The nature of the claims and the circumstances under which they were presented;

(*2*) The degree of culpability;

(*3*) History of prior offenses (including whether claims were submitted while the provider was either excluded or suspended pursuant to prior administrative action);

(*4*) Number of claims involved;

(*5*) Dollar amount of claims involved;

(*6*) Whether, if a crime was involved, it was a felony or misdemeanor;

(*7*) If patients were injured financially, mentally, or physically; the number of patients; and the seriousness of the injury(ies);

(*8*) The previous record of the provider under CHAMPUS;

(*9*) Whether restitution has been made or arrangements for repayment accepted by the Government;

(*10*) Whether the provider has resolved the conflict of interest situations or implemented procedures acceptable to the Director, OCHAMPUS, or a designee, which will prevent conflict of interest in the future; and,

(*11*) Such other factors as may be deemed appropriate.

(2) *Terminations.* When a provider's status as an authorized CHAMPUS provider is ended, other than through exclusion or suspension, the termination is based on a finding that the provider does not meet the qualifications to be an authorized provider, as set forth in this part. Therefore, the period of termination in all cases will be indefinite and will end only after the provider has successfully met the established qualifications for authorized provider status under CHAMPUS and has been reinstated under CHAMPUS. Except as otherwise provided in this subparagraph, the following guidelines control the termination of authorized CHAMPUS provider status for a provider whose license to practice (or, in the case of an institutional provider, to operate) has been temporarily or permanently suspended or revoked by the jurisdiction issuing the license.

(i) Termination of the provider under CHAMPUS shall continue even if the provider obtains a license to practice in a second jurisdiction during the period of suspension or revocation of the provider's license by the original licensing jurisdiction. A provider who has licenses to practice in two or more jurisdictions and has one or more license(s) suspended or revoked will also be terminated as a CHAMPUS provider.

(A) Professional providers shall remain terminated from the CHAMPUS until the jurisdiction(s) suspending or revoking the provider's license(s) to practice restores it or removes the impediment to restoration.

(B) Institutional providers shall remain terminated under CHAMPUS until their license is restored. In the event the facility is sold, transferred, or reorganized as a new legal entity, and a license issued under a new name or to a different legal entity, the new entity must submit an application to be an authorized CHAMPUS provider.

(ii) If the CHAMPUS provider status is terminated due to the loss of the provider's license, the effective date shall be retroactive to the date the provider lost the license; however, in the case of a professional provider who has licenses in two or more jurisdictions and submitted claims from a jurisdiction from which he/she had a valid license, the effective date of the termination will be 15 calendar days from the date of the written initial determination of termination for purposes of claims from the jurisdiction in which the provider still has a valid license.

(h) *Procedures for initiating and implementing the administrative remedies*—(1) *Temporary suspension of claims processing.* (i) In general, temporary suspension of claims processing may be invoked to protect the interests of the Government for a period reasonably necessary to complete investigation or appropriate criminal, civil, and administrative proceedings. The temporary suspension only delays the ultimate payment of otherwise appropriate claims. When claims processing involving a participating provider is temporarily suspended, the participation agreement remains in full force and the provider cannot repudiate the agreement because of the delay in the final disposition of the claim(s). Once it has been determined appropriate to end the temporary suspension of claims processing, CHAMPUS claims which were the subject of the suspension and which are otherwise determined to be in compliance with the requirements of law and regulation, will be processed to completion and payment *unless* such action is deemed inappropriate as a result of criminal, civil, or administrative remedies ultimately invoked in the case.

(ii) When adequate evidence exists to determine that a provider or beneficiary is submitting fraudulent or false claims or claims involving practices that may be fraud or abuse as defined by this part, the Director, OCHAMPUS, or a designee, may suspend CHAMPUS claims processing (in whole or in part) for claims submitted

by the beneficiary or any CHAMPUS claims involving care furnished by the provider. The temporary suspension of claims processing for care furnished by a provider may be invoked against all such claims, whether or not the claims are submitted by the beneficiary or by the provider as a participating CHAMPUS provider. In cases involving a provider, notice of the suspension of claims processing may also be given to the beneficiary community either directly or indirectly through notice to appropriate military facilities, health benefit advisors, and the information or news media.

(A) Adequate evidence is any information sufficient to support the reasonable belief that a particular act or omission has occurred.

(B) Indictment or any other initiation of criminal charges, filing of a complaint for civil fraud, issuance of an administrative complaint under the Program Fraud Civil Remedies Act, or issuance of an initial determination under this part for submitting fraudulent or false claims or claims involving practices that may be fraud or abuse as defined by this part, shall constitute adequate evidence for invoking temporary suspension of claims processing.

(iii) The Director, OCHAMPUS, or a designee, may suspend CHAMPUS claims processing without first notifying the provider or beneficiary of the intent to suspend payments. Following a decision to invoke a temporary suspension, however, the Director, OCHAMPUS, or a designee, shall issue written notice advising the provider or beneficiary that:

(A) A temporary suspension of claims processing has been ordered and a statement of the basis of the decision to suspend payment. Unless the suspension is based on any of the actions set forth in paragraph (h)(1)(ii)(B) of this section, the notice shall describe the suspected acts or omissions in terms sufficient to place the provider or beneficiary on notice without disclosing the Government's evidence.

(B) Within 30 days (or, upon written request received by OCHAMPUS during the 30 days and for good cause shown, within 60 days) from the date of the notice, the provider or beneficiary may:

(*1*) Submit to the Director, OCHAMPUS, or a designee, in writing, information (including documentary evidence) and argument in opposition to the suspension, provided the additional specific information raises a genuine dispute over the material facts, or

(*2*) Submit a written request to present in person evidence or argument to the Director, OCHAMPUS, or a designee. All such presentations shall be made at the Office of Civilian Health and Medical Program of the Uniformed Services (OCHAMPUS) in Aurora, Colorado, at the provider's or beneficiary's own expense.

(C) Additional proceedings to determine disputed material facts may be conducted unless:

(*1*) The suspension is based on any of the actions set forth in paragraph (h)(1)(ii)(B) of this section, or,

(*2*) A determination is made, on the basis of the advice of the responsible Government official (e.g., an official of the Department of Justice, the designated Reviewing Official under the Program Fraud Civil Remedies Act, etc.), that the substantial interests of the Government in pending or contemplated legal or administrative proceedings based on the same facts as the suspension would be prejudiced.

(iv) If the beneficiary or provider submits, either in writing or in person, additional information or argument in opposition to the suspension, the Director, OCHAMPUS, or a designee, shall issue a suspending official's decision which modifies, terminates, or leaves in force the suspension of claims processing. However, a decision to terminate or modify the suspension shall be without prejudice to the subsequent imposition of suspension of claims processing, imposition of sanctions under this §199.9, the recovery of erroneous payments under §199.11 of this part, or any other administrative or legal action authorized by law or regulation. The suspending official's decision shall be in writing as follows:

(A) A written decision based on all the information in the administrative record, including any submission by the beneficiary or provider, shall be final in a case:

(*1*) Based on any of the actions set forth in paragraph (h)(1)(ii)(B) of this section,

(*2*) In which the beneficiary's or provider's submission does not raise a genuine dispute over material facts, or

(*3*) In which additional proceedings to determine disputed material facts have been denied on the basis of advice of a responsible Government official that the substantial interests of the Government in pending or contemplated legal or administrative proceedings would be prejudiced.

(B) In a case in which additional proceedings are necessary as to disputed material facts, the suspending official's decision shall advise the beneficiary or provider that the case has been referred for handling as a hearing under § 199.10 of this part.

(v) A suspension of claims processing may be modified or terminated for reasons such as:

(A) Newly discovered evidence;

(B) Elimination of any of the causes for which the suspension was invoked; or

(C) Other reasons the Director, OCHAMPUS, or a designee, deems appropriate.

(vi) A suspension of claims processing shall be for a temporary period pending the completion of investigation and any ensuing legal or administrative proceedings, unless sooner terminated by the Director, OCHAMPUS, or a designee, or as provided in this subparagraph.

(A) If legal or administrative proceedings are not initiated within 12 months after the date of the suspension notice, the suspension shall be terminated unless the Government official responsible for initiation of the legal or administrative action requests its extension, in which case it may be extended for an additional 6 months. In no event may a suspension extend beyond 18 months, unless legal or administrative proceedings have been initiated during that period.

(B) The Director, OCHAMPUS, or a designee, shall notify the Government official responsible for initiation of the legal or administrative action of the proposed termination of the suspension, at least 30 days before the 12-month period expires, to give the official an opportunity to request an extension.

(2) *Notice of proposed administrative sanction.* (i) A provider shall be notified in writing of the proposed action to exclude, suspend, or terminate the provider's status as an authorized CHAMPUS provider.

(A) The notice shall state which sanction will be taken and the effective date of that sanction as determined in accordance with the provisions of this part.

(B) The notice shall inform the provider of the situation(s), circumstance(s), or action(s) which form the basis for the proposed sanction and reference the paragraph of this part under which the administrative action is being taken.

(C) The notice will be sent to the provider's last known business or office address (or home address if there is no known business address.)

(D) The notice shall offer the provider an opportunity to respond within 30 days (or, upon written request received by OCHAMPUS during the 30 days and for good cause shown, within 60 days) from the date on the notice with either:

(*1*) Documentary evidence and written argument contesting the proposed action; or,

(*2*) A written request to present in person evidence or argument to the Director, OCHAMPUS, or a designee. All such presentations shall be made at the Office of the Civilian Health and Medical Program of the Uniformed Services (OCHAMPUS) in Aurora, Colorado, at the provider's own expense.

(3) *Initial determination.* (i) If, after the provider has exhausted, or failed to comply with, the procedures specified in paragraph (h)(2) of this section, the Director, OCHAMPUS, or a designee, decides to invoke an administrative remedy of exclusion, suspension, or termination of a provider under CHAMPUS, written notice of the decision will be sent to the provider by certified mail. Except in those cases where the sanction has a retroactive effective date, the written notice shall be dated no later than 15 days before the decision becomes effective. For terminations under paragraph (f)(2)(ii)(B)

of this section, the initial determination may be issued without first implementing or exhausting the procedures specified in paragraph (h)(2) of this section.

(ii) The initial determination shall include:

(A) A statement of the sanction being invoked;

(B) A statement of the effective date of the sanction;

(C) A statement of the facts, circumstances, or actions which form the basis for the sanction and a discussion of any information submitted by the provider relevant to the sanction;

(D) A statement of the factors considered in determining the period of sanction;

(E) The earliest date on which a request for reinstatement under CHAMPUS will be accepted;

(F) The requirements and procedures for reinstatement; and,

(G) Notice of the available hearing upon request of the sanctioned provider.

(4) *Reinstatement procedures*—(i) *Restitution.* (A) There is no entitlement under CHAMPUS for payment (cost-sharing) of any claim that involves either criminal or civil fraud as defined by law, or fraud or abuse or conflict of interest as defined by this part. In addition, except as specifically provided in this part, there is no entitlement under CHAMPUS for payment (cost-sharing) of any claim for services or supplies furnished by a provider who does not meet the requirements to be an authorized CHAMPUS provider. In any of the situations described above, CHAMPUS payment shall be denied whether the claim is submitted by the provider as a participating claim or by the beneficiary for reimbursement. If an erroneous payment has been issued in any such case, collection of the payment will be processed under §199.11 of this part.

(B) If the Government has made erroneous payments to a provider because of claims involving fraud, abuse, or conflicts of interest, restitution of the erroneous payments shall be made before a request for reinstatement as a CHAMPUS authorized provider will be considered. Without restitution or resolution of the debt under §199.11 of this part, a provider shall not be reinstated as an authorized CHAMPUS provider. This is not an appealable issue under §199.10 of this part.

(C) For purposes of authorization as a CHAMPUS provider, a provider who is excluded or suspended under this §199.9 and who submits participating claims for services furnished on or after the effective date of the exclusion or suspension is considered to have forfeited or waived any right or entitlement to bill the beneficiary for the care involved in the claims. Similarly, because a provider is expected to know the CHAMPUS requirements for qualification as an authorized provider, any participating provider who fails to meet the qualification requirements for CHAMPUS is considered to have forfeited or waived any right or entitlement to bill the beneficiary for the care involved in the CHAMPUS claims. If, in either situation, the provider bills the beneficiary, restitution to the beneficiary may be required by the Director, OCHAMPUS, or a designee, as a condition for consideration of reinstatement as a CHAMPUS authorized provider.

(ii) *Terminated providers.* A terminated provider who subsequently achieves the minimum qualifications to be an authorized CHAMPUS provider or who has had his/her license reinstated or the impediment to reinstatement removed by the appropriate licensing jurisdiction may submit a written request for reinstatement under CHAMPUS to the Director, OCHAMPUS, or a designee. If restitution or proper reinstatement of license is not at issue, the Director, OCHAMPUS, or a designee, will process the request for reinstatement under the procedures established for initial requests for authorized CHAMPUS provider status.

(iii) *Providers (other than entities) excluded or suspended under CHAMPUS.* (A) A provider excluded or suspended from CHAMPUS (other than an entity excluded under §199.9(f)(1)(i)) may seek reinstatement by submitting a written request to the Director, OCHAMPUS, or a designee, any time after the date specified in the notice of exclusion or suspension or any earlier date specified

in an appeal decision issued in the provider's appeal under §199.10 of this part. The request for reinstatement shall include:

(*1*) Documentation sufficient to establish the provider's qualifications under this part to be a CHAMPUS authorized provider;

(*2*) A statement from the provider setting forth the reasons why the provider should be reinstated, accompanied by written statements from professional associates, peer review bodies, and/or probation officers (if appropriate), attesting to their belief that the violations that led to exclusion or suspension will not be repeated.

(B) A provider entity excluded from CHAMPUS under §199.9(f)(1)(i) may seek reinstatement by submitting a written request to the Director, OCHAMPUS, or a designee, with documentation sufficient to establish the provider's qualifications under this part to be a CHAMPUS authorized provider and either:

(*1*) Documentation showing the CHAMPUS reinstatement of the excluded individual provider whose conviction led to the CHAMPUS exclusion or suspension of the provider entity; *or*

(*2*) Documentation acceptable to the Director, OCHAMPUS, or a designee, that shows that the individual whose conviction led to the entity's exclusion:

(*i*) Has reduced his or her ownership or control interest in the entity below 5 percent; or

(*ii*) Is no longer an officer, director, agent or managing employee of the entity; or

(*iii*) Continues to maintain a 5 percent or more ownership or control interest in such entity, and that the entity due to circumstances beyond its control, is unable to obtain a divestiture.

NOTE: Under paragraph (h)(4)(iii)(B)(*2*) of this section, the request for reinstatement may be submitted any time prior to the date specified in the notice of exclusion or suspension or an earlier date specified in the appeal decision issued under §199.10 of this part.

(iv) *Action on request for reinstatement.* In order to reinstate a provider as a CHAMPUS authorized provider, the Director, OCHAMPUS, or a designee, must determine that:

(A) The provider meets all requirements under this part to be an authorized CHAMPUS provider;

(B) No additional criminal, civil, or administrative action has been taken or is being considered which could subject the provider to exclusion, suspension, or termination under this section;

(C) In the case of a provider entity, verification has been made of the divestiture or termination of the owner, controlling party, officer, director, agent or managing employee whose conviction led to the entity's exclusion, *or* that the provider entity should be reinstated because the entity, due to circumstances beyond its control, cannot obtain a divestiture of the 5 percent or more ownership or controlling interest by the convicted party.

(v) *Notice of action on request for reinstatement*—(A) *Notice of approval of request.* If the Director, OCHAMPUS, or a designee, approves the request for reinstatement, he or she will:

(*1*) Give written notice to the sanctioned party specifying the date when the authorized provider status under CHAMPUS may resume; and

(*2*) Give notice to those agencies and groups that were originally notified, in accordance with §199.9(k), of the imposition of the sanction. General notice may also be given to beneficiaries and other parties as deemed appropriate by the Director, OCHAMPUS, or a designee.

(B) *Notice of denial of request.* If the Director, OCHAMPUS, or a designee, does not approve the request for reinstatement, written notice will be given to the provider. If established procedures for processing initial requests for authorized provider status are used to review the request for reinstatement, the established procedures may be used to provide the notice that the provider does not meet requirements of this part for such status. If the provider continues to be excluded, suspended, or terminated under the provisions of this section, the procedures set forth in this paragraph (h) may be followed in denying the provider's request for reinstatement.

(5) *Reversed or vacated convictions or civil judgments involving CHAMPUS*

fraud. (i) If a CHAMPUS provider is excluded or suspended *solely* on the basis of a criminal conviction or civil judgment involving a CHAMPUS fraud and the conviction or judgment is reversed or vacated on appeal, CHAMPUS will void the exclusion of a provider. Such action will not preclude the initiation of additional independent administrative action under this section or any other administrative remedy based on the same facts or events which were the subject of the criminal conviction or civil judgment.

(ii) If an exclusion is voided under paragraph (h)(5)(i) of this section, CHAMPUS will make payment, either to the provider or the beneficiary (if the claim was not a participating claim) for otherwise authorized services under CHAMPUS that are furnished or performed during the period of exclusion.

(iii) CHAMPUS will also void the exclusion of any entity that was excluded under §199.9(f)(1)(i) based *solely* on an individual's conviction that has been reversed or vacated on appeal.

(iv) When CHAMPUS voids the exclusion of a provider or an entity, notice will be given to the agencies and others that were originally notified, in accordance with §199.9(k).

(i) *Evidence required for determinations to invoke administrative remedies*—(1) *General*. Any relevant evidence may be used by the Director, OCHAMPUS, or a designee, if it is the type of evidence on which reasonable persons are accustomed to rely in the conduct of serious affairs, regardless of the existence of any common law or statutory rule that might make improper the admission of such evidence over objection in civil or criminal courts.

(2) *Types of evidence*. The types of evidence which the Director, OCHAMPUS, or a designee, may rely on in reaching a determination to invoke administrative remedies under this section include but are not limited to the following:

(i) Results of audits conducted by or on behalf of the Government. Such audits can include the results of 100 percent review of claims and related records or a statistically valid sample audit of the claims or records. A statistical sampling shall constitute *prima facie* evidence of the number and amount of claims and the instances of fraud, abuse, or conflict of interest.

(ii) Reports, including sanction reports, from various sources including a peer review organization (PRO) for the area served by the provider; state or local licensing or certification authorities; peer or medical review consultants of the Government, including consultants for Government contractors; state or local professional societies; or other sources deemed appropriate by the Director, OCHAMPUS, or a designee.

(iii) Orders or documents issued by Federal, state, foreign, or other courts of competent jurisdiction which issue findings and/or criminal convictions or civil judgments involving the provider, and administrative rulings, findings, or determinations by any agency of the Federal Government, a state, or local licensing or certification authority regarding the provider's status with that agency or authority.

(j) *Suspending Administrative Action*. (1) All or any administrative action may be suspended by the Director, OCHAMPUS, or a designee, pending action in the case by the Department of Defense—Inspector General, Defense Criminal Investigative Service, or the Department of Justice (including the responsible United States Attorney). However, action by the Department of Defense—Inspector General or the Department of Justice, including investigation, criminal prosecution, or civil litigation, does not preclude administrative action by OCHAMPUS.

(2) The normal OCHAMPUS procedure is to suspend action on the administrative process pending an investigation by the Department of Defense—Inspector General or final disposition by the Department of Justice.

(3) Though OCHAMPUS administrative action is taken independently of any action by the Department of Defense-Inspector General or by the Department of Justice, once a case is forwarded to the Department of Defense-Inspector General or the Department of Justice for legal action (criminal or civil), administrative action may be held in abeyance.

(4) In some instances there may be dual jurisdiction between agencies; as

in, for example, the joint regulations issued by the Department of Justice and the Government Accounting Office regarding debt collection.

(k) *Notice to Other Agencies.* (1) When CHAMPUS excludes, suspends, or terminates a provider, the Director, OCHAMPUS, or a designee, will notify other appropriate agencies (for example, the Department of Health and Human Services and the state licensing agency that issued the provider's license to practice) that the individual has been excluded, suspended, or terminated as an authorized provider under CHAMPUS. An exclusion, suspension, or termination action is considered a public record. Such notice can include the notices and determinations sent to the suspended provider and other public documents such as testimony given at a hearing or exhibits or depositions given in a lawsuit or hearing. Notice may also be given to Uniformed Services Military Treatment Facilities, Health Benefit Advisors, beneficiaries and sponsors, the news media, and institutional providers if inpatient care was involved.

(2) If CHAMPUS has temporarily suspended claims processing, notice of such action normally will be given to the affected provider and Uniformed Services Medical Treatment Facilities, Health Benefits Advisors, beneficiaries, and sponsors. Notice may also be given to any information or news media and any other individual, professional provider, or institutional provider, as deemed appropriate. However, since a ''temporary suspension of claims processing'' is by definition not a final or formal agency action, the basis for the action generally will not be disclosed. It is noted that the basis for the action can be a result of questions arising from routine audits to investigation of possible criminal violations.

(l) *Compromise, Settlement, and Resolution Authority.* (1) In lieu of invoking any remedy provided by this Section, the Director, OCHAMPUS, or a designee, may elect to enter into an agreement with the provider intended to correct the situation within an established time period and subject to any remedies deemed appropriate by the Director, OCHAMPUS, or a designee.

(2) When it is in the best interest of CHAMPUS, the Director, OCHAMPUS, has the discretionary authority to waive an action or enter into compromise or settlement of administrative actions taken under this § 199.9.

(m) *Government-wide effect of exclusion or suspension from CHAMPUS.* As provided by section 2455 of the Federal Acquisition Streamlining Act of 1994, Pub. L. 103–355, October 13 1994, and Executive Order 12549, ''Debarment and Suspension from Federal Financial and Nonfinancial Assistance Programs,'' February 18, 1986, any health care provider excluded or suspended from CHAMPUS under this section shall, as a general rule, also be debarred, suspended, or otherwise excluded from all other programs and activities involving Federal financial assistance. Among the other programs for which this debarment, suspension, or exclusion shall operate are the Medicare and Medicaid programs. This debarment, suspension, or termination requirement is subject to limited exceptions in the regulations governing the respective Federal programs affected. (Note: Other regulations related to this government-wide exclusion or suspension authority are 32 CFR Part 25 and 45 CFR Part 76.)

(n) Third-party billing agents as defined in § 199.2(b) of this part, while not considered providers, are subject to the provisions of this section to the same extent as such provisions apply to providers.

[54 FR 25246, June 14, 1989, as amended at 63 FR 48445, Sept. 10, 1998; 78 FR 12954, Feb. 26, 2013; 85 FR 60705, Sept. 28, 2020]

§ 199.10 Appeal and hearing procedures.

(a) *General.* This Section sets forth the policies and procedures for appealing decisions made by OCHAMPUS, OCHAMPUSEUR, and CHAMPUS contractors adversely affecting the rights and liabilities of CHAMPUS beneficiaries, CHAMPUS participating providers, and providers denied the status of authorized provider under CHAMPUS. An appeal under CHAMPUS is an administrative review of program determinations made under the provisions of law and regulation.

An appeal cannot challenge the propriety, equity, or legality of any provision of law or regulation.

(1) *Initial determination*—(i) *Notice of initial determination and right to appeal.* (A) OCHAMPUS, OCHAMPUSEUR, and CHAMPUS contractors shall mail notices of initial determinations to the affected provider or CHAMPUS beneficiary (or representative) at the last known address. For beneficiaries who are under 18 years of age or who are incompetent, a notice issued to the parent, guardian, or other representative, under established CHAMPUS procedures, constitutes notice to the beneficiary.

(B) CHAMPUS contractors and OCHAMPUSEUR shall notify a provider of an initial determination on a claim only if the provider participated in the claim. (See §199.7 of this part.)

(C) CHAMPUS peer review organizations shall notify providers and fiscal intermediaries of a denial determination on a claim.

(D) Notice of an initial determination on a claim processed by a CHAMPUS contractor or OCHAMPUSEUR normally will be made on a CHAMPUS Explanation of Benefits (CEOB) form.

(E) Each notice of an initial determination on a request for benefit authorization, a request by a provider for approval as an authorized CHAMPUS provider, or a decision to disqualify or exclude a provider as an authorized provider under CHAMPUS shall state the reason for the determination and the underlying facts supporting the determination.

(F) In any case when the initial determination is adverse to the beneficiary or participating provider, or to the provider seeking approval as an authorized CHAMPUS provider, the notice shall include a statement of the beneficiary's or provider's right to appeal the determination. The procedure for filing the appeal also shall be explained.

(ii) *Effect of initial determination.* (A) The initial determination is final unless appealed in accordance with this chapter, or unless the initial determination is reopened by the TRICARE Management Activity, the CHAMPUS contractor, or the CHAMPUS peer review organization.

(B) An initial determination involving a CHAMPUS beneficiary entitled to Medicare Part A, who is enrolled in Medicare Part B, may be appealed by the beneficiary or their provider under this section of this Part only when the claimed services or supplies are payable by CHAMPUS and are not payable under Medicare. Both Medicare and CHAMPUS offer an appeal process when a claim for healthcare services or supplies is denied and most healthcare services and supplies are a benefit payable under both Medicare and CHAMPUS. In order to avoid confusion on the part of beneficiaries and providers and to expedite the appeal process, services and supplies denied payment by Medicare will not be considered for coverage by CHAMPUS if the Medicare denial of payment is appealable under Medicare. Because such claims are not considered for payment by CHAMPUS, there can be no CHAMPUS appeal. If, however, a Medicare claim or appeal results in some payment by Medicare, the services and supplies paid by Medicare will be considered for payment by CHAMPUS. In that situation, any decision to deny CHAMPUS payment will be appealable under this section. The following examples of CHAMPUS appealable issues involving Medicare-eligible CHAMPUS beneficiaries are illustrative; they are not all-inclusive.

(*1*) If Medicare processes a claim for a healthcare service or supply that is a Medicare benefit and the claim is denied by Medicare for a patient-specific reason, the claim is appealable through the Medicare appeal process. The Medicare decision will be final if the claim is denied by Medicare. The claimed services or supplies will not be considered for CHAMPUS payment and there is no CHAMPUS appeal of the CHAMPUS decision denying the claim.

(*2*) If Medicare processes a claim for a healthcare service or supply that is a Medicare benefit and the claim is paid, either on initial submission or as a result of a Medicare appeal decision, the claim will be submitted to CHAMPUS for processing as a second payer to

Medicare. If CHAMPUS denies payment of the claim, the Medicare-eligible beneficiary or their provider have the same appeal rights as other CHAMPUS beneficiaries and their providers under this section.

(*3*) If Medicare processes a claim and the claim is denied by Medicare because it is not a healthcare service or supply that is a benefit under Medicare, the claim is submitted to CHAMPUS. CHAMPUS will process the claim under this Part 199 as primary payer (or as secondary payer if another double coverage plan exists). If any part of the claim is denied, the Medicare-eligible beneficiary and their provider will have the same appeal rights as other CHAMPUS beneficiaries and their providers under this section.

(2) *Participation in an appeal.* Participation in an appeal is limited to any party to the initial determination, including CHAMPUS, and authorized representatives of the parties. Any party to the initial determination, except CHAMPUS, may appeal an adverse determination. The appealing party is the party who actually files the appeal.

(i) *Parties to the initial determination.* For purposes of the CHAMPUS appeals and hearing procedures, the following are not parties to an initial determination and are not entitled to administrative review under this section.

(A) A provider disqualified or excluded as an authorized provider under CHAMPUS based on a determination of abuse or fraudulent practices or procedures under another Federal or federally funded program is not a party to the CHAMPUS action and may not appeal under this section.

(B) A beneficiary who has an interest in receiving care or has received care from a particular provider cannot be an appealing party regarding the exclusion, suspension, or termination of the provider under § 199.9 of this part.

(C) A sponsor or parent of a beneficiary under 18 years of age or guardian or an incompetent beneficiary is not a party to the initial determination and may not serve as the appealing party, although such persons may represent the appealing party in an appeal.

(D) A third party, such as an insurance company, is not a party to the initial determination and is not entitled to appeal even though it may have an indirect interest in the initial determination.

(E) A nonparticipating provider is not a party to the initial determination and may not appeal.

(ii) *Representative.* Any party to the initial determination may appoint a representative to act on behalf of the party in connection with an appeal. Generally, the parent of a minor beneficiary and the legally appointed guardian of an incompetent beneficiary shall be presumed to have been appointed representative without specific designation by the beneficiary. The custodial parent or legal guardian (appointed by a cognizant court) of a minor beneficiary may initiate an appeal based on the above presumption. However, should a minor beneficiary turn 18 years of age during the course of an appeal, then any further requests to appeal on behalf of the beneficiary must be from the beneficiary or pursuant to the written authorization of the beneficiary appointing a representative. For example, if the beneficiary is 17 years of age and the sponsor (who is a custodial parent) requests a formal review, absent written objection by the minor beneficiary, the sponsor is presumed to be acting on behalf of the minor beneficiary. Following the issuance of the formal review, the sponsor requests a hearing; however if, at the time of the request for a hearing, the beneficiary is 18 years of age or older, the request must either be by the beneficiary or the beneficiary must appoint a representative. The sponsor, in this example, could not pursue the request for hearing without being appointed by the beneficiary as the beneficiary's representative.

(A) The representative shall have the same authority as the party to the appeal and notice given to the representative shall constitute notice required to be given to the party under this part.

(B) To avoid possible conflicts of interest, an officer or employee of the United States, such as an employee or member of a Uniformed Service, including an employee or staff member of a Uniformed Service legal office, or a

CHAMPUS advisor, subject to the exceptions in 18 U.S.C. 205, is not eligible to serve as a representative. An exception usually is made for an employee or member of a Uniformed Service who represents an immediate family member. In addition, the Director, OCHAMPUS, or designee, may appoint an officer or employee of the United States as the CHAMPUS representative at a hearing.

(3) *Burden of proof.* The burden of proof is on the appealing party to establish affirmatively by substantial evidence the appealing party's entitlement under law and this part to the authorization of CHAMPUS benefits, approval of authorized CHAMPUS provider status, or removal of sanctions imposed under §199.9 of this part. If a presumption exists under the provisions of this part or information constitutes *prima facie* evidence under the provisions of this part, the appealing party must produce evidence reasonably sufficient to rebut the presumption or *prima facie* evidence as part of the appealing party's burden of proof. CHAMPUS shall not pay any part of the cost or fee, including attorney fees, associated with producing or submitting evidence in support of an appeal.

(4) *Evidence in appeal and hearing cases.* Any relevant evidence may be used in the administrative appeal and hearing process if it is the type of evidence on which reasonable persons are accustomed to rely in the conduct of serious affairs, regardless of the existence of any common law or statutory rule that might make improper the admission of such evidence over objection in civil or criminal courts.

(5) *Late filing.* If a request for reconsideration, formal review, or hearings is filed after the time permitted in this section, written notice shall be issued denying the request. Late filing may be permitted only if the appealing party reasonably can demonstrate to the satisfaction of the Director, OCHAMPUS, or a designee, that the timely filing of the request was not feasible due to extraordinary circumstances over which the appealing party had no practical control. Each request for an exception to the filing requirement will be considered on its own merits. The decision of the Director, OCHAMPUS, or a designee, on the request for an exception to the filing requirement shall be final.

(6) *Appealable issue.* An appealable issue is required in order for an adverse determination to be appealed under the provisions of this section. Examples of issues that are not appealable under this section include:

(i) A dispute regarding a requirement of the law or regulation.

(ii) The amount of the CHAMPUS-determined allowable cost or charge, since the methodology for determining allowable costs or charges is established by this part.

(iii) The establishment of diagnosis-related groups (DRGs), or the methodology for the classification of inpatient discharges within the DRGs, or the weighting factors that reflect the relative hospital resources used with respect to discharges within each DRG, since each of these is established by this part.

(iv) Certain other issues on the basis that the authority for the initial determination is not vested in CHAMPUS. Such issues include but are not limited to the following examples:

(A) Determination of a person's eligibility as a CHAMPUS beneficiary is the responsibility of the appropriate Uniformed Service. Although OCHAMPUS, OCHAMPUSEUR, and CHAMPUS contractors must make determinations concerning a beneficiary's eligibility in order to ensure proper disbursement of appropriated funds on each CHAMPUS claim processed, ultimate responsibility for resolving a beneficiary's eligibility rests with the Uniformed Services. Accordingly, disputed question of fact concerning a beneficiary's eligibility will not be considered an appealable issue under the provisions of this section, but shall be resolved in accordance with §199.3 of this part.

(B) Similarly, decisions relating to the issuance of a Nonavailability Statement (DD Form 1251) in each case are made by the Uniformed Services. Disputes over the need for a Nonavailability Statement or a refusal to issue a Nonavailability Statement are not appealable under this section. The one exception is when a dispute arises over whether the facts of the case demonstrate a medical emergency for which a Nonavailability Statement is

not required. Denial of payment in this one situation is an appealable issue.

(C) Any sanction, including the period of the sanction, imposed under §199.9 of this part which is based solely on a provider's exclusion or suspension by another agency of the Federal Government, a state, or a local licensing authority is not appealable under this section. The provider must exhaust administrative appeal rights offered by the other agency that made the initial determination to exclude or suspend the provider. Similarly, any sanction imposed under §199.9 which is based solely on a criminal conviction or civil judgment against the provider is not appealable under this section. If the sanction imposed under §199.9 is not based solely on the provider's criminal conviction or civil judgment or on the provider's exclusion or suspension by another agency of the Federal Government, a state, or a local licensing authority, that portion of the CHAMPUS administrative determination which is in addition to the criminal conviction/civil judgment or exclusion/suspension by the other agency may be appealed under this section.

(v) A decision by the Director, OCHAMPUS, or a designee, as a suspending official when the decision is final under the provisions of §199.9(h)(1)(iv)(A).

(7) *Amount in dispute.* An amount in dispute is required for an adverse determination to be appealed under the provisions of this section, except as set forth below.

(i) The amount in dispute is calculated as the amount of money CHAMPUS would pay if the services and supplies involved in dispute were determined to be authorized CHAMPUS benefits. Examples of amounts of money that are excluded by the Regulation from CHAMPUS payments for authorized benefits include, but are not limited to:

(A) Amounts in excess of the CHAMPUS-determined allowable charge or cost.

(B) The beneficiary's CHAMPUS deductible and cost-share amounts.

(C) Amounts that the CHAMPUS beneficiary, or parent, guardian, or other responsible person has no legal obligation to pay.

(D) Amounts excluded under the provisions of §199.8 of this part.

(ii) The amount of dispute for appeals involving a denial of a request for authorization in advance of obtaining care shall be the estimated allowable charge or cost for the services requested.

(iii) There is no requirement for an amount in dispute when the appealable issue involves a denial of a provider's request for approval as an authorized CHAMPUS provider or the determination to exclude, suspend, or terminate a provider's authorized CHAMPUS provider status.

(iv) Individual claims may be combined to meet the required amount in dispute if all of the following exist:

(A) The claims involve the same beneficiary.

(B) The claims involve the same issue.

(C) At least one of the claims so combined has had a reconsideration decision issued by OCHAMPUSEUR, a CHAMPUS contractor, or a CHAMPUS peer review organization.

NOTE: A request for administrative review under this appeal process which involves a dispute regarding a requirement of law or regulation (paragraph (a)(6)(i) of this section) or does not involve a sufficient amount in dispute (paragraph (a)(7) of this section) may not be rejected at the reconsideration level of appeal. However, an appeal shall involve an appealable issue and sufficient amount in dispute under these paragraphs to be granted a formal review or hearing.

(8) *Levels of appeal.* The sequence and procedures of a CHAMPUS appeal vary, depending on whether the initial determination was made by OCHAMPUS, OCHAMPUSEUR, a CHAMPUS contractor, or a CHAMPUS peer review organization.

(i) *Appeal levels for initial determination made by OCHAMPUSEUR, CHAMPUS contractor, or CHAMPUS peer review organization.* (A) Reconsideration by OCHAMPUSEUR, CHAMPUS contractor, or CHAMPUS peer review organization.

(B) Formal review by OCHAMPUS (except for CHAMPUS peer review organization reconsiderations).

(C) Hearing.

(ii) *Appeal levels for initial determination made by OCHAMPUS.* (A) Reconsideration by OCHAMPUSEUR or CHAMPUS contractor.

(B) Formal review by OCHAMPUS *except* (*1*) initial determinations involving the suspension of claims processing where the Director, OCHAMPUS, or a designee, determines that additional proceedings are necessary as to disputed material facts and the suspending official's decision is not final under the provisions of §199.9(h)(1)(iv)(A) or (*2*) initial determinations involving the sanctioning (exclusion, suspension, or termination) of CHAMPUS providers. Initial determinations involving these matters shall be appealed directly to the hearing level.

(C) Hearing.

(9) *Appeal decision.* An appeal decision at any level may address all pertinent issues which arise under the appeal or are otherwise presented by the information in the case record (for example, the entire episode of care in the appeal), and shall not be limited to addressing the specific issue appealed by a party. In the case of sanctions imposed under §199.9, the final decision may affirm, increase or reduce the sanction period imposed by CHAMPUS, or otherwise modify or reverse the imposition of the sanction.

(b) *Reconsideration.* Any party to the initial determination made by the CHAMPUS contractor, or a CHAMPUS peer review organization may request reconsideration.

(1) *Requesting a reconsideration*—(i) *Written request required.* The request must be in writing, shall state the specific matter in dispute, and shall include a copy of the notice of initial determination (such as the CEOB form) made by OCHAMPUSEUR, the CHAMPUS contractor, or the CHAMPUS peer review organization.

(ii) *Where to file.* The request shall be submitted to the office that made the initial determination (i.e., OCHAMPUSEUR, the CHAMPUS contractor, or the CHAMPUS peer review organization) or any other CHAMPUS contractor designated in the notice of initial determination.

(iii) *Allowed time to file.* The request must be mailed within 90 days after the date of the notice of initial determination.

(iv) *Official filing date.* A request for a reconsideration shall be deemed filed on the date it is mailed and postmarked. If the request does not have a postmark, it shall be deemed filed on the date received by OCHAMPUSEUR, the CHAMPUS contractor or the CHAMPUS peer review organization.

(2) *The reconsideration process.* The purpose of the reconsideration is to determine whether the initial determination was made in accordance with law, regulation, policies, and guidelines in effect at the time the care was provided or requested, or at the time of the initial determination and/or reconsideration decision involving a provider request for approval as an authorized provider under CHAMPUS. The reconsideration is performed by a member of the OCHAMPUSEUR, CHAMPUS contractor, or CHAMPUS peer review organization staff who was not involved in making the initial determination and is a thorough and independent review of the case. The reconsideration is based on the information submitted that led to the initial determination, plus any additional information that the appealing party may submit or OCHAMPUSEUR, the CHAMPUS contractor, or CHAMPUS peer review organization may obtain.

(3) *Timeliness of reconsideration determination.* OCHAMPUSEUR, the CHAMPUS contractor, or CHAMPUS peer review organization normally shall issue its reconsideration determination no later than 60 days from the date of receipt of the request for reconsideration by OCHAMPUSEUR, the CHAMPUS contractor, or the CHAMPUS peer review organization.

(4) *Notice of reconsideration determination.* OCHAMPUSEUR, the CHAMPUS contractor, or the CHAMPUS peer review organization shall issue a written notice of the reconsideration determination to the appealing party at his or her last known address. The notice of the reconsideration must contain the following elements:

(i) A statement of the issues or issue under appeal.

(ii) The provisions of law, regulation, policies, and guidelines that apply to the issue or issues under appeal.

(iii) A discussion of the original and additional information that is relevant to the issue or issues under appeal.

(iv) Whether the reconsideration upholds the initial determination or reverses it, in whole or in part, and the rationale for the action.

(v) A statement of the right to appeal further in any case when the reconsideration determination is less than fully favorable to the appealing party and the amount in dispute is $50 or more.

(5) *Effect of reconsideration determination.* The reconsideration determination is final if either of the following exist:

(i) The amount in dispute is less than $50.

(ii) Appeal rights have been offered, but a request for formal review is not received by OCHAMPUS within 60 days of the date of the notice of the reconsideration determination.

(c) *Formal review.* Except as explained in this paragraph, any party to an initial determination made by OCHAMPUS, or a reconsideration determination made by the CHAMPUS contractor, may request a formal review by OCHAMPUS if the party is dissatisfied with the initial or reconsideration determination unless the initial or reconsideration determination is final under paragraph (b)(5) of this section; involves the sanctioning of a provider by the exclusion, suspension or termination of authorized provider status; involves a written decision issued pursuant to §199.9(h)(1)(iv)(A) regarding the temporary suspension of claims processing; or involves a reconsideration determination by a CHAMPUS peer review organization. A hearing, but not a formal review level of appeal, may be available to a party to an initial determination involving the sanctioning of a provider or to a party to a written decision involving a temporary suspension of claims processing. A beneficiary (or an authorized representative of a beneficiary), but not a provider (except as provided in §199.15), may request a hearing, but not a formal review, of a reconsideration determination made by a CHAMPUS peer review organization.

(1) *Requesting a formal review.* (i) *Written request required.* The request must be in writing, shall state the specific matter in dispute, shall include copies of the written determination (notice of reconsideration determination or OCHAMPUS initial determination) being appealed, and shall include any additional information or documents not submitted previously.

(ii) *Where to file.* The request shall be submitted to the Chief, Office of Appeals and Hearings, TRICARE Management Activity, 16401 East Centretech Parkway, Auroa, Colorado 80011–9066.

(iii) *Allowed time to file.* The request shall be mailed within 60 days after the date of the notice of the reconsideration determination or OCHAMPUS initial determination being appealed.

(iv) *Official filing date.* A request for a formal review shall be deemed filed on the date it is mailed and postmarked. If the request does not have a postmark, it shall be deemed filed on the date received by OCHAMPUS.

(2) *The formal review process.* The purpose of the formal review is to determine whether the initial determination or reconsideration determination was made in accordance with law, regulation, policies, and guidelines in effect at the time the care was provided or requested or at the time of the initial determination, reconsideration, or formal review decision involving a provider request for approval as an authorized CHAMPUS provider. The formal review is performed by the Chief, Office of Appeals and Hearings, OCHAMPUS, or a designee, and is a thorough review of the case. The formal review determination shall be based on the information, upon which the initial determination and/or reconsideration determination was based, and any additional information the appealing party may submit or OCHAMPUS may obtain.

(3) *Timeliness of formal review determination.* The Chief, Office of Appeals and Hearings, OCHAMPUS, or a designee normally shall issue the formal review determination no later than 90 days from the date of receipt of the request for formal review by the OCHAMPUS.

(4) *Notice of formal review determination.* The Chief, Office of Appeals and Hearings, OCHAMPUS, or a designee

shall issue a written notice of the formal review determination to the appealing party at his or her last known address. The notice of the formal review determination must contain the following elements:

(i) A statement of the issue or issues under appeal.

(ii) The provisions of law, regulation, policies, and guidelines that apply to the issue or issues under appeal.

(iii) A discussion of the original and additional information that is relevant to the issue or issues under appeal.

(iv) Whether the formal review upholds the prior determination or determinations or reverses the prior determination or determinations in whole or in part and the rationale for the action.

(v) A statement of the right to request a hearing in any case when the formal review determination is less than fully favorable, the issue is appealable, and the amount in dispute is $300 or more.

(5) *Effect of formal review determination*. The formal review determination is final if one or more of the following exist:

(i) The issue is not appealable. (See paragraph (a)(6) of this section.)

(ii) The amount in dispute is less than $300. (See paragraph (a)(7) of this section.)

(iii) Appeal rights have been offered but a request for hearing is not received by OCHAMPUS within 60 days of the date of the notice of the formal review determination.

(d) *Hearing*. Any party to the initial determination may request a hearing if the party is dissatisfied with the formal review determination and the formal review determination is not final under the provisions of paragraph (c)(5), of this section, *or* the initial determination involves the sanctioning of a provider under §199.9 of this part and involves an appealable issue.

(1) *Requesting a hearing*—(i) *Written request required*. The request shall be in writing, state the specific matter in dispute, include a copy of the appropriate initial determination or formal review determination being appealed, and include any additional information or documents not submitted previously.

(ii) *Where to file*. The request shall be submitted to the Chief, Appeals and Hearings, OCHAMPUS, Aurora, Colorado 80045–6900.

(iii) *Allowed time to file*. The request shall be mailed within 60 days after the date of the notice of the initial determination or formal review determination being appealed.

(iv) *Official filing date*. A request for hearing shall be deemed filed on the date it is mailed and postmarked. If a request for hearing does not have a postmark, it shall be deemed filed on the day received by OCHAMPUS.

(2) *Hearing process*. A hearing is an administrative proceeding in which facts relevant to the appealable issue(s) in the case are presented and evaluated in relation to applicable law, regulation, policies, and guidelines in effect at the time the care in dispute was provided or requested; at the time of the initial determination, formal review determination, or hearing decision involving a provider request for approval under CHAMPUS as an authorized provider; or at the time of the act or event which is the basis for the imposition of sanctions under this part. A hearing, except for an appeal involving a provider sanction, generally shall be conducted as a nonadversary, administrative proceeding. However, an authorized party to any hearing, including CHAMPUS, may submit additional evidence or testimony relevant to the appealable issue(s) and may appoint a representative, including legal counsel, to participate in the hearing process.

(3) *Timeliness of hearing*. (i) Except as otherwise provided in this section, within 60 days following receipt of a request for hearing, the Director, OCHAMPUS, or a designee, normally will appoint a hearing officer to hear the appeal. Copies of all records in the possession of OCHAMPUS that are pertinent to the matter to be heard or that formed the basis of the formal review determination shall be provided to the hearing officer and, upon request, to the appealing party.

(ii) The hearing officer, except as otherwise provided in this Section, normally shall have 60 days from the date of written notice of assignment to review the file, schedule and hold the

hearing, and issue a recommended decision to the Director, OCHAMPUS, or designee.

(iii) The Director, OCHAMPUS, or designee, may delay the case assignment to the hearing officer if additional information is needed that cannot be obtained and included in the record within the time period specified above. The appealing party will be notified in writing of the delay resulting from the request for additional information. The Director, OCHAMPUS, or a designee, in such circumstances, will assign the case to a hearing officer within 30 days of receipt of all such additional information, or within 60 days of receipt of the request for hearing, whichever shall occur last.

(iv) The hearing officer may delay submitting the recommended decision if, at the close of the hearing, any party to the hearing requests that the record remain open for submission of additional information. In such circumstances, the hearing officer will have 30 days following receipt of all such additional information including comments from the other parties to the hearing concerning the additional information to submit the recommended decision to the Director, OCHAMPUS, or a designee.

(4) *Representation at a hearing.* Any party to the hearing may appoint a representative to act on behalf of the party at the hearing, unless such person currently is disqualified or suspended from acting in another Federal administrative proceeding, or unless otherwise prohibited by law, this part, or any other DoD regulation (see paragraph (a)(2)(ii) of this section). A hearing officer may refuse to allow any person to represent a party at the hearing when such person engages in unethical, disruptive, or contemptuous conduct, or intentionally fails to comply with proper instructions or requests of the hearing officer, or the provisions of this part. The representative shall have the same authority as the appealing party and notice given to the representative shall constitute notice required to be given to the appealing party.

(5) *Consolidation of proceedings.* The Director, OCHAMPUS, or a designee, may consolidate any number of proceedings for hearing when the facts and circumstances are similar and no substantial right of an appealing party will be prejudiced.

(6) *Authority of the hearing officer.* The hearing officer in exercising the authority to conduct a hearing under this part will be bound by 10 U.S.C. chapter 55 and this part. The hearing officer in addressing substantive, appealable issues shall be bound by policy manuals, instructions, procedures, and other guidelines issued by the ASD(HA), or a designee, or by the Director, OCHAMPUS, or a designee, in effect for the period in which the matter in dispute arose. A hearing officer may not establish or amend policy, procedures, instructions, or guidelines. However, the hearing officer may recommend reconsideration of the policy, procedures, instructions or guidelines by the ASD(HA), or a designee, when the final decision is issued in the case.

(7) *Disqualification of hearing officer.* A hearing officer voluntarily shall disqualify himself or herself and withdraw from any proceeding in which the hearing officer cannot give fair or impartial hearing, or in which there is a conflict of interest. A party to the hearing may request the disqualification of a hearing officer by filing a statement detailing the reasons the party believes that a fair and impartial hearing cannot be given or that a conflict of interest exists. Such request immediately shall be sent by the appealing party or the hearing officer to the Director, OCHAMPUS, or a designee, who shall investigate the allegations and advise the complaining party of the decision in writing. A copy of such decision also shall be mailed to all other parties to the hearing. If the Director, OCHAMPUS, or a designee, reassigns the case to another hearing officer, no investigation shall be required.

(8) *Notice and scheduling of hearing.* The hearing officer shall issue by certified mail, when practicable, a written notice to the parties to the hearing of the time and place for the hearing. Such notice shall be mailed at least 15 days before the scheduled date of the hearing. The notice shall contain sufficient information about the hearing procedure, including the party's right to representation, to allow for effective

preparation. The notice also shall advise the appealing party of the right to request a copy of the record before the hearing. Additionally, the notice shall advise the appealing party of his or her responsibility to furnish the hearing officer, no later than 7 days before the scheduled date of the hearing, a list of all witnesses who will testify and a copy of all additional information to be presented at the hearing. The time and place of the hearing shall be determined by the hearing officer, who shall select a reasonable time and location mutually convenient to the appealing party and OCHAMPUS.

(9) *Dismissal of request for hearing.* (i) *By application of appealing party.* A request for hearing may be dismissed by the Director, OCHAMPUS, or a designee, at any time before the mailing of the final decision, upon the application of the appealing party. A request for dismissal must be in writing and filed with the Chief, Appeals and Hearings, OCHAMPUS, or the hearing officer. When dismissal is requested, the formal review determination in the case shall be deemed final, unless the dismissal is vacated in accordance with paragraph (d)(9)(v) of this section.

(ii) *By stipulation of the parties to the hearing.* A request for a hearing may be dismissed by the Director, OCHAMPUS, or a designee, at any time before to the mailing of notice of the final decision under a stipulation agreement between the appealing party and OCHAMPUS. When dismissal is entered under a stipulation, the formal review decision shall be deemed final, unless the dismissal is vacated in accordance with paragraph (d)(9)(v) of this section.

(iii) *By abandonment.* The Director, OCHAMPUS, or a designee, may dismiss a request for hearing upon abandonment by the appealing party.

(A) An appealing party shall be deemed to have abandoned a request for hearing, other than when personal appearance is waived in accordance with §199.10(d)(11)(xii), if neither the appealing party nor an appointed representative appears at the time and place fixed for the hearing and if, within 10 days after the mailing of a notice by certified mail to the appealing party by the hearing officer to show cause, such party does not show good and sufficient cause for such failure to appear and failure to notify the hearing officer before the time fixed for hearing that an appearance could not be made.

(B) An appealing party shall be deemed to have abandoned a request for hearing if, before assignment of the case to the hearing officer, OCHAMPUS is unable to locate either the appealing party or an appointed representative.

(C) An appealing party shall be deemed to have abandoned a request for hearing if the appealing party fails to prosecute the appeal. Failure to prosecute the appeal includes, but is not limited to, an appealing party's failure to provide information reasonably requested by OCHAMPUS or the hearing officer for consideration in the appeal.

(D) If the Director, OCHAMPUS, or a designee, dismisses the request for hearing because of abandonment, the formal review determination in the case shall be deemed to be final, unless the dismissal is vacated in accordance with paragraph (d)(9)(v) of this section.

(iv) *For cause.* The Director, OCHAMPUS, or a designee, may dismiss for cause a request for hearing either entirely or as to any stated issue. If the Director, OCHAMPUS, or a designee, dismisses a hearing request for cause, the formal review determination in the case shall be deemed to be final, unless the dismissal is vacated in accordance with paragraph (d)(9)(v) of this section. A dismissal for cause may be issued under any of the following circumstances:

(A) When the appealing party requesting the hearing is not a proper party under paragraph (a)(2)(i) of this section, or does not otherwise have a right to participate in a hearing.

(B) When the appealing party who filed the hearing request dies, and there is no information before the Director, OCHAMPUS, or a designee, showing that a party to the initial determination who is not an appealing party may be prejudiced by the formal review determination.

(C) When the issue is not appealable (see §199.10(a)(6)).

(D) When the amount in dispute is less than $300 (see §199.10(a)(7)).

(E) When all appealable issues have been resolved in favor of the appealing party.

(v) *Vacation of dismissal.* Dismissal of a request for hearing may be vacated by the Director, OCHAMPUS, or a designee, upon written request of the appealing party, if the request is received within 6 months of the date of the notice of dismissal mailed to the last known address of the party requesting the hearing.

(10) *Preparation for hearing.* (i) *Prehearing statement of contentions.* The hearing officer may on reasonable notice require a party to the hearing to submit a written statement of contentions and reasons. The written statement shall be provided to all parties to the hearing before the hearing takes place.

(ii) *Discovery.* Upon the written request of a party to the initial determination (including OCHAMPUS) and for good cause shown, the hearing officer will allow that party to inspect and copy all documents, unless privileged, relevant to issues in the proceeding that are in the possession or control of the other party participating in the appeal. The written request shall state clearly what information and documents are required for inspection and the relevance of the documents to the issues in the proceeding. Depositions, interrogatories, requests for admissions, and other forms of prehearing discovery are generally not authorized and the Department of Defense does not have subpoena authority for purposes of administrative hearings under this Section. If the hearing officer finds that good cause exists for taking a deposition or interrogatory, the expense shall be assessed to the requesting party, with copies furnished to the hearing officer and the other party or parties to the hearing.

(iii) *Witnesses and evidence.* All parties to a hearing are responsible for producing, at each party's expense, meaning without reimbursement of payment by CHAMPUS, witnesses and other evidence in their own behalf, and for furnishing copies of any such documentary evidence to the hearing officer and other party or parties to the hearing. The Department of Defense is not authorized to subpoena witnesses or records. The hearing officer may issue invitations and requests to individuals to appear and testify without cost to the Government, so that the full facts in the case may be presented.

(11) *Conduct of hearing.* (i) *Right to open hearing.* Because of the personal nature of the matters to be considered, hearings normally shall be closed to the public. However, the appealing party may request an open hearing. If this occurs, the hearing shall be open except when protection of other legitimate Government purposes dictates closing certain portions of the hearing.

(ii) *Right to examine parties to the hearing and their witnesses.* Each party to the hearing shall have the right to produce and examine witnesses, to introduce exhibits, to question opposing witnesses on any matter relevant to the issue even though the matter was not covered in the direct examination, to impeach any witness regardless of which party to the hearing first called the witness to testify, and to rebut any evidence presented. Except for those witnesses employed by OCHAMPUS at the time of the hearing, or records in the possession of OCHAMPUS, a party to a hearing shall be responsible, that is to say no payment or reimbursement shall be made by CHAMPUS for the cost or fee associated with producing witnesses or other evidence in the party's own behalf, or for furnishing copies of documentary evidence to the hearing officer and other party or parties to the hearing.

(iii) *Taking of evidence.* The hearing officer shall control the taking of evidence in a manner best suited ascertain the facts and safeguard the rights of the parties to the hearing. Before taking evidence, the hearing officer shall identify and state the issues in dispute on the record and the order in which evidence will be received.

(iv) *Questioning and admission of evidence.* A hearing officer may question any witness and shall admit any relevant evidence. Evidence that is irrelevant or unduly repetitious shall be excluded.

(v) *Relevant evidence.* Any relevant evidence shall be admitted, unless unduly repetitious, if it is the type of evidence on which responsible persons are accustomed to rely in the conduct of

serious affairs, regardless of the existence of any common law or statutory rule that might make improper the admission of such evidence over objection in civil or criminal actions.

(vi) *CHAMPUS determination first*. The basis of the CHAMPUS determinations shall be presented to the hearing officer first. The appealing party shall then be given the opportunity to establish affirmatively why this determination is held to be in error.

(vii) *Testimony*. Testimony shall be taken only on oath, affirmation, or penalty of perjury.

(viii) *Oral argument and briefs*. At the request of any party to the hearing made before the close of the hearing, the hearing officer shall grant oral argument. If written argument is requested, it shall be granted, and the parties to the hearing shall be advised as to the time and manner within which such argument is to be filed. The hearing officer may require any party to the hearing to submit written memoranda pertaining to any or all issues raised in the hearing.

(ix) *Continuance of hearing*. A hearing officer may continue a hearing to another time or place on his or her own motion or, upon showing of good cause, at the request of any party. Written notice of the time and place of the continued hearing, except as otherwise provided here, shall be in accordance with this part. When a continuance is ordered during a hearing, oral notice of the time and place of the continued hearing may be given to each party to the hearing who is present at the hearing.

(x) *Continuance for additional evidence*. If the hearing officer determines, after a hearing has begun, that additional evidence is necessary for the proper determination of the case, the following procedures may be invoked:

(A) *Continue hearing*. The hearing may be continued to a later date in accordance with §199.10(d)(11)(ix), above.

(B) *Closed hearing*. The hearing may be closed, but the record held open in order to permit the introduction of additional evidence. Any evidence submitted after the close of the hearing shall be made available to all parties to the hearing, and all parties to the hearing shall have the opportunity for comment. The hearing officer may reopen the hearing if any portion of the additional evidence makes further hearing desirable. Notice thereof shall be given in accordance with paragraph (d)(8) of this section.

(xi) *Transcript of hearing*. A verbatim taped record of the hearing shall be made and shall become a permanent part of the record. Upon request, the appealing party shall be furnished a duplicate copy of the tape. A typed transcript of the testimony will be made only when determined to be necessary by OCHAMPUS. If a typed transcript is made, the appealing party shall be furnished a copy without charge. Corrections shall be allowed in the typed transcript by the hearing officer solely for the purpose of conforming the transcript to the actual testimony.

(xii) *Waiver of right to appear and present evidence*. If all parties waive their right to appear before the hearing officer for presenting evidence and contentions personally or by representation, it will not be necessary for the hearing officer to give notice of, or to conduct a formal hearing. A waiver of the right to appear must be in writing and filed with the hearing officer or the Chief, Appeals and Hearings, OCHAMPUS. Such waiver may be withdrawn by the party by written notice received by the hearing officer or Chief, Appeals and Hearings, no later than 7 days before the scheduled hearing or the mailing of notice of the final decision, whichever occurs first. For purposes of this Section, failure of a party to appear personally or by representation after filing written notice of waiver, will not be cause for finding of abandonment and the hearing officer shall make the recommended decision on the basis of all evidence of record.

(12) *Recommended decision*. At the conclusion of the hearing and after the record has been closed, the matter shall be taken under consideration by the hearing officer. Within the time frames previously set forth in this Section, the hearing officer shall submit to the Director, OCHAMPUS, or a designee, a written recommended decision containing a statement of findings and a statement of reasons based on the evidence adduced at the hearing and

otherwise included in the hearing record.

(i) *Statement of findings.* A statement of findings is a clear and concise statement of fact evidenced in the record or conclusions that readily can be deduced from the evidence of record. Each finding must be supported by substantial evidence that is defined as such evidence as a reasonable mind can accept as adequate to support a conclusion.

(ii) *Statement of reasons.* A reason is a clear and concise statement of law, regulation, policies, or guidelines relating to the statement of findings that provides the basis for the recommended decision.

(e) *Final decision*—(1) *Director, OCHAMPUS.* The recommended decision shall be reviewed by the Director, OCHAMPUS, or a designee, who shall adopt or reject the recommended decision or refer the recommended decision for review by the Assistant Secretary of Defense (Health Affairs). The Director, OCHAMPUS, or designee, normally will take action with regard to the recommended decision within 90 days of receipt of the recommended decision or receipt of the revised recommended decision following a remand order to the Hearing Officer.

(i) *Final action.* If the Director, OCHAMPUS, or a designee, concurs in the recommended decision, no further agency action is required and the recommended decision, as adopted by the Director, OCHAMPUS, is the final agency decision in the appeal. In the case of rejection, the Director, OCHAMPUS, or a designee, shall state the reason for disagreement with the recommended decision and the underlying facts supporting such disagreement. In these circumstances, the Director, OCHAMPUS, or a designee, may have a final decision prepared based on the record, or may remand the matter to the Hearing Officer for appropriate action. In the latter instance, the Hearing Officer shall take appropriate action and submit a new recommended decision within 60 days of receipt of the remand order. The decision by the Director, OCHAMPUS, or a designee, concerning a case arising under the procedures of this section, shall be the final agency decision and the final decision shall be sent by certified mail to the appealing party or parties. A final agency decision under paragraph (e)(1) of this section will not be relied on, used, or cited as precedent by the Department of Defense in the administration of CHAMPUS.

(ii) *Referral for review by ASD(HA).* The Director, OCHAMPUS, or a designee, may refer a hearing case to the Assistant Secretary of Defense (Health Affairs) when the hearing involves the resolution of CHAMPUS policy and issuance of a final decision which may be relied on, used, or cited as precedent in the administration of CHAMPUS. In such a circumstance, the Director, OCHAMPUS, or a designee, shall forward the recommended decision, together with the recommendation of the Director, OCHAMPUS, or a designee, regarding disposition of the hearing case.

(2) *ASD(HA).* The ASD(HA), or a designee, after reviewing a case arising under the procedures of this section may issue a final decision based on the record in the hearing case or remand the case to the Director, OCHAMPUS, or a designee, for appropriate action. A decision issued by the ASD(HA), or a designee, shall be the final agency decision in the appeal and a copy of the final decision shall be sent by certified mail to the appealing party or parties. A final decision of the ASD(HA), or a designee, issued under this paragraph (e)(2) may be relied on, used, or cited as precedent in the administration of CHAMPUS.

[51 FR 24008, July 1, 1986, as amended at 52 FR 33007, Sept. 1, 1987; 54 FR 25255, June 14, 1989; 55 FR 43341, Nov. 16, 1990; 56 FR 59880, Nov. 26, 1991; 66 FR 40607, Aug. 3, 2001; 68 FR 11973, Mar. 13, 2003; 68 FR 23033, Apr. 30, 2003; 68 FR 32362, May 30, 2003; 69 FR 6920, Feb. 12, 2004]

§ 199.11 Overpayments recovery.

(a) *General.* Actions to recover overpayments arise when the government has a right to recover money, funds, or property from any person, partnership, association, corporation, governmental body or other legal entity, foreign or domestic, except another Federal agency, because of an erroneous payment of benefits under both CHAMPUS and the TRICARE program under this part. The

term ''Civilian Health and Medical Program of the Uniformed Services'' (CHAMPUS) is defined in 10 U.S.C. 1072(2), referred to as the CHAMPUS basic program. Prior to January 1, 2018, the term ''TRICARE program'' referred to the triple-option of health benefits known as TRICARE Prime, TRICARE Extra, and TRICARE Standard. Specifically, TRICARE Standard was the TRICARE program under which the basic program of health care benefits generally referred to as CHAMPUS was made available to eligible beneficiaries under this Part 199. Effective January 1, 2018, the term ''TRICARE program'' is defined in 10 U.S.C. 1072(2) and includes TRICARE Prime, TRICARE Select and TRICARE for Life. It is the purpose of this section to prescribe procedures for investigation, determination, assertion, collection, compromise, waiver and termination of claims in favor of the United States for erroneous benefit payments arising out of the administration CHAMPUS and the TRICARE program. For the purpose of this section, references herein to TRICARE beneficiaries, claims, benefits, payments, or appeals shall include CHAMPUS beneficiaries, claims, benefits, payments, or appeals. A claim against several joint debtors arising from a single incident or transaction is considered one claim. The Director, or a designee, may pursue collection against all joint debtors and is not required to allocate the burden of payment between debtors.

(b) *Authority*—(1) *Federal statutory authority*. The Federal Claims Collection Act, 31 U.S.C. 3701, *et seq.*, as amended by the Debt Collection Act of 1982 and the Debt Collection Improvement Act of 1996 (DCIA), provides the basic authority under which claims may be asserted pursuant to this section. The DCIA is implemented by the Federal Claims Collection Standards, joint regulations issued by the Department of the Treasury (Treasury) and the Department of Justice (DOJ) (31 CFR Parts 900–904), that prescribe government-wide standards for administrative collection, offset, compromise, suspension, or termination of agency collection action, disclosure of debt information to credit reporting agencies, referral of debts to private collection contractors for resolution, and referral to the Department of Justice for litigation to collect debts owed the Federal government. The regulations under this part are also issued under Treasury regulations implementing the DCIA (31 CFR part 285) and related statutes and regulations governing the offset of Federal salaries (5 U.S.C. 5514; 5 CFR part 550, subpart K), administrative offset (31 U.S.C. 3716; 31 CFR part 285, subpart A); administrative offset of tax refunds (31 U.S.C. 3720A) and offset of military pay (37 U.S.C. 1007(c); Volume 7A, Chapter 50 and Volume 7B, Chapter 28 of the Department of Defense Financial Management Regulation, DOD 7000.14–R[1] (DoDFMR)).

(2) *Other authority*. Federal claims may arise under authorities other than the federal statutes, referenced above. These include, but are not limited to:

(i) State worker's compensation laws.

(ii) State hospital lien laws.

(iii) State no-fault automobile statutes.

(iv) Contract rights under terms of insurance policies.

(c) *Policy*. The Director, TMA, or a designee, shall aggressively collect all debts arising out of its activities. Claims arising out of any incident, which has or probably will generate a claim in favor of the government, will not be compromised, except as otherwise provided in this section, nor will any person not authorized to take final action on the government's claim, compromise or terminate collection action. Title 28 U.S.C. 2415–2416 establishes a statute of limitation applicable to the government where previously neither limitations nor latches were available as a defense. Claims falling within the provisions of this statute will be referred to the Department of Justice without attempting administrative collection action, if such action cannot be accomplished in sufficient time to preclude the running of the statute of limitations.

(d) *Appealability*. This section describes the procedures to be followed in the recovery and collection of federal claims in favor of the United States arising from the operation of

[1] Copies may be obtained at *http://www.dtic.mil/whs/directives/*.

TRICARE. Actions taken under this section are not initial determinations for the purpose of the appeal procedures of §199.10 of this part. However, the proper exercise of the right to appeal benefit or provider status determinations under the procedures set forth in §199.10 of this part may affect the processing of federal claims arising under this section. Those appeal procedures afford a TRICARE beneficiary or participating provider an opportunity for administrative appellate review in cases in which benefits have been denied and in which there is an appealable issue. For example, a TRICARE contractor may erroneously make payment for services, which are excluded as TRICARE benefits because they are determined to be not medically necessary. In that event, the contractor will initiate recoupment action, and at the same time, the contractor will offer an administrative appeal as provided in §199.10 of this part on the medical necessity issue raised by the adverse benefit determination. The recoupment action and the administrative appeal are separate actions. However, in an appropriate case, the pendency of the appeal may provide a basis for the suspension of collection in the recoupment case. If an appeal were resolved entirely in favor of the appealing party, it would provide a basis for the termination of collection action in the recoupment case.

(e) *Delegation.* Subject to the limitations imposed by law or contained in this section, the authority to assert, settle, and compromise or to suspend or terminate collection action arising on claims under the Federal Claims Collection Act has been delegated to the Director, TMA, or a designee.

(f) *Recoupment of erroneous payments.* (1) Erroneous payments are expenditures of government funds, which are not authorized by law or this part. Examples which are sometimes encountered in the administration of TRICARE include mathematical errors, payment for care provided to an ineligible person, payment for care which is not an authorized benefit, payment for duplicate claims, incorrect application of the deductible or co-payment or payment for services which were not medically necessary. Claims in favor of the government arising as the result of the filing of false TRICARE claims or other fraud fall under the cognizance of the Department of Justice. Consequently, procedures in this section apply to such claims only when specifically authorized or directed by the Department of Justice. (*See* 31 CFR 900.3.) Due to the nature of contractual agreements between network providers and TRICARE prime contractors, recoupment procedures may be modified or adapted to conform to network agreements. The provisions of §199.11 shall apply if recoupment under the network agreements is not successful.

(2) *Scope*—(i) *General.* Paragraph (f) of this section and the paragraphs following contain requirements and procedures for the assertion, collection or compromise of, and the suspension or termination of collection action on claims for erroneous payments against a sponsor, patient, beneficiary, provider, physician or other supplier of products or services under TRICARE.

(ii) *Debtor defined.* As used herein, ''debtor'' means a sponsor, beneficiary, provider, physician, other supplier of services or supplies, or any other person who for any reason has been erroneously paid under TRICARE. It includes an individual, partnership, corporation, professional corporation or association, estate, trust or any other legal entity.

(iii) *Delinquency defined.* A debt is ''delinquent'' if it has not been paid by the date specified in the initial written demand for payment (that is, the initial written notification) or other applicable contractual agreement, unless other satisfactory payment arrangements have been made by the date specified in the initial written demand for payment. A debt is considered delinquent if at any time after entering into a repayment agreement, the debtor fails to satisfy any obligations under that agreement.

(3) Claims arising from erroneous TRICARE payments in situations where the beneficiary has entitlement to an insurance, medical service, health and medical plan, including any plan offered by a third party payer as defined in 10 U.S.C. 1095(h)(1) or other government program, except in the

case of a plan administered under Title XIX of the Social Security Act (42 U.S.C. 1396, *et seq.*) through employment, by law, through membership in an organization, or as a student, or through the purchase of a private insurance or health plan, shall be recouped following the procedures in paragraph (f) of this section. If the other plan has not made payment to the beneficiary or provider, the contractor shall first attempt to recover the overpayment from the other plan through the contractor's coordination of benefits procedures. If the overpayment cannot be recovered from the other plan, or if the other plan has made payment, the overpayment will be recovered from the party that received the erroneous payment from TRICARE. Nothing in this section shall be construed to require recoupment from any sponsor, beneficiary, provider, supplier and/or the Medicare Program under Title XVIII of the Social Security Act in the event of a retroactive determination of entitlement to SSDI and Medicare Part A coverage made by the Social Security Administration as discussed in §199.8(d) of this part.

(4) *Claim denials due to clarification or change.* In those instances where claim review results in the denial of benefits previously provided, but now denied due to a change, clarification or interpretation of the public law or this part, no recoupment action need be taken to recover funds expended prior to the effective date of such change, clarification or interpretation.

(5) *Good faith payment.* (i) The Department of Defense, through the Defense Enrollment Eligibility Reporting System (DEERS), is responsible for establishing and maintaining a file listing of persons eligible to receive benefits under TRICARE. However, it is the responsibility of the Uniformed Services to provide eligible TRICARE beneficiaries with accurate and appropriate means of identification. When sources of civilian medical care exercise reasonable care and precaution identifying persons claiming to be eligible TRICARE beneficiaries, and furnish otherwise covered services and supplies to such persons in good faith, TRICARE benefits may be paid subject to prior approval by the Director, TMA, or a designee, notwithstanding the fact that the person receiving the services and supplies is subsequently determined to be ineligible for benefits. Good faith payments will not be authorized for services and supplies provided by a civilian source of medical care because of its own careless identification procedures.

(ii) When it is determined that a person was not a TRICARE beneficiary, the TRICARE contractor and the civilian source of medical care are expected to make all reasonable efforts to obtain payment or to recoup the amount of the good faith payment from the person who erroneously claimed to be the TRICARE beneficiary. Recoupment of good faith payments initiated by the TRICARE contractor will be processed pursuant to the provisions of paragraph (f) of this section.

(6) *Recoupment procedures.* (i) *Initial action.* When an erroneous payment is discovered, the TRICARE contractor normally will be required to take the initial action to effect recoupment. Such actions will be in accordance with the provisions of this part and the TRICARE contracts and will include a demand (or demands) for refund or an offset against any other TRICARE payment(s) becoming due the debtor. When the efforts of the TRICARE contractor to effect recoupment are not successful within a reasonable time, recoupment cases will be referred to the Office of General Counsel, TMA, for further action in accordance with the provisions of paragraph (f) of this section. All requests to debtors for refund or notices of intent to offset shall be in writing.

(ii) *Demand for payment.* Written demand(s) for payment shall inform the debtor of the following:

(A) The basis for and amount of the debt and the consequences of failing to cooperate to resolve the debt;

(B) The right to inspect and copy TRICARE records pertaining to the debt;

(C) The opportunity to request an administrative review by the TRICARE contractor; and that such a request must be received by the TRICARE contractor within 90 days from the date of the initial demand letter;

(D) That payment of the debt is due within 30 days from the date of the initial demand notification;

(E) That interest will be assessed on the debt at the Treasury Current Value of Funds rate, pursuant to 31 U.S.C. 3717, and will begin to accrue on the date of the initial demand letter; and that interest will be waived on the debt, or any portion thereof, which is paid within 30 days from the date of the initial demand notification letter;

(F) That administrative costs and penalties will be charged pursuant to 31 CFR 901.9;

(G) That collection by offset against current or subsequent claims or other amounts payable from the government may be taken;

(H) The opportunity to enter into a written agreement to repay the debt;

(I) The name, address, and phone number of a contact person or office that the debtor may contact regarding the debt.

(iii) A minimum of one demand letter is required. However, the specific content, timing and number of demand letters may be tailored to the type and amount of the debt, and the debtor's response, if any. Contractors' demand letters must be mailed or hand-delivered on the same date they are dated.

(iv) The initial or subsequent demand letters may also inform the debtor of the requirement to report delinquent debts to credit reporting agencies and to collection agencies, the requirement to refer debts to the Treasury Offset Program for offset from Federal income tax refunds and other amounts payable by the Government, offset from state payments, the requirement to refer debts to Treasury for collection and TRICARE policies concerning the referral of delinquent debts to the Department of Justice for enforced collection action. The initial or subsequent demand letter may also inform the debtor of TRICARE policies concerning waiver. When necessary to protect the Government's interest (for example to prevent the running of a statute of limitations), written demand may be preceded by other appropriate actions under this regulation, including referral to the Department of Justice for litigation. There should be no undue delay in responding to any communication received from the debtor. Responses to communications from debtors should be made within 30 days of receipt whenever feasible. If prior to the initiation of the demand process or at any time during or after completion of the demand process, the Director, TMA, or a designee, determines to pursue or is required to pursue offset, the procedures applicable to administrative offset, found at paragraph (f)(6)(v) of this section, must be followed. If it appears that initial collection efforts are not productive or if immediate legal action on the claim appears necessary, the claim shall be referred promptly by the contractor to the Office of General Counsel, TMA.

(v) *Collection by administrative offset.* Collections by offset will be undertaken administratively in every instance when feasible. Collections may be taken by administrative offset under 31 U.S.C. 3716, the common law or other applicable statutory authority. No collection by offset may be undertaken unless the debtor has been sent a written demand for payment, including the procedural safeguards described in paragraph (f)(6)(ii) of this section, unless the failure to take the offset would substantially prejudice the Government's ability to collect the debt, and the time before payment is to be made does not reasonably permit the time for sending written notice. Such prior offset must be promptly followed by sending a written notice and affording the debtor the opportunity for a review by the TRICARE contractor. Examples of erroneous payments include, but are not limited to, claims submitted by individuals ineligible for TRICARE benefits, claims submitted for non-covered services or supplies, claims for which payments by another insurance or health plan reduce TRICARE liability, and from claims made from participating providers in which payment was initially erroneously made to the beneficiary. The resolution of recoupment claims rarely involves issues of credibility or veracity and a review of the written record is ordinarily an adequate means to correct prior mistakes. For this reason, the pre-offset oral hearing requirements of the Federal Claims Collection Standards, 31 CFR 901.3(e) do not apply

to the recoupment of erroneous TRICARE payments. However, in instances where an oral hearing is not required, the debtor will be afforded an administrative review if the TRICARE contractor receives a written request for an administrative review within 90 days from the date of the initial demand letter. The appeals procedures described in §199.10 of this part, afford a TRICARE beneficiary or participating provider an opportunity for an administrative appellate review, including under certain circumstances, the right to an oral hearing before a hearing officer when an appealable issue exists. TRICARE contractors may take administrative action to offset erroneous payments against other current TRICARE payments owing a debtor. Payments on the claims of a debtor pending at or filed subsequent to the time collection action is initiated should be suspended pending the outcome of the collection action so that these funds will be available for offset. All or part of a debt may be offset depending on the amount available for offset. Any requests for offset received from other agencies and garnishment orders issued by courts of competent jurisdiction will be forwarded to the Office of General Counsel, TMA. Unless otherwise provided by law, administrative offset of payments under the authority of 31 U.S.C. 3716 may not be conducted more than 10 years after the Government's right to collect the debt first accrued, unless facts material to the Government's right to collect the debt were not known and could not reasonably have been known by the TRICARE official or officials charged with the responsibility to discover and collect such debts. This limitation does not apply to debts reduced to judgment. This section does not apply to debts arising under the Social Security Act, except as provided in 42 U.S.C. 404, payments made under the Social Security Act, except as provided for in 31 U.S.C. 3716(c), debts arising under, or payments made under, the Internal Revenue Code, except for offset of tax refunds or tariff laws of the United States; offsets against Federal salaries to the extent these standards are inconsistent with regulations published to implement such offsets under 5 U.S.C. 5514 and 31 U.S.C. 3716; offsets under 31 U.S.C. 3728 against a judgment obtained by a debtor against the United States; offset or recoupment under common law, state law, or federal statutes specifically prohibiting offset or recoupment of particular types of debts or offsets in the course of judicial proceedings, including bankruptcy.

(A) *Referral for centralized administrative offset.* When cost-effective, legally enforceable non-tax debts delinquent over 180 days that are eligible for collection through administrative offset shall be referred to Treasury for administrative offset, unless otherwise exempted from referral. Referrals shall include certification that the debt is past due and legally enforceable and that TMA has complied with all due process requirements of the statute-authorizing offset. Administrative offset, including administrative offset against tax refunds due debtors under 26 U.S.C. 6402, in accordance with 31 U.S.C. 3720A, shall be effected through referral for centralized administrative offset, after debtors have been afforded at least sixty (60) days notice required in paragraph (f)(6) of this section. Salary offsets shall be effected through referral for centralized administrative offset, after debtors have been afforded due process required by 5 U.S.C. 5514, in accordance with 31 CFR 285.7. Referrals for salary offset shall include certification that the debts are past due, legally enforceable debts and that TMA has complied with all due process requirements under 5 U.S.C. 5514 and applicable agency regulations. The Treasury, Financial Management Service (FMS) may waive the salary offset certification requirement set forth in 31 CFR 285.7, as a prerequisite to submitting the debt to FMS for offset from other payment types. If FMS waives the certification requirement, before an offset occurs, TMA will provide the employee with the notice and opportunity for a hearing as required by 5 U.S.C. 5514 and applicable regulations, and will certify to FMS that the requirements of 5 U.S.C. 5514 and applicable agency regulations have been met.

TMA is not required to duplicate notice and administrative review or salary offset hearing opportunities before referring debts for centralized administrative offset when the debtor has been previously given them.

(B) *Referral for non-centralized administrative offset.* Unless otherwise prohibited by law, when centralized administrative offset is not available or appropriate, past due legally enforceable non-tax-delinquent debts that are eligible for referral may be collected through non-centralized administrative offset through a request directly to the payment-authorizing agency. Referrals shall include certification that the debts are past due and that the agency has complied with due process requirements under 31 U.S.C. 3716(a) or other applicable authority and applicable agency regulations concerning administrative offset. Generally, non-centralized administrative offsets will be made on an *ad hoc* case-by-case basis, in cooperation with the agency certifying or authorizing payments to the debtor.

(vi) *Collection by transfer of debts to Treasury or a Treasury-designated debt collection center for collection through cross servicing.* (A) The Director, TMA or a designee, is required to transfer legally enforceable non-tax debts that are delinquent 180 days or more to Treasury for collection through cross-servicing (31 U.S.C. 3711(g); 31 CFR 285.12.) Debts referred or transferred to Treasury or Treasury-designated debt collection centers shall be serviced, collected, or compromised, or the collection action will be suspended or terminated, in accordance with the statutory requirements and authorities applicable to the collection of such debts. Agencies operating Treasury-designated debt collection centers are authorized to charge a fee for services rendered regarding referred or transferred debts. This fee may be paid out of amounts collected and may be added to the debt as an administrative cost. Referrals will include certification that the debts transferred are valid, legally enforceable debts, that there are no legal bars to collection and that the agency has complied with all prerequisites to a particular collection action under the applicable laws, regulations or policies, unless the agency and Treasury agree that Treasury will do so on behalf of the agency.

(B) The requirement of paragraph (f)(1) of this section does not apply to any debt that:

(*1*) Is in litigation or foreclosure.

(*2*) Will be disposed of under an approved asset sale program.

(*3*) Has been referred to a private collection contractor for a period of time acceptable to Treasury.

(*4*) Will be collected under internal offset procedures within 3 years after the debt first became delinquent.

(*5*) Is exempt from this requirement based on a determination by the Secretary of the Treasury that exemption for a certain class of debt is in the best interest of the United States.

(vii) *Collection by salary offset.* When a debtor is a member of the military service or a retired member and collection by offset against other TRICARE payments due the debtor cannot be accomplished, and there have been no positive responses to a demand for payment, the Director, TMA, or a designee, may refer the debt for offset from the debtor's pay account pursuant to 37 U.S.C. 1007(c), as implemented by Volume 7A, Chapter 50 and Volume 7B, Chapter 28 of the DoDFMR. Collection from a Federal employee may be effected through salary offset under 5 U.S.C. 5514.

(A) For collections by salary offset the Director, TMA, or designee, will issue written notification, as required by 5 CFR 550.1104(d) at least 30 days before any offsets are taken. In addition, the notification will advise the employee that if he or she retires, resigns or his or her employment ends before collection of the debt is completed, collection may be made from subsequent payments of any nature due from the United States (e.g., final salary payment, lump-sum leave under 31 U.S.C. 3716 due the employee as of date of separation.) A debtor's involuntary payment of all or part of a debt being collected will not be construed as a waiver of any rights the debtor may have under 5 U.S.C. 5514 or any other provision of contract or law, unless there are statutory or contractual provisions

to the contrary or the employee's paying agency is directed by an administrative or judicial order to refund amounts deducted from his or her current pay. No interest will be paid on amounts waived or determined not to be owed unless there are statutory or contractual provisions to the contrary.

(B) *Petition for hearing.* The notice of the proposed offset will advise the debtor of his or her right to petition for a hearing. The petition for hearing must be signed by the debtor or his or her representative and must state whether he or she is contesting debt validity, debt amount and/or the terms of the proposed offset schedule. It must explain with reasonable specificity all the facts, evidence and witnesses, if any (in the case of an oral hearing and a summary of their anticipated testimony), which the debtor believes support his or her position, and include any supporting documentation. If contesting the terms of the proposed offset schedule, the debtor must provide financial information including a completed Department of Justice Financial Statement of Debtor form (OBD–500 or other form prescribed by DOJ), including specific details concerning income and expenses of the employee, his or her spouse and dependents for 1-year period preceding the debt notification and projected income and expenses for the proposed offset period and a statement of the reason why the debtor believes the salary offset schedule will impose extreme financial hardship. Upon receipt of the petition for hearing, the Director, TMA, or a designee, will complete reconsideration. If the Director, TMA, or a designee determines that the debt amount is not owed, that a less amount is owed, or that the terms of the employee's proposed offset schedule are acceptable, it will advise the debtor and request that the employee accept the results of the reconsideration in lieu of a hearing. If the employee declines to accept the results of reconsideration in lieu of a hearing, the debtor will be afforded a hearing. Ordinarily, a petition for hearing and required submissions that are not timely filed, shall be accepted after expiration of the deadline provided in the notice of the proposed offset, only when the debtor can demonstrate to the Director, TMA, or a designee, that the timely filing of the request was not feasible due to extraordinary circumstances over which the appealing party had no practical control or because of failure to receive notice of the time limit (unless he or she was otherwise aware of it). Each request for an exception to the timely filing requirement will be considered on its own merits. The decision of the Director, TMA, or a designee, on a request for an exception to the timely filing requirement shall be final.

(C) *Extreme financial hardship.* The maximum authorized amount that may be collected through involuntary salary offset is the lesser of 15 percent of the employee's disposable pay or the full amount of the debt. An employee who has petitioned for a hearing may assert that the maximum allowable rate of involuntary offset produces extreme financial hardship. An offset produces an extreme financial hardship if the offset prevents the employee from meeting the costs necessarily incurred for the essential expenses of the employee, employee's spouse and dependents. These essential expenses include costs incurred for food, housing, necessary public utilities, clothing, transportation and medical care. In determining whether the offset would prevent the employee from meeting the essential expenses identified above, the following shall be considered:

(*1*) Income from all sources of the employee, the employee's spouse, and dependents;

(*2*) The extent to which assets of the employee, employee's spouse and dependents are available to meet the offset and essential subsistence expenses;

(*3*) Whether these essential subsistence expenses have been minimized to the greatest extent possible;

(*4*) The extent to which the employee or the employee's spouse can borrow money to meet the offset and other essential expenses; and

(*5*) The extent to which the employee and the employee's spouse and dependents have other exceptional expenses that should be taken into account and whether these expenses have been minimized.

(D) *Form and content of hearings.* The resolution of recoupment claims rarely

involves issues of credibility or veracity and a review of the written record is ordinarily an adequate means to determine the validity or amount of the debt and/or the terms of a proposed offset schedule. The Director, TMA, or a designee, will determine whether an oral hearing is required. A debtor who has petitioned for a hearing, but who is not entitled to an oral hearing will be given an administrative hearing, based on the written documentation submitted by the debtor and the Director, TMA, or a designee. If the Director, TMA, or a designee, determines that the debtor should be afforded the opportunity for an oral hearing, the debtor may elect to have a hearing based on the written record in lieu of an oral hearing. The Director, TMA, or a designee, will provide the debtor (or his representative) notification of the time, date and location of the oral hearing to be held if the debtor has been afforded an oral hearing. Copies of records documenting the debt will be provided to the debtor or his representative (if they have not been previously provided), at least 3 calendar days prior to the date of the oral hearing. At oral hearings, the only evidence permitted, except oral testimony, will be that which was previously submitted as prehearing submissions. At oral hearings, the debtor may not raise any issues not previously raised with TMA. In the absence of good cause shown, a debtor who fails to appear at an oral hearing will be deemed to have waived the right to a hearing and salary offset may be initiated.

(E) *Costs for attendance at oral hearings.* Debtors and their witnesses will bear their own costs for attendance at oral hearings.

(F) *Hearing official's decision.* The Hearing Official's decision will be in writing and will identify the documentation reviewed. It will indicate the amount of debt that he or she determined is valid and shall state the amount of the offset and the estimated duration of the offset. The determination of a hearing official designated under this section is considered an official certification regarding the existence and amount of the debt and/or the terms of the proposed offset schedule for the purposes of executing salary offset under 5 U.S.C. 5514. The Hearing Official's decision must be issued at the earliest practical date, but not later than 60 days from the date the petition for hearing is received by the Office of General Counsel, TMA, unless the debtor requests, and the Hearing Official grants a delay in the proceedings. If a hearing official determines that the debt may not be collected by salary offset, but the Director, TMA, or a designee, finds the debt is still valid, the Director, TMA or a designee, may seek collection through other means, including but not limited to, offset from other payments due from the United States.

(viii) [Reserved]

(ix) *Collection of installments.* Debts, including interest, penalty and administrative costs shall be collected in one lump sum whenever possible. However, when the debtor is financially unable to pay the debt in one lump sum, the TRICARE contractor or the Director, TMA, or designee, may accept payment in installments. Debtors claiming that lump sum payment will create financial hardship may be required to complete a Department of Justice Financial Statement of Debtor form or provide other financial information that will permit TMA to verify such representations. TMA may also obtain credit reports to assess installment requests. Normally, debtors will make installment payments on a monthly basis. Installment payment shall bear a reasonable relationship to the size of the debt and the debtor's ability to pay. Except when a debtor can demonstrate financial hardship or another reasonable cause exists, installment payments should be sufficient in size and frequency to liquidate the debt in 3 years or less. (31 CFR 901.8(b)). Normally, installment payments of $75 or less will not be accepted unless the debtor demonstrates financial hardship. Any installment agreement with a debtor in which the total amount of deferred installments will exceed $750, should normally include an executed promissory agreement. Copies of installment agreements will be retained in the contractor's or TMA, Office of General Counsel's files.

(x) *Interest, penalties, and administrative costs.* Title 31 U.S.C. 3717 and the

Federal Claims Collection Standards, 31 CFR 901.9, require the assessment of interest, penalty and administrative costs on delinquent debts. Interest shall accrue from the date the initial debt notification is mailed to the debtor. The rate of interest assessed shall be the rate of the current value of funds to the United States Treasury (the Treasury tax and loan account rate). The collection of interest on the debt or any portion of the debt, which is paid within 30 days after the date on which interest begins to accrue, shall be waived. The Director, TMA, or designee, may extend this 30-day period on a case-by-case basis, if it reasonably determines that such action is appropriate. The rate of interest as initially assessed shall remain fixed for the duration of the indebtedness; except that where the debtor has defaulted on a repayment agreement and seeks to enter into a new agreement, a new interest rate may be set which reflects the current value of funds to the Treasury at the time the new agreement is executed. Interest shall not be compounded; that is, interest shall not be charged on interest, penalties, or administrative costs required by this section. However, if a debtor defaults on a previous repayment agreement, charges that accrued but were not collected under the defaulted agreement, shall be added to the principal under the new repayment agreement. The collection of interest, penalties and administrative costs may be waived in whole or in part as a part of the compromise of a debt as provided in paragraph (g) of this section. In addition, the Director, TMA, or designee may waive in whole or in part, the collection of interest, penalties, or administrative costs assessed herein if he or she determines that collection would be against equity and good conscience and not in the best interest of the United States. Some situations in which a waiver may be appropriate include:

(A) Waiver of interest consistent with 31 CFR 903.2(c)(2) in connection with a suspension of collection when a TRICARE appeal is pending under §199.10 of this part where there is a substantial issue of fact in dispute.

(B) Waiver of interest where the original debt arose through no fault or lack of good faith on the part of the debtor and the collection of interest would impose a financial hardship or burden on the debtor. Some examples in which such a waiver would be appropriate include: A debt arising when a TRICARE beneficiary in good faith files and is paid for a claim for medical services or supplies, which are later determined not to be covered benefits, or a debt arising when a TRICARE beneficiary is overpaid as the result of a calculation error on the part of the TRICARE contractor or TMA.

(C) Waiver of interest where there has been an agreement to repay a debt in installments, there is no indication of fault or lack of good faith on the part of the debtor, and the amount of interest is so large in relation to the size of the installments that the debtor can reasonably afford to pay, that it is likely the debt will never be repaid in full. When a debt is paid in installments, the installment payments first will be applied to the payment of outstanding penalty and administrative cost charges, second, to accrued interest and then to principal. Administrative costs incurred as the result of a debt becoming delinquent (as defined in paragraph (f)(2)(iii) of this section) shall be assessed against a debtor. These administrative costs represent the additional costs incurred in processing and handling the debt because it became delinquent. The calculation of administrative costs should be based upon cost analysis establishing an average of actual additional costs incurred in processing and handling claims against other debtors in similar stages of delinquency. A penalty charge, not exceeding six percent a year, shall be assessed on the amount due on a debt that is delinquent for more than 90 days. This charge, which need not be calculated until the 91st day of delinquency, shall accrue from the date that the debt became delinquent.

(xi) *Referral to private collection agencies.* TMA shall use government-wide debt collection contracts to obtain debt collection services provided by private contractors in accordance with 31 CFR 901.5(b).

(xii) *Reporting delinquent debts to credit reporting agencies.* Delinquent consumer debts shall be reported to credit reporting agencies. Delinquent debts are debts which are not paid or for which satisfactory payment arrangements are not made by the due date specified in the initial debt notification letter, or those for which the debtor has entered into a written payment agreement and installment payments are past due 30 days or longer. Such referrals shall comply with the Bankruptcy Code and the Privacy Act of 1974, 5 U.S.C. 552a, as amended. The provisions of the Privacy Act do not apply to credit bureaus (31 CFR 901.4(1)). There is no requirement to duplicate the notice and review opportunities before referring debts to credit bureaus. Debtors will be advised of the specific information to be transmitted (i.e., name, address, and taxpayer identification number, information about the debt). Procedures developed for such referrals must ensure that an accounting of the disclosures shall be kept which is available to the debtor; that the credit reporting agencies are provided with corrections and annotations of disagreements of the debtor; and that reasonable efforts are made to ensure that the information to be reported is accurate, complete, timely and relevant. When requested by a credit-reporting agency, verification of the information disclosed will be provided promptly. Once a claim has been reviewed and determined to be valid, a complete explanation of the claim will be given the debtor. When the claim is overdue, the individual will be notified in writing that payment is overdue; that within not less than 60 days, disclosure of the claim shall be made to a consumer reporting agency unless satisfactory payment arrangements are made, or unless the debtor requests an administrative review and demonstrates some basis on which the debt is legitimately disputed; and of the specific information to be disclosed to the consumer reporting agency. The information to be disclosed to the credit reporting agency will be limited to information necessary to establish the identity of the debtor, including name, address and taxpayer identification number; the amount, status and history of the claim; and the agency or program under which the claim arose. Reasonable action will be taken to locate an individual for whom a current address is not available. The requirements of this section do not apply to commercial debts, although commercial debts shall be reported to commercial credit bureaus. Treasury will report debts transferred to it for collection to credit reporting agencies on behalf of the Director, TMA, or a designee.

(xiii) *Use and disclosure of mailing addresses.* In attempting to locate a debtor in order to collect or compromise a debt under this section, the Director, TMA, or a designee, may send a written request to the Secretary of the Treasury, or a designee, for current address information from records of the Internal Revenue Service. TMA may disclose mailing addresses obtained under this authority to other agencies and to collection agencies for collection purposes.

(g) *Compromise, suspension or termination of collection actions arising under the Federal Claims Collection Act*—(1) *Basic considerations.* Federal claims against the debtor and in favor of the United States arising out of the administration of TRICARE may be compromised or collection action taken thereon may be suspended or terminated in compliance with the Federal Claims Collection Act, 31 U.S.C. 3711, as implemented by the Federal Claims Collection Standards, 31 CFR parts 900–904. The provisions concerning compromise, suspension or termination of collection activity pursuant to 31 U.S.C. 3711 apply to debts, which do not exceed $100,000 or any higher amount authorized by the Attorney General, exclusive of interest, penalties, and administrative costs, after deducting the amount of partial payments or collections, if any. If, after deducting the amount of any partial payments or collections, the principal amount of a debt exceeds $100,000, or any higher amount authorized by the Attorney General, exclusive of interest, penalties and administrative costs, the authority to suspend or terminate rests solely with the DOJ.

(2) *Authority.* TRICARE contractors are not authorized to compromise or to suspend or terminate collection action

on TRICARE claims. Only the Director, TMA, or designee or Uniformed Services claims officers acting under the provisions of their own regulations are so authorized.

(3) *Basis for compromise.* A compromise should be for an amount that bears a reasonable relation to the amount that can be recovered by enforced collection procedures, with regard to the exemptions available to the debtor and the time collection will take. A claim may be compromised hereunder if the government cannot collect the full amount if:

(i) The debtor or the estate of a debtor does not have the present or prospective ability to pay the full amount within a reasonable time;

(ii) The cost of collecting the claim does not justify enforced collection of the full amount; or

(iii) The government is unable to enforce collection of the full amount within a reasonable time by enforced collection proceedings; or

(iv) There is significant doubt concerning the Government's ability to prove its case in court for the full amount claimed; or

(v) The cost of collecting the claim does not justify enforced collection of the full amount.

(4) *Basis for suspension.* Collection action may be suspended for the following reasons if future collection action may be sufficiently productive to justify periodic review and action on the claim, considering its size and the amount, which may be realized thereon:

(i) The debtor cannot be located; or

(ii) The debtor's financial condition is expected to improve; or

(iii) The debtor is unable to make payments on the government's claim or effect a compromise at the time, but the debtor's future prospects justify retention of the claim for periodic review and action and;

(A) The applicable statute of limitations has been tolled or started running anew; or

(B) Future collections can be effected by administrative offset, notwithstanding the expiration of the applicable statute of limitations for litigation of claims with due regard to the 10-year limitation for administrative offset under 31 U.S.C. 3716(e)(1); or

(C) The debtor agrees to pay interest on the amount of the debt on which collection action will be temporarily suspended and such temporary suspension is likely to enhance the debtor's ability fully to pay the principal amount of the debt with interest at a later date.

(iv) Consideration may be given by the Director, TMA, or designee to suspend collection action pending action on a request for a review of the government's claim against the debtor or pending an administrative review under §199.10 of this part of any TRICARE claim or claims directly involved in the government's claim against the debtor. Suspension under this paragraph will be made on a case-by-case basis as to whether:

(A) There is a reasonable possibility that the debt (in whole or in part) will be found not owing from the debtor;

(B) The government's interest would be protected if suspension were granted by reasonable assurance that the debt would be recovered if the debtor does not prevail; and

(C) Collection of the debt will cause undue hardship.

(5) Collection action may be terminated for one or more of the following reasons:

(i) TMA cannot collect or enforce collection of any substantial amount through its own efforts or the efforts of others, including consideration of the judicial remedies available to the government, the debtor's future financial prospects, and the exemptions available to the debtor under state and federal law;

(ii) The debtor cannot be located, and either;

(iii) The costs of collection are anticipated to exceed the amount recoverable; or

(iv) It is determined that the debt is legally without merit or enforcement of the debt is barred by any applicable statute of limitations; or

(v) The debt cannot be substantiated; or

(vi) The debt against the debtor has been discharged in bankruptcy. Collection activity may be continued subject to the provisions of the Bankruptcy

Code, such as collection of any payments provided under a plan of reorganization or in cases when TMA did not receive notice of the bankruptcy proceedings.

(6) In determining whether the debt should be compromised, suspended or terminated, the responsible TMA collection authority will consider the following factors:

(i) Age and health of the debtor; present and potential income; inheritance prospects; the possibility that assets have been concealed or improperly transferred by the debtor; and the availability of assets or income which may be realized by enforced collection proceedings;

(ii) Applicability of exemptions available to a debtor under state or federal law;

(iii) Uncertainty as to the price which collateral or other property may bring at a forced sale;

(iv) The probability of proving the claim in court because of legal issues involved or because of a bona fide dispute of the facts; the probability of full or partial recovery; the availability of necessary evidence and related pragmatic considerations. Debtors may be required to provide a completed Department of Justice Financial Statement of Debtor form (OBD–500 or such other form that DOJ shall prescribe) or other financial information that will permit TMA to verify debtors' representations. TMA may obtain credit reports or other financial information to enable it independently to verify debtors' representations.

(7) Payment of compromised claims. (i) *Time and manner.* Compromised claims are to be paid in one lump sum whenever possible. However, if installment payments of a compromised claim are necessary, a legally enforceable compromise agreement must be obtained. Payment of the amount that TMA has agreed to accept as a compromise in full settlement of a TRICARE claim must be made within the time and in the manner prescribed in the compromise agreement. Any such compromised amount is not settled until full payment of the compromised amount has been made within the time and manner prescribed. Compromise agreements must provide for the reinstatement of the prior indebtedness, less sums paid thereon, and acceleration of the balance due upon default in the payment of any installment.

(ii) *Failure to pay the compromised amount.* Failure of any debtor to make payment as provided in the compromise agreement will have the effect of reinstating the full amount of the original claim, less any amounts paid prior to default.

(iii) Effect of compromise, waiver, suspension or termination of collection action. Pursuant to the Internal Revenue Code, 26 U.S.C. 6050P, compromises and terminations of undisputed debts totaling $600 or more for the year will be reported to the Internal Revenue Service in the manner prescribed. Amounts, other than those discharged in bankruptcy, will be included in the debtor's gross income for that year. Any action taken under paragraph (g) of this section regarding the compromise of a federal claim, or waiver or suspension or termination of collection action on a federal claim is not an initial determination for the purposes of the appeal procedures in §199.10.

(h) *Referrals for collection*—(1) *Prompt referral.* Federal claims of $2,500, exclusive of interest, penalties and administrative costs, or such other amount as the Attorney General shall from time to time prescribe on which collection action has been taken under the provisions of this section which cannot be collected or compromised or on which collection action cannot be suspended or terminated as provided herein, will be promptly referred to the Department of Justice for litigation in accordance with 31 CFR part 904. Such referrals shall be made as early as possible consistent with aggressive collection action made by TRICARE contractors and TMA. Referral will be made with sufficient time to bring timely suit against the debtor. Referral shall be made by submission of a completed Claims Collection Litigation Report (CCLR), accompanied by a signed Certificate of Indebtedness. Claims of less than the minimum amount shall not be referred unless litigation to collect

such smaller claims is important to ensure compliance with TRICARE's policies or programs; the claim is being referred solely for the purpose of securing a judgment against the debtor, which will be filed as a lien against the debtor's property pursuant to 28 U.S.C. 3201 and returned to the referring office for enforcement; or the debtor has the clear ability to pay the claim and the Government effectively can enforce payment, with due regard for the exemptions available to the debtor under state and Federal law and judicial remedies available to the Government.

(2) *Preservation of evidence.* The Director, TMA, or a designee will take such action as is necessary to ensure that all files, records and exhibits on claims referred, hereunder, are properly preserved.

(i) *Claims involving indication of fraud, filing of false claims or misrepresentation.* Any case in which there is an indication of fraud, the filing of a false claim or misrepresentation on the part of the debtor or any party having an interest in the claim, shall be promptly referred to the Director, TMA, or designee. The Director, TMA, or a designee, will investigate and evaluate the case and either refer the case to an appropriate investigative law enforcement agency or return the claim for other appropriate administrative action, including collection action under this section. Payment on all TRICARE beneficiary or provider claims in which fraud, filing false claims or misrepresentation is suspected will be suspended until the Director, TMA, or designee, authorizes payment or denial of the claims. Collection action on all claims in which a suspicion of fraud, misrepresentation or filing false claims arises, will be suspended pending referral to the appropriate law enforcement agencies by the Director, TMA, or a designee. Only the Department of Justice has authority to compromise, suspend or terminate collection of such debts.

(ii) [Reserved]

[73 FR 71547, Nov. 25, 2008, as amended at 77 FR 38176, June 27, 2012; 82 FR 45447, Sept. 29, 2017]

§ 199.12 Third party recoveries.

(a) *General.* This section deals with the right of the United States to recover from third-parties the costs of medical care furnished to or paid on behalf of TRICARE beneficiaries. These third-parties may be individuals or entities that are liable for tort damages to the injured TRICARE beneficiary or a liability insurance carrier covering the individual or entity. These third-parties may also include other entities who are primarily responsible to pay for the medical care provided to the injured beneficiary by reason of an insurance policy, workers' compensation program or other source of primary payment.

Authority—(1) *Third-party payers.* This part implements the provisions of 10 U.S.C. 1095b which, in general, allow the Secretary of Defense to authorize certain TRICARE claims to be paid, even though a third-party payer may be primary payer, with authority to collect from the third-party payer the TRICARE costs incurred on behalf of the beneficiary. (See §199.2 for definition of ''third-party payer.'') Therefore, 10 U.S.C. 1095b establishes the statutory obligation of third-party payers to reimburse the United States the costs incurred on behalf of TRICARE beneficiaries who are also covered by the third-party payer's plan.

(2) *Federal Medical Care Recovery Act*—(i) *In general.* In many cases covered by this section, the United States has a right to collect under both 10 U.S.C. 1095b and the Federal Medical Care Recovery Act (FMCRA), Public Law 87–693 (42 U.S.C. 2651 *et. seq.*). In such cases, the authority is concurrent and the United States may pursue collection under both statutory authorities.

(ii) *Cases involving tort liability.* In cases in which the right of the United States to collect from an automobile liability insurance carrier is premised on establishing some tort liability on some third person, matters regarding the determination of such tort liability shall be governed by the same substantive standards as would be applied under the FMCRA including reliance on state law for determinations regarding tort liability. In addition, the provisions of 28 CFR part 43 (Department of Justice regulations pertaining to the FMCRA) shall apply to claims made under the concurrent authority of the

FMCRA and 10 U.S.C. 1095b. All other matters and procedures concerning the right of the United States to collect shall, if a claim is made under the concurrent authority of the FMCRA and this section, be governed by 10 U.S.C. 1095b and this part.

(c) *Appealability*. This section describes the procedures to be followed in the assertion and collection of third-party recovery claims in favor of the United States arising from the operation of TRICARE. Actions taken under this section are not initial determinations for the purpose of the appeal procedures of §199.10 of this part. However, the proper exercise of the right to appeal benefit or provider status determinations under the procedures set forth in §199.10 may affect the processing of federal claims arising under this section. Those appeal procedures afford a TRICARE beneficiary or participating provider an opportunity for administrative appellate review in cases in which benefits have been denied and in which there is a significant factual dispute. For example, a TRICARE contractor may deny payment for services that are determined to be excluded as TRICARE benefits because they are found to be not medically necessary. In that event the TRICARE contractor will offer an administrative appeal as provided in §199.10 of this part on the medical necessity issue raised by the adverse benefit determination. If the care in question results from an accidental injury and if the appeal results in a reversal of the initial determination to deny the benefit, a third-party recovery claim may arise as a result of the appeal decision to pay the benefit. However, in no case is the decision to initiate such a claim itself appealable under §199.10.

(d) *Statutory obligation of third-party payer to pay*—(1) *Basic Rule*. Pursuant to 10 U.S.C. 1095b, when the Secretary of Defense authorizes certain TRICARE claims to be paid, even though a third-party payer may be primary payer (as specified under §199.8(c)(2)), the right to collect from a third-party payer the TRICARE costs incurred on behalf of the beneficiary is the same as exists for the United States to collect from third-party payers the cost of care provided by a facility of the uniformed services under 10 U.S.C. 1095 and part 220 of this title. Therefore the obligation of a third-party payer to pay is to the same extent that the beneficiary would be eligible to receive reimbursement or indemnification from the third-party payer if the beneficiary were to incur the costs on the beneficiary's own behalf.

(2) *Application of cost shares*. If the third-party payer's plan includes a requirement for a deductible or copayment by the beneficiary of the plan, then the amount the United States may collect from the third-party payer is the cost of care incurred on behalf of the beneficiary less the appropriate deductible or copayment amount.

(3) *Claim from the United States exclusive*. The only way for a third-party payer to satisfy its obligation under 10 U.S.C. 1095b is to pay the United States or authorized representative of the United States. Payment by a third-party payer to the beneficiary does not satisfy 10 U.S.C. 1095b.

(4) *Assignment of benefits not necessary*. The obligation of the third-party to pay is not dependent upon the beneficiary executing an assignment of benefits to the United States.

(e) *Exclusions impermissible*—(1) *Statutory requirement*. With the same right to collect from third-party payers as exists under 10 U.S.C. 1095(b), no provision of any third-party payer's plan having the effect of excluding from coverage or limiting payment for certain care if that care is provided or paid by the United States shall operate to prevent collection by the United States.

(2) *Regulatory application*. No provision of any third-party payer's plan or program purporting to have the effect of excluding or limiting payment for certain care that would not be given such effect under the standards established in part 220 of this title to implement 10 U.S.C. 1095 shall operate to exclude or limit payment under 10 U.S.C. 1095b or this section.

(f) *Records available*. When requested, TRICARE contractors or other representatives of the United States shall make available to representatives of any third-party payer from which the United States seeks payment under 10

U.S.C. 1095b, for inspection and review, appropriate health care records (or copies of such records) of individuals for whose care payment is sought. Appropriate records which will be made available are records which document that the TRICARE costs incurred on behalf of beneficiaries which are the subject of the claims for payment under 10 U.S.C. 1095b were incurred as claimed and the health care service were provided in a manner consistent with permissible terms and conditions of the third-party payer's plan. This is the sole purpose for which patient care records will be made available. Records not needed for this purpose will not be made available.

(g) *Remedies.* Pursuant to 10 U.S.C. 1095b, when the Director, TRICARE Management Activity, or a designee, authorizes certain TRICARE claims to be paid, even though a third-party payer may be primary payer, the right to collect from a third-party payer the TRICARE costs incurred on behalf of the beneficiary is the same as exists for the United States to collect from third-party payers the cost of care provided by a facility of the uniformed services under 10 U.S.C. 1095.

(1) This includes the authority under 10 U.S.C. 1095(e)(1) for the United States to institute and prosecute legal proceedings against a third-party payer to enforce a right of the United States under 10 U.S.C. 1095b and this section.

(2) This also includes the authority under 10 U.S.C. 1095(e)(2) for an authorized representative of the United States to compromise, settle or waive a claim of the United States under 10 U.S.C. 1095b and this section.

(3) The authorities provided by the Federal Claims Collection Act of 1966, as amended (31 U.S.C. 3701 *et. seq.*) and any implementing regulations (including §199.11) regarding collection of indebtedness due the United States shall also be available to effect collections pursuant to 10 U.S.C. 1095b and this section.

(h) *Obligations of beneficiaries.* To insure the expeditious and efficient processing of third-party payer claims, any person furnished care and treatment under TRICARE, his or her guardian, personal representative, counsel, estate, dependents or survivors shall be required:

(1) To provide information regarding coverage by a third-party payer plan and/or the circumstances surrounding an injury to the patient as a conditional precedent of the processing of a TRICARE claim involving possible third-party payer coverage.

(2) To furnish such additional information as may be requested concerning the circumstances giving rise to the injury or disease for which care and treatment are being given and concerning any action instituted or to be instituted by or against a third person; and,

(3) To cooperate in the prosecution of all claims and actions by the United States against such third person.

(i) *Responsibility for recovery.* The Director, TRICARE Management Activity, or a designee, is responsible for insuring that TRICARE claims arising under 10 U.S.C. 1095b and this section (including claims involving the FMCRA) are properly referred to and coordinated with designated claims authorities of the uniformed services who shall assert and recover TRICARE costs incurred on behalf of beneficiaries. Generally, claims arising under this section will be processed as follows:

(1) *Identification and referral.* In most cases where civilian providers provide medical care and payment for such care has been by a TRICARE contractor, initial identification of potential third-party payers will be by the TRICARE contractor. In such cases, the TRICARE contractor is responsible for conducting a preliminary investigation and referring the case to designated appropriate claims authorities of the Uniformed Services.

(2) *Processing TRICARE claims.* When the TRICARE contractor initially identifies a claim as involving a potential third-party payer, it shall request additional information concerning the circumstances of the injury or disease and/or the identify of any potential third-party payer from the beneficiary or other responsible party unless adequate information is submitted with the claim. The TRICARE claim will be

suspended and no payment issued pending receipt of the requested information. If the requested information is not received, the claim will be denied. A TRICARE beneficiary may expedite the processing of his or her TRICARE claim by submitting appropriate information with the first claim for treatment of an accidental injury. Third-party payer information normally is required only once concerning any single accidental injury on episode of care. Once the third-party payer information pertaining to a single incident or episode of care is received, subsequent claims associated with the same incident or episode of care may be processed to payment in the usual manner. If, however, the requested third-party payer information is not received, subsequent claims involving the same incident or episode of care will be suspended or denied as stated above.

(3) *Ascertaining total potential liability.* It is essential that the appropriate claims responsible for asserting the claim against the third-party payer receive from the TRICARE contractor a report of all amounts expended by the United States for care resulting from the incident upon which potential liability in the third party is based (including amounts paid by TRICARE for both inpatient and outpatient care). Prior to assertion and final settlement of a claim, it will be necessary for the responsible claims authority to secure from the TRICARE contractor updated information to insure that all amounts expended under TRICARE are included in the government's claim. It is equally important that information on future medical payments be obtained through the investigative process and included as a part of the government's claim. No TRICARE-related claim will be settled, compromised or waived without full consideration being given to the possible future medical payment aspects of the individual case.

(j) *Reporting requirements.* Pursuant to 10 U.S.C. 1079a, all refunds and other amounts collected in the administration of TRICARE shall be credited to the appropriation available for that program for the fiscal year in which the refund or amount is collected. Therefore, the Department of Defense requires an annual report stating the number and dollar amount of claims asserted against, and the number and dollar amount of recoveries from third-party payers (including FMCRA recoveries) arising from the operation of the TRICARE. To facilitate the preparation of this report and to maintain program integrity, the following reporting requirements are established:

(1) *TRICARE contractors.* Each TRICARE contractor shall submit on or before January 31 of each year an annual report to the Director, TRICARE Management Activity, or a designee, covering the 12 months of the previous calendar year. This report shall contain, as a minimum, the number and total dollar of cases of potential third-party payer/FMCRA liability referred to uniformed services claims authorities for further investigation and collection. These figures are to be itemized by the states and uniformed services to which the cases are referred.

(2) *Uniformed Services.* Each uniformed service will submit to the Director, TRICARE Management Activity, or designee, an annual report covering the 12 calendar months of the previous year, setting forth, as a minimum, the number and total dollar amount of cases involving TRICARE payments received from TRICARE contractors, the number and dollar amount of cases involving TRICARE payments received from other sources, and the number and dollar amount of claims actually asserted against, and the dollar amount of recoveries from, third-payment payers or under the FMCRA. The report, itemized by state and foreign claims jurisdictions, shall be provided no later than February 28 of each year.

(3) *Implementation of the reporting requirements.* The Director, TRICARE Management Activity, or a designee shall issue guidance for implementation of the reporting requirements prescribed by this section.

[68 FR 6619, Feb. 10, 2003]

§ 199.13 TRICARE Dental Program.

(a) *General provisions*—(1) *Purpose.* This section prescribes guidelines and

policies for the delivery and administration of the TRICARE Dental Program (TDP) of the Uniformed Services of the Army, the Navy, the Air Force, the Marine Corps, the Coast Guard, the Commissioned Corps of the U.S. Public Health Service (USPHS) and the National Oceanic and Atmospheric Administration (NOAA) Corps. The TDP is a premium based indemnity dental insurance coverage plan that is available to specified categories of individuals who are qualified for these benefits by virtue of their relationship to one of the seven (7) Uniformed Services and their voluntary decision to accept enrollment in the plan and cost share (when applicable) with the Government in the premium cost of the benefits. The TDP is authorized by 10 U.S.C. 1076a, TRICARE dental program, and this section was previously titled the ''Active Duty Dependents Dental Plan''. The TDP incorporates the former 10 U.S.C. 1076b, Selected Reserve dental insurance, and the section previously titled the ''TRICARE Selected Reserve Dental Program'', §199.21.

(2) *Applicability*—(i) *Geographic scope.* (A) The TDP is applicable geographically within the fifty (50) States of the United States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, and the U.S. Virgin Islands. These areas are collectively referred to as the ''CONUS (or Continental United States) service area''.

(B) Extension of the TDP to areas outside the CONUS service area. In accordance with the authority cited in 10 U.S.C. 1076a(h), the Assistant Secretary of Defense (Health Affairs) (ASD(HA)) may extend the TDP to areas other than those areas specified in paragraph (a)(2)(i)(A) of this section for the eligible members and eligible dependents of members of the Uniformed Services. These areas are collectively referred to as the ''OCONUS (or outside the Continental United States) service area''. In extending the TDP outside the CONUS service area, the ASD(HA), or designee, is authorized to establish program elements, methods of administration and payment rates and procedures to providers that are different from those in effect for the CONUS service area to the extent the ASD(HA), or designee, determines necessary for the effective and efficient operation of the TDP. This includes provisions for preauthorization of care if the needed services are not available in a Uniformed Service overseas dental treatment facility and payment by the Department of certain cost-shares (or copayments) and other portions of a provider's billed charges for certain beneficiary categories. Other differences may occur based on limitations in the availability and capabilities of the Uniformed Service overseas dental treatment facility and a particular nation's civilian sector providers in certain areas. These differences include varying licensure and certification requirements of OCONUS providers, Uniformed Service provider selection criteria and local results of provider selection, referral, beneficiary pre-authorization and marketing procedures, and care for beneficiaries residing in distant areas. The Director, Office of Civilian Health and Medical Program of the Uniformed Services (OCHAMPUS) shall issue guidance, as necessary, to implement the provisions of paragraph (a)(2)(i)(B). Beneficiaries will be eligible for the same TDP benefits in the OCONUS service area although services may not be available or accessible in all OCONUS countries.

(ii) *Agency.* The provisions of this section apply throughout the Department of Defense (DoD), the United States Coast Guard, the USPHS and NOAA.

(iii) *Exclusion of benefit services performed in military dental care facilities.* Except for emergency treatment, dental care provided outside the United States, services incidental to noncovered services, and services provided under paragraph (a)(2)(iv), dependents of active duty, Selected Reserve and Individual Ready Reserve members enrolled in the TDP may not obtain those services that are benefits of the TDP in military dental care facilities, as long as those covered benefits are available for cost-sharing under the TDP. Enrolled dependents of active duty, Selected Reserve and Individual Ready Reserve members may continue to obtain noncovered services from military dental care facilities subject to the provisions for space available care.

(iv) *Exception to the exclusion of services performed in military dental care facilities.*

(A) Dependents who are 12 years of age or younger and are covered by a dental plan established under this section may be treated by postgraduate dental residents in a dental treatment facility of the uniformed services under a graduate dental education program accredited by the American Dental Association if

(*1*) Treatment of pediatric dental patients is necessary in order to satisfy an accreditation standard of the American Dental Association that is applicable to such program, or training in pediatric dental care is necessary for the residents to be professionally qualified to provide dental care for dependent children accompanying members of the uniformed services outside the United States; and

(*2*) The number of pediatric patients at such facility is insufficient to support satisfaction of the accreditation or professional requirements in pediatric dental care that apply to such programs or students.

(B) The total number of dependents treated in all facilities of the uniformed services under paragraph (a)(2)(iv) in a fiscal year may not exceed 2,000.

(3) *Authority and responsibility*—(i) *Legislative authority*—(A) *Joint regulations.* 10 U.S.C. 1076a authorized the Secretary of Defense, in consultation with the Secretary of Health and Human Services, and the Secretary of Transportation, to prescribe regulations for the administration of the TDP.

(B) *Administration.* 10 U.S.C. 1073 authorizes the Secretary of Defense to administer the TDP for the Army, Navy, Air Force, and Marine Corps under DoD jurisdiction, the Secretary of Transportation to administer the TDP for the Coast Guard, when the Coast Guard is not operating as a service in the Navy, and the Secretary of Health and Human Services to administer the TDP for the Commissioned Corps of the USPHS and the NOAA Corps.

(ii) *Organizational delegations and assignments*—(A) *Assistant Secretary of Defense (Health Affairs) (ASD(HA)).* The Secretary of Defense, by 32 CFR part 367, delegated authority to the ASD(HA) to provide policy guidance, management control, and coordination as required for all DoD health and medical resources and functional areas including health benefit programs. Implementing authority is contained in 32 CFR part 367. For additional implementing authority see §199.1. Any guidelines or policy necessary for implementation of this §199.13 shall be issued by the Director, OCHAMPUS.

(B) *Evidence of eligibility.* DoD, through the Defense Enrollment Eligibility Reporting System (DEERS), is responsible for establishing and maintaining a listing of persons eligible to receive benefits under the TDP.

(4) *Preemption of State and local laws.* (i) Pursuant to 10 U.S.C. 1103 and section 8025 (fourth proviso) of the Department of Defense Appropriations Act, 1994, DoD has determined that, in the administration of 10 U.S.C. chapter 55, preemption of State and local laws relating to health insurance, prepaid health plans, or other health care delivery or financing methods is necessary to achieve important Federal interests, including, but not limited to, the assurance of uniform national health programs for Uniformed Service beneficiaries and the operation of such programs at the lowest possible cost to DoD, that have a direct and substantial effect on the conduct of military affairs and national security policy of the United States. This determination is applicable to the dental services contracts that implement this section.

(ii) Based on the determination set forth in paragraph (a)(4)(i) of this section, any State or local law relating to health or dental insurance, prepaid health or dental plans, or other health or dental care delivery or financing methods is preempted and does not apply in connection with the TDP contract. Any such law, or regulation pursuant to such law, is without any force or effect, and State or local governments have no legal authority to enforce them in relation to the TDP contract. (However, DoD may, by contract, establish legal obligations on the part of the dental plan contractor to conform with requirements similar or identical to requirements of State or local laws or regulations.)

(iii) The preemption of State and local laws set forth in paragraph (a)(4)(ii) of this section includes State and local laws imposing premium taxes on health or dental insurance carriers or underwriters or other plan managers, or similar taxes on such entities. Such laws are laws relating to health insurance, prepaid health plans, or other health care delivery or financing methods, within the meaning of the statutes identified in paragraph (a)(4)(i) of this section. Preemption, however, does not apply to taxes, fees, or other payments on net income or profit realized by such entities in the conduct of business relating to DoD health services contracts, if those taxes, fees, or other payments are applicable to a broad range of business activity. For purposes of assessing the effect of Federal preemption of State and local taxes and fees in connection with DoD health and dental services contracts, interpretations shall be consistent with those applicable to the Federal Employees Health Benefits Program under 5 U.S.C. 8909(f).

(5) *Plan funds*—(i) *Funding sources.* The funds used by the TDP are appropriated funds furnished by the Congress through the annual appropriation acts for DoD, the Department of Health and Human Services and the Department of Transportation and funds collected by the Uniformed Services or contractor through payroll deductions or through direct billing as premium shares from beneficiaries.

(ii) *Disposition of funds.* TDP funds are paid by the Government (or in the case of direct billing, by the beneficiary) as premiums to an insurer, service, or prepaid dental care organization under a contract negotiated by the Director, OCHAMPUS, or a designee, under the provisions of the Federal Acquisition Regulation (FAR) (48 CFR chapter 1).

(iii) *Plan.* The Director, OCHAMPUS, or designee provides an insurance policy, service plan, or prepaid contract of benefits in accordance with those prescribed by law and regulation; as interpreted and adjudicated in accord with the policy, service plan, or contract and a dental benefits brochure; and as prescribed by requirements of the dental plan contractor's contract with the Government.

(iv) *Contracting out.* The method of delivery of the TDP is through a competitively procured contract. The Director, OCHAMPUS, or a designee, is responsible for negotiating, under provisions of the FAR, a contract for dental benefits insurance or prepayment that includes responsibility for:

(A) Development, publication, and enforcement of benefit policy, exclusions, and limitations in compliance with the law, regulation, and the contract provisions;

(B) Adjudicating and processing claims; and conducting related supporting activities, such as enrollment, disenrollment, collection of premiums, eligibility verification, provider relations, and beneficiary communications.

(6) *Role of Health Benefits Advisor (HBA).* The HBA is appointed (generally by the commander of an Uniformed Services medical treatment facility) to serve as an advisor to patients and staff in matters involving the TDP. The HBA may assist beneficiaries in applying for benefits, in the preparation of claims, and in their relations with OCHAMPUS and the dental plan contractor. However, the HBA is not responsible for the TDP's policies and procedures and has no authority to make benefit determinations or obligate the TDP's funds. Advice given to beneficiaries by HBAs as to determination of benefits or level of payment is not binding on OCHAMPUS or the dental plan contractor.

(7) *Right to information.* As a condition precedent to the provision of benefits hereunder, the Director, OCHAMPUS, or designee, shall be entitled to receive information from an authorized provider or other person, institution, or organization (including a local, State, or United States Government agency) providing services or supplies to the beneficiary for which claims for benefits are submitted. While establishing enrollment and eligibility, benefits, and benefit utilization and performance reporting information standards, the Government has established and does maintain a system of records for dental information under the TDP. By contract, the Government audits the adequacy and accuracy of

the dental plan contractor's system of records and requires access to information and records to meet plan accountabilities, to assist in contractor surveillance and program integrity investigations and to audit OCONUS financial transactions where the Department has a financial stake. Such information and records may relate to attendance, testing, monitoring, examination, or diagnosis of dental disease or conditions; or treatment rendered; or services and supplies furnished to a beneficiary; and shall be necessary for the accurate and efficient administration and payment of benefits under this plan. To assist in claims adjudication, grievance and fraud investigations, and the appeals process, and before an interim or final determination can be made on a claim of benefits, a beneficiary or active duty, Selected Reserve or individual Ready Reserve member must provide particular additional information relevant to the requested determination, when necessary. Failure to provide the requested information may result in denial of the claim and inability to effectively investigate the grievance or fraud or process the appeal. The recipient of such information shall in every case hold such records confidential except when:

(i) Disclosure of such information is necessary to the determination by a provider or the dental plan contractor of beneficiary enrollment or eligibility for coverage of specific services;

(ii) Disclosure of such information is authorized specifically by the beneficiary;

(iii) Disclosure is necessary to permit authorized Government officials to investigate and prosecute criminal actions;

(iv) Disclosure constitutes a routine use of a routine use of a record which is compatible with the purpose for which it was collected. This includes a standard and acceptable business practice commonly used among dental insurers which is consistent with the principle of preserving confidentiality of personal information and detailed clinical data. For example, the release of utilization information for the purpose of determining eligibility for certain services, such as the number of dental prophylaxis procedures performed for a beneficiary, is authorized;

(v) Disclosure is pursuant to an order from a court of competent jurisdiction; or

(vi) Disclosure by the Director, OCHAMPUS, or designee, is for the purpose of determining the applicability of, and implementing the provisions of, other dental benefits coverage or entitlement.

(8) *Utilization review and quality assurance.* Claims submitted for benefits under the TDP are subject to review by the Director, OCHAMPUS, or designee, for quality of care and appropriate utilization. The Director, OCHAMPUS, or designee, is responsible for appropriate utilization review and quality assurance standards, norms, and criteria consistent with the level of benefits.

(b) *Definitions.* For most definitions applicable to the provisions of this section, refer to Sec. 199.2. The following definitions apply only to this section:

(1) *Assignment of benefits.* Acceptance by a nonparticipating provider of payment directly from the insurer while reserving the right to charge the beneficiary or active duty, Selected Reserve or Individual Ready Reserve member for any remaining amount of the fees for services which exceeds the prevailing fee allowance of the insurer.

(2) *Authorized provider.* A dentist, dental hygienist, or certified and licensed anesthetist specifically authorized to provide benefits under the TDP in paragraph (f) of this section.

(3) *Beneficiary.* A dependent of an active duty, Selected Reserve or Individual Ready Reserve member, or a member of the Selected Reserve or Individual Ready Reserve, who has been enrolled in the TDP, and has been determined to be eligible for benefits, as set forth in paragraph (c) of this section.

(4) *Beneficiary liability.* The legal obligation of the beneficiary, his or her estate, or responsible family member to pay for the costs of dental care or treatment received. Specifically, for the purposes of services and supplies covered by the TDP, beneficiary liability including cost-sharing amounts or any amount above the network maximum allowable charge where the provider selected by the beneficiary is not

a participating provider or a provider within an approved alternative delivery system. In cases where a nonparticipating provider does not accept assignment of benefits.

(5) *By report.* Dental procedures which are authorized as benefits only in unusual circumstances requiring justification of exceptional conditions related to otherwise authorized procedures. These services are further defined in paragraph (e) of this section.

(6) *Contingency operation.* Defined in 10 U.S.C. 101(a)(13) as a military operation designated as a contingency operation by the Secretary of Defense or a military operation that results in the exercise of authorities for ordering Reserve Component members to active duty without their consent and is therefore automatically a contingency operation.

(7) *Cost-share.* The amount of money for which the beneficiary (or active duty, Selected Reserve or Individual Ready Reserve member) is responsible in connection with otherwise covered dental services (other than disallowed amounts) as set forth in paragraph (e) of this section. A cost-share may also be referred to as a ''co-payment.''

(8) *Defense Enrollment Eligibility Reporting System (DEERS).* The automated system that is composed of two (2) phases:

(i) Enrolling all active duty, Reserve and retired service members, their dependents, and the dependents of deceased service members; and

(ii) Verifying their eligibility for health care benefits in the direct care facilities and through the TDP.

(9) *Dental hygienist.* Practitioner in rendering complete oral prophylaxis services, applying medication, performing dental radiography, and providing dental education services with a certificate, associate degree, or bachelor's degree in the field, and licensed by an appropriate authority.

(10) *Dentist.* Doctor of Dental Medicine (D.M.D.) or Doctor of Dental Surgery (D.D.S.) who is licensed to practice dentistry by an appropriate authority.

(11) *Diagnostic services.* Category of dental services including:

(i) Clinical oral examinations;

(ii) Radiographic examinations; and

(iii) Diagnostic laboratory tests and examinations provided in connection with other dental procedures authorized as benefits of the TDP and further defined in paragraph (e) of the section.

(12) *Endodontics.* The etiology, prevention, diagnosis, and treatment of diseases and injuries affecting the dental pulp, tooth root, and periapical tissue as further defined in paragraph (e) of this section.

(13) *Initial determination.* A formal written decision on a TDP claim, a request for TDP benefit pre-determination, a request by a provider for approval as an authorized provider, or a decision suspending, excluding or terminating a provider as an authorized provider under the TDP. Rejection of a claim or pre-determination, or of a request for benefit or provider authorization for failure to comply with administrative requirements, including failure to submit reasonably requested information, is not an initial determination. Responses to general or specific inquiries regarding TDP benefits are not initial determinations.

(14) *Nonparticipating provider.* A dentist or dental hygienist that furnished dental services to a TDP beneficiary, but who has not agreed to participate in the contractor's network and accept reimbursement in accordance with the contractor's network agreement. A nonparticipating provider looks to the beneficiary or active duty, Selected Reserve or Individual Ready Reserve member for final responsibility for payment of his or her charge, but may accept payment (assignment of benefits) directly from the insurer or assist the beneficiary in filing the claim for reimbursement by the dental plan contractor. Where the nonparticipating provider does not accept payment directly from the insurer, the insurer pays the beneficiary or active duty, Selected Reserve or Individual Ready Reserve member, not the provider.

(15) *Oral and maxillofacial surgery.* Surgical procedures performed in the oral cavity as further defined in paragraph (e) of this section.

(16) *Orthodontics.* The supervision, guidance, and correction of the growing or mature dentofacial structures, including those conditions that require movement of teeth or correction of

malrelationships and malformations of their related structures and adjustment of relationships between and among teeth and facial bones by the application of forces and/or the stimulation and redirection of functional forces within the craniofacial complex as further defined in paragraph (e) of this section.

(17) *Participating provider*. A dentist or dental hygienist who has agreed to participate in the contractor's network and accept reimbursement in accordance with the contractor's network agreement as the total charge (even though less than the actual billed amount), including provision for payment to the provider by the beneficiary (or active duty, Selected Reserve or Individual Ready Reserve member) or any cost-share for covered services.

(18) *Party to the initial determination*. Includes the TDP, a beneficiary of the TDP and a participating provider of services whose interests have been adjudicated by the initial determination. In addition, provider who has been denied approval as an authorized TDP provider is a party to the initial determination, as is a provider who is suspended, excluded or terminated as an authorized provider, unless the provider is excluded or suspended by another agency of the Federal Government, a state, or a local licensing authority.

(19) *Periodontics*. The examination, diagnosis, and treatment of diseases affecting the supporting structures of the teeth as further defined in paragraph (e) of this section.

(20) *Preventive services*. Traditional prophylaxis including scaling deposits from teeth, polishing teeth, and topical application of fluoride to teeth, as well as other dental services authorized in paragraph (e) of this section.

(21) *Prosthodontics*. The diagnosis, planning, making, insertion, adjustment, refinement, and repair of artificial devices intended for the replacement of missing teeth and associated tissues as further defined in paragraph (e) of this section.

(22) *Provider*. A dentist, dental hygienist, or certified and licensed anesthetist as specified in paragraph (f) of this section. This term, when used in relation to OCONUS service area providers, may include other recognized professions authorized to furnish care under laws of that particular country.

(23) *Restorative services*. Restoration of teeth including those procedures commonly described as amalgam restorations, resin restorations, pin retention, and stainless steel crowns for primary teeth as further defined in paragraph (e) of this section.

(c) *Eligibility and enrollment*—(1) *General*. 10 U.S.C. 1076a, 1072(2)(A), (D), or (I), 1072(6), 10143 and 10144 set forth those persons who are eligible for voluntary enrollment in the TDP. A determination that a person is eligible for voluntary enrollment does not automatically entitle that person to benefit payments. The person must be enrolled in accordance with the provisions set forth in this section and meet any additional eligibility requirements in this part in order for dental benefits to be extended.

(2) *Eligibility*—(i) *Persons eligible*. Eligibility for the TDP is continuous in situations where the sponsor or member changes status between any of these eligible categories and there is no break in service or transfer to a non-eligible status.

(A) A person who bears one of the following relationships to an active duty member (under a call or order that does not specify a period of thirty (30) days or less) or a member of the Selected Reserve (as specified in 10 U.S.C. 10143) or Individual Ready Reserve (as specified in 10 U.S.C. 10144):

(*1*) *Spouse*. A lawful husband or wife, regardless of whether or not dependent upon the active duty, Selected Reserve or Individual Ready Reserve member.

(*2*) *Child*. To be eligible, the child must be unmarried and meet one of the requirements set forth in section 199.3(b)(2)(ii)(A)–(F) or 199.3(b)(2)(ii)(H).

(B) A member of the Selected Reserve of the Ready Reserve (as specified in 10 U.S.C. 10143).

(C) A member of the Individual Ready Reserve of the Ready Reserve (as specified in 10 U.S.C. 10144(b)) who is subject to being ordered to active duty involuntarily in accordance with 10 U.S.C. 12304.

(D) All other members of the Individual Ready Reserve of the Ready Reserve (as specified in 10 U.S.C. 10144(a)).

(ii) *Determination of eligibility status and evidence of eligibility*—(A) *Eligibility determination responsibility of the Uniformed Services.* Determination of a person's eligibility for the TDP is the responsibility of the member's Uniformed Service. For the purpose of program integrity, the appropriate Uniformed Service shall, upon request of the Director, OCHAMPUS, or designee, review the eligibility of a specified person when there is reason to question the eligibility status. In such cases, a report on the result of the review and any action taken will be submitted to the Director, OCHAMPUS, or designee.

(B) *Procedures for determination of eligibility.* Uniformed Service identification cards do not distinguish eligibility for the TDP. Procedures for the determination of eligibility are identified in §199.3(f)(2), except that Uniformed Service identification cards do not provide evidence of eligibility for the TDP. Although OCHAMPUS and the dental plan contractor must make determinations concerning a member or dependent's eligibility in order to ensure proper enrollment and proper disbursement of appropriated funds, ultimate responsibility for resolving a member or dependent's eligibility rests with the Uniformed Services.

(C) *Evidence of eligibility required.* Eligibility and enrollment in the TDP will be verified through the DEERS. Eligibility and enrollment information established and maintained in the DEERS file is the only acceptable evidence of TDP eligibility and enrollment. It is the responsibility of the active duty, Selected Reserve or Individual Ready Reserve member or TDP beneficiary, parent, or legal representative, when appropriate, to provide adequate evidence for entry into the DEERS file to establish eligibility for the TDP, and to ensure that all changes in status that may affect eligibility are reported immediately to the appropriate Uniformed Service for action. Ineligibility for benefits is presumed in the absence of prescribed eligibility evidence in the DEERS file.

(3) *Enrollment*—(i) *Previous plans*—(A) *Basic Active Duty Dependents Dental Benefit Plan.* The Basic Active Duty Dependents Dental Plan was effective from August 1, 1987, up to the date of implementation of the Expanded Active Duty Dependents Dental Benefit Plan. The Basic Active Duty Dependents Dental Benefit Plan terminated upon implementation of the expanded plan.

(B) *Expanded Active Duty Dependents Dental Benefit Plan.* The Expanded Active Duty Dependents Dental Benefit Plan (also known as the TRICARE Family Member Dental Plan) was effective from August 1, 1993, up to the date of implementation of the TDP. The Expanded Active Duty Dependents Dental Benefit Plan terminates upon implementation of the TDP.

(ii) *TRICARE Dental Program (TDP)*—(A) *Election of coverage.* (*1*) Except as provided in paragraph (c)(3)(ii)(A)(2) of this section, active duty, Selected Reserve and Individual Ready Reserve service members may voluntarily elect to enroll their eligible dependents and members of the Selected Reserve and Individual Ready Reserve may voluntarily elect to enroll themselves following implementation of the TDP. In order to obtain TDP coverage, written or telephonic election by the active duty, Selected Reserve or Individual Ready Reserve member must be made and will be accomplished by submission or telephonic completion of an application to the dental plan contractor. This election can also be accomplished via electronic means.

(*2*) Eligible dependents of active duty members enrolled in the Expanded Active Duty Dependents Dental Benefit Plan at the time of implementation of the TDP will automatically be enrolled in the TDP. Eligible members of the Selected Reserve enrolled in the TRICARE Selected Reserve Dental Program at the time of implementation of the TDP will automatically be enrolled in the TDP. No election to enroll in the TDP will be required by the active duty or Selected Reserve member.

(B) *Premiums*—(*1*) Enrollment will be by either single or family premium as defined as follows:

(*i*) Single premium. One (1) covered eligible dependent or one (1) covered eligible Selected Reserve or Individual Ready Reserve member.

(*ii*) Family premium. Two (2) or more covered eligible dependents. Under the

family premium, all eligible dependents of the active duty, Selected Reserve or Individual Ready Reserve member are enrolled.

(*2*) *Exceptions.* (*i*) An active duty, Selected Reserve or Individual Ready Reserve member may elect to enroll only those eligible dependents residing in one (1) location when the active duty, Selected Reserve or Individual Ready Reserve member has eligible dependents residing in two or more geographically separate locations (e.g., children living with a divorced spouse; a child attending college).

(*ii*) Instances where a dependent of an active duty member requires a hospital or special treatment environment (due to a medical, physical handicap, or mental condition) for dental care otherwise covered by the TDP, the dependent may be excluded from TDP enrollment and may continue to receive care from a military treatment facility.

(*iii*) A member of the Selected Reserve or Individual Ready Reserve may enroll separately from his or her eligible dependents. A member of the Selected Reserve or Individual Ready Reserve does not have to be enrolled in order for his or her eligible dependents to enroll under the TDP.

(C) *Enrollment period—*(*1*) *General.* Enrollment of eligible dependents or members is for a period of one (1) year followed by month-to-month enrollment as long as the active duty, Selected Reserve or Individual Ready Reserve member chooses to continue enrollment. Active duty members may enroll their eligible dependents and eligible members of the Selected Reserve or Individual Ready Reserve may enroll themselves or their eligible dependents in the TDP provided there is an intent to remain on active duty or as a member of the Selected Reserve or Individual Ready Reserve (or any combination thereof without a break in service or transfer to a non-eligible status) for a period of not less than one (1) year by the service member and their parent Uniformed Service. Beneficiaries enrolled in the TDP must remain enrolled for a minimum period of one (1) year unless one of the conditions for disenrollment specified in paragraph (c)(3)(ii)(E) of this section is met.

(*2*) *Special enrollment period for Reserve component members ordered to active duty in support of contingency operations.* The mandatory twelve (12) month enrollment period does not apply to Reserve component members ordered to active duty (other than for training) in support of a contingency operation as designated by the Secretary of Defense. Affected Reserve component members may enroll in the TDP only if their orders specify that they are ordered to active duty in support of a contingency operation, as defined by 10 U.S.C., for a period of thirty-one (31) days or more. An affected Reserve component member must elect to enroll in the TDP and complete the enrollment application within thirty (30) days following entry on active duty or within sixty (60) days following implementation of the TDP. Following enrollment, beneficiaries must remain enrolled, with the member paying premiums, until the end of the member's active duty period in support of the contingency operation or twelve (12) months, whichever occurs first unless one of the conditions for disenrollment specified in paragraph (c)(3)(ii)(E) of this section is met.

(*3*) *Continuation of enrollment from Expanded Active Duty Dependents Dental Benefit Plan.* Beneficiaries enrolled in the Expanded Active Duty Dependents Dental Benefit Plan at the time when TDP coverage begins must complete their two (2) year enrollment period established under this former plan except if one of the conditions for disenrollment specified in paragraph (c)(3)(ii)(E) of this section is met. Once this original two (2) year enrollment period is met, the active duty member may continue TDP enrollment on a month-to-month basis. A new one (1) year enrollment period will only be incurred if the active duty member disenrolls and attempts to reenroll in the TDP at a later date.

(*4*) *Continuation of enrollment from TRICARE Selected Reserve Dental Program.* Beneficiaries enrolled in the TRICARE Selected Reserve Dental Program at the time when TDP coverage begins must complete their one (1) year enrollment period established under this former program except if one of the conditions for disenrollment specified in paragraph (c)(3)(ii)(E) of

this section is met. Once this original one (1) year enrollment period is met, the Selected Reserve member may continue TDP enrollment on a month-to-month basis. A new one (1) year enrollment period will only be incurred if the Selected Reserve member disenrolls and attempts to reenroll in the TDP at a later date.

(D) *Beginning dates of eligibility*. The beginning date of eligibility for TDP benefits is the first day of the month following the month in which the election of enrollment is completed, signed, and the enrollment and premium is received by the dental plan contractor, subject to a predetermined and publicized dental plan contractor monthly cut-off date, except that the date of eligibility shall not be earlier than the first day of the month in which the TDP is implemented. This includes any changes between single and family member premium coverage and coverage of newly eligible or enrolled dependents or members.

(E) *Changes in and termination of enrollment—(1) Changes in status of active duty, Selected Reserve or Individual Ready Reserve member*. When the active duty, Selected Reserve or Individual Ready Reserve member is separated, discharged, retired, transferred to the Standby or Retired Reserve, his or her enrolled dependents and/or the enrolled Selected Reserve or Individual Ready Reserve member loses eligibility and enrollment as of 11:59 p.m. on the last day of the month in which the change in status takes place. When the Selected Reserve or Individual Ready Reserve member is ordered to active duty for a period of more than 30 days without a break in service, the member loses eligibility and is disenrolled, if previously enrolled; however, their enrolled dependents maintain their eligibility and previous enrollment subject to eligibility, enrollment and disenrollment provisions described in this section and in the TDP contract.

(*i*) *Reserve component members separated from active duty in support of a contingency operation*. When a member of a reserve component who is separated from active duty to which called or ordered in support of a contingency operation if the active duty is for more than 30 days, the member becomes eligible for Transitional Health Care pursuant to 10 U.S.C. 1145(a) and the member is entitled to dental care to which a member of the uniformed services on active duty for more than 30 days is entitled. Thus the member has no requirement for the TDP and is not eligible to purchase the TDP. Upon the termination of Transitional Health Care eligibility, the member regains TDP eligibility and is reenrolled, if previously enrolled.

(*ii*) *Dependents of members separated from active duty in support of a contingency operation*. Dependents of a member of a reserve component who is separated from active duty to which called or ordered in support of a contingency operation if the active duty is active for more than 30 days maintain their eligibility and previous enrollment, subject to eligibility, enrollment and disenrollment provisions described in this section and in the TDP contract. During the member's Transitional Health Care eligibility, the dependents are considered family members of Reserve Component members.

(*iii*) *Members separated from active duty and not covered by 10 U.S.C. 1145(a)(2)(B)*. When the previously enrolled active duty member is transferred back to the Selected Reserve or Individual Ready Reserve, and is not covered by 10 U.S.C. 1145(a)(2)(B), without a break in service, the member regains TDP eligibility and is reenrolled; however, enrolled dependents maintain their eligibility and previous enrollment subject to eligibility, enrollment and disenrollment provisions described in this section and in the TDP contract.

(*iv*) Eligible dependents of an active duty, Selected Reserve or Individual Ready Reserve member serving a sentence of confinement in conjunction with a sentence of punitive discharge are still eligible for the TDP until such time as the active duty, Selected Reserve or Individual Ready Reserve member's discharge is executed.

(*2*) *Survivor eligibility*. Eligible dependents of active duty members who die while on active duty for a period of more than 30 days and eligible dependents of members of the Ready Reserve (*i.e.*, Selected Reserve or Individual Ready Reserve, as specified in 10 U.S.C.

10143 and 10144(b) respectively) who die, shall be eligible for survivor enrollment in the TDP. During the period of survivor enrollment, the government will pay both the government and the eligible dependent's portion of the premium share. This survivor enrollment shall be up to (3) three years from the date of the member's death, except that, in the case of a dependent of the deceased who is described in 10 U.S.C. 1072(2)(D) or (I), the period of survivor enrollment shall be the longer of the following periods beginning on the date of the member's death:

(*i*) Three years.

(*ii*) The period ending on the date on which such dependent attains 21 years of age.

(*iii*) In the case of such dependent who, at 21 years of age, is enrolled in a full-time course of study in a secondary school or in a full-time course of study in an institution of higher education approved by the administering Secretary and was, at the time of the member's death, in fact dependent on the member for over one-half of such dependent's support, the period ending on the earlier of the following dates: The date on which such dependent ceases to pursue such a course of study, as determined by the administering Secretary; or the date on which such dependent attains 23 years of age.

(*3*) *Changes in status of dependent*—(*i*) *Divorce.* A spouse separated from an active duty, Selected Reserve or Individual Ready Reserve member by a final divorce decree loses all eligibility based on his or her former marital relationship as of 11:59 p.m. of the last day of the month in which the divorce becomes final. The eligibility of the active duty, Selected Reserve or Individual Ready Reserve member's own children (including adopted and eligible illegitimate children) is unaffected by the divorce. An unadopted stepchild, however, loses eligibility with the termination of the marriage, also as of 11:59 p.m. of the last day of the month in which the divorce becomes final.

(*ii*) *Annulment.* A spouse whose marriage to an active duty, Selected Reserve or Individual Ready Reserve member is dissolved by annulment loses eligibility as of 11:59 p.m. of the last day of the month in which the court grants the annulment order. The fact that the annulment legally declares the entire marriage void from its inception does not affect the termination date of eligibility. When there are children, the eligibility of the active duty, Selected Reserve or Individual Ready Reserve member's own children (including adopted and eligible illegitimate children) is unaffected by the annulment. An unadopted stepchild, however, loses eligibility with the annulment of the marriage, also as of 11:59 p.m. of the last day of the month in which the court grants the annulment order.

(*iii*) *Adoption.* A child of an active duty, Selected Reserve or Individual Ready Reserve member who is adopted by a person, other than a person whose dependents are eligible for TDP benefits while the active duty, Selected Reserve or Individual Ready Reserve member is living, thereby severing the legal relationship between the child and the active duty, Selected Reserve or Individual Ready Reserve member, loses eligibility as of 11:59 p.m. of the last day of the month in which the adoption becomes final.

(*iv*) *Marriage of child.* A child of an active duty, Selected Reserve or Individual Ready Reserve member who marries a person whose dependents are not eligible for the TDP, loses eligibility as of 11:59 p.m. on the last day of the month in which the marriage takes place. However, should the marriage be terminated by death, divorce, or annulment before the child is twenty-one (21) years old, the child again become eligible for enrollment as a dependent as of 12:00 a.m. of the first day of the month following the month in which the occurrence takes place that terminates the marriage and continues up to age twenty-one (21) if the child does not remarry before that time. If the marriage terminates after the child's 21st birthday, there is no reinstatement of eligibility.

(*v*) *Disabling illness or injury of child age 21 or 22 who has eligibility based on his or her student status.* A child twenty-one (21) or twenty-two (22) years old who is pursuing a full-time course of

higher education and who, either during the school year or between semesters, suffers a disabling illness or injury with resultant inability to resume attendance at the institution remains eligible for the TDP for six (6) months after the disability is removed or until the student passes his or her 23rd birthday, whichever occurs first. However, if recovery occurs before the 23rd birthday and there is resumption of a full-time course of higher education, the TDP can be continued until the 23rd birthday. The normal vacation periods during an established school year do not change the eligibility status of a dependent child twenty-one (21) or twenty-two (22) years old in full-time student status. Unless an incapacitating condition existed before, and at the time of, a dependent child's 21st birthday, a dependent child twenty-one (21) or twenty-two (22) years old in student status does not have eligibility related to mental or physical incapacity as described in §199.3(b)(2)(iv)(C)(*2*).

(*4*) *Other*—(*i*) *Disenrollment because of no eligible beneficiaries.* When an active duty, Selected Reserve or Individual Ready Reserve member ceases to have any eligible beneficiaries, enrollment is terminated for those enrolled dependents.

(*ii*) *Option to disenroll as a result of a change in active duty station.* When an active duty member transfers with enrolled dependents to a duty station where space-available dental care for the enrolled dependents is readily available at the local Uniformed Service dental treatment facility, the active duty member may elect, within ninety (90) calendar days of the transfer, to disenroll their dependents from the TDP. If the active duty member is later transferred to a duty station where dental care for the dependents is not available in the local Uniformed Service dental treatment facility, the active duty member may reenroll their eligible dependents in the TDP provided the member, as of the date of reenrollment, otherwise meets the requirements for enrollment, including the intent to remain on active duty for a period of not less than one (1) year. This disenrollment provision does not apply to enrolled dependents of members of the Selected Reserve or Individual Ready Reserve or to enrolled members of the Selected Reserve or Individual Ready Reserve.

(*iii*) *Option to disenroll due to transfer to OCONUS service area.* When an enrolled dependent of an active duty, Selected Reserve or Individual Ready Reserve member or an enrolled Selected Reserve or Individual Ready Reserve member relocates to locations within the OCONUS service area, the active duty, Selected Reserve or Individual Ready Reserve member may elect, within ninety (90) calendar days of the relocation, to disenroll their dependents from the TDP, or in the case of enrolled members of the Selected Reserve or Individual Ready Reserve, to disenroll themselves from the TDP. The active duty, Selected Reserve or Individual Ready Reserve member may reenroll their eligible dependents, or in the case of members of the Selected Reserve or Individual Ready Reserve, may reenroll themselves in the TDP provided the member, as of the date of reenrollment, otherwise meets the requirements for enrollment, including the intent to remain on active duty or as a member of the Selected Reserve or Individual Ready Reserve (or any combination thereof without a break in service or transfer to a non-eligible status) for a period of not less than one (1) year.

(*iv*) *Option to disenroll after an initial one (1) year enrollment.* When a dependent's enrollment under an active duty, Selected Reserve or Individual Ready Reserve member or a Selected Reserve or Individual Ready Reserve member's own enrollment has been in effect for a continuous period of one (1) year, the active duty, Selected Reserve or Individual Ready Reserve member may disenroll their dependents, or in the case of enrolled members of the Selected Reserve or Individual Ready Reserve may disenroll themselves at any time following procedures as set up by the dental plan contractor. Subsequent to the disenrollment, the active duty, Selected Reserve or Individual Ready Reserve member may reenroll their eligible dependents, or in the case of members of the Selected Reserve or Individual Ready Reserve may reenroll themselves, for another minimum period of one (1) year. If, during any one

(1) year enrollment period, the active duty, Selected Reserve or Individual Ready Reserve member disenrolls their dependents, or in the case of members of the Selected Reserve or Individual Ready Reserve disenrolls themselves, for reasons other than those listed in this paragraph (c)(3)(ii)(E) or fails to make premium payments, dependents enrolled under the active duty, Selected Reserve or Individual Ready Reserve member, or enrolled members of the Selected Reserve and Individual Ready Reserve, will be subject to a lock-out period of twelve (12) months. Following this period of time, active duty, Selected Reserve or Individual Ready Reserve members will be able to reenroll their eligible dependents, or members of the Selected Reserve or Individual Ready Reserve will be able to reenroll themselves, if they so choose. The twelve (12) month lock-out period applies to enrolled dependents of a Reserve component member who disenrolls for reasons other than those listed in this paragraph (c)(3)(ii)(E) or fails to make premium payments after the member has enrolled pursuant to paragraph (c)(3)(ii)(C) of this section.

(*5*) TRICARE Dental Program coverage shall terminate for members who no longer qualify for the TRICARE Dental Program as specified in paragraph (c)(2) of this section, with one exception. If a member is involuntarily separated from the Selected Reserve under other than adverse conditions, as characterized by the Secretary concerned, and TRICARE Dental Program coverage is in effect for the member and/or the family on the last day of his or her membership in the Selected Reserve; then the TRICARE Dental Program coverage that was actually in effect may terminate no earlier than 180 days after the date on which the member is separated from the Selected Reserve. This exception expires December 31, 2018.

(d) *Premium sharing*—(1) *General.* Active duty, Selected Reserve or Individual Ready Reserve members enrolling their eligible dependents, or members of the Selected Reserve or Individual Ready Reserve enrolling themselves, in the TDP shall be required to pay all or a portion of the premium cost depending on their status.

(i) *Members required to pay a portion of the premium cost.* This premium category includes active duty members (under a call or order to active duty that does not specify a period of thirty (30) days or less) on behalf of their enrolled dependents. It also includes members of the Selected Reserve (as specified in 10 U.S.C. 10143) and the Individual Ready Reserve (as specified in 10 U.S.C. 10144(b)) enrolled on their own behalf.

(ii) *Members required to pay the full premium cost.* This premium category includes members of the Selected Reserve (as specified in 10 U.S.C. 10143), and the Individual Ready Reserve (as specified in 10 U.S.C. 10144), on behalf of their enrolled dependents. It also includes members of the Individual Ready Reserve (as specified in 10 U.S.C. 10144(a)) enrolled on their own behalf.

(2) *Proportion of premium share.* The proportion of premium share to be paid by the active duty, Selected Reserve and Individual Reserve member pursuant to paragraph (d)(1)(i) of this section is established by the ASD(HA), or designee, at not more than forty (40) percent of the total premium. The proportion of premium share to be paid by the Selected Reserve and Individual Reserve member pursuant to paragraph (d)(1)(ii) of this section is established by the ASD(HA), or designee, at one hundred (100) percent of the total premium.

(3) *Provision for increases in active duty, Selected Reserve and Individual Ready Reserve member's premium share.* (i) Although previously capped at $20 per month, the law has been amended to authorize the cap on active duty, Selected Reserve and Individual Ready Reserve member's premiums pursuant to paragraph (d)(1)(i) of this section to rise, effective as of January 1 of each year, by the percent equal to the lesser of:

(A) The percent by which the rates of basic pay of members of the Uniformed Services are increased on such date; or

(B) The sum of one-half percent and the percent computed under 5 U.S.C. 5303(a) for the increase in rates of basic pay for statutory pay systems for pay periods beginning on or after such date.

(ii) Under the legislation authorizing an increase in the monthly premium

cap, the methodology for determining the active duty, Selected Reserve and Individual Ready Reserve member's TDP premium pursuant to paragraph (d)(1)(i) of this section will be applied as if the methodology had been in continuous use since December 31, 1993.

(4) *Reduction of premium share for enlisted members.* For enlisted members in pay grades E–1 through E–4, the ASD(HA) or designee, may reduce the monthly premium these active duty, Selected Reserve and Individual Ready Reserve members pay pursuant to paragraph (d)(1)(i) of this section.

(5) *Reduction of cost-shares for enlisted members.* For enlisted members in pay grades E–1 through E–4, the ASD(HA) or designee, may reduce the cost-shares that active duty, Selected Reserve and Individual Ready Reserve members pay on behalf of their enrolled dependents and that members of the Selected Reserve and Individual Ready Reserve pay on their own behalf for selected benefits as specified in paragraph (e)(3)(i) of this section.

(6) *Premium payment method.* The active duty, Selected Reserve and Individual Ready Reserve member's premium share may be deducted from the active duty, Selected Reserve or Individual Ready Reserve member's basic pay or compensation paid under 37 U.S.C. 206, if sufficient pay is available. For members who are otherwise eligible for TDP benefits and who do not receive such pay and dependents who are otherwise eligible for TDP benefits and whose sponsors do not receive such pay, or if insufficient pay is available, the premium payment may be collected pursuant to procedures established by the Director, OCHAMPUS, or designee.

(7) *Annual notification of premium rates.* TDP premium rates will be determined as part of the competitive contracting process. Information on the premium rates will be widely distributed by the dental plan contractor and the Government.

(e) *Plan benefits*—(1) *General*—(i) *Scope of benefits.* The TDP provides coverage for diagnostic and preventive services, sealants, restorative services, endodontics, periodontics, prosthodontics, orthodontics and oral and maxillofacial surgery.

(ii) *Authority to act for the plan.* The authority to make benefit determinations and authorize plan payments under the TDP rests primarily with the insurance, service plan, or prepayment dental plan contractor, subject to compliance with Federal law and regulation and Government contract provisions. The Director, OCHAMPUS, or designee, provides required benefit policy decisions resulting from changes in Federal law and regulation and appeal decisions. No other persons or agents (such as dentists or Uniformed Services HBAs) have such authority.

(iii) *Dental benefits brochure*—(A) *Content.* The Director, OCHAMPUS, or designee, shall establish a comprehensive dental benefits brochure explaining the benefits of the plan in common lay terminology. The brochure shall include the limitations and exclusions and other benefit determination rules for administering the benefits in accordance with the law and this part. The brochure shall include the rules for adjudication and payment of claims, appealable issues, and appeal procedures in sufficient detail to serve as a common basis for interpretation and understanding of the rules by providers, beneficiaries, claims examiners, correspondence specialists, employees and representatives of other Government bodies, HBAs, and other interested parties. Any conflict, which may occur between the dental benefits brochure and law or regulation, shall be resolved in favor of law and regulation.

(B) *Distribution.* The dental benefits brochure will be available through the dental plan contractor and will be distributed with the assistance of the Uniformed Services HBAs and major personnel centers at Uniformed Service installations and headquarters to all members enrolling themselves or their eligible dependents.

(iv) *Alternative course of treatment policy.* The Director, OCHAMPUS, or designee, may establish, in accordance with generally accepted dental benefit practices, an alternative course of treatment policy which provides reimbursement in instances where the dentist and beneficiary select a more expensive service, procedure, or course of

treatment than is customarily provided. The alternative course of treatment policy must meet following conditions:

(A) The service, procedure, or course of treatment must be consistent with sound professional standards of dental practice for the dental condition concerned.

(B) The service, procedure, or course of treatment must be a generally accepted alternative for a service or procedure covered by the TDP for the dental condition.

(C) Payment for the alternative service or procedure may not exceed the lower of the prevailing limits for the alternative procedure, the prevailing limits or dental plan contractor's scheduled allowance for the otherwise authorized benefit procedure for which the alternative is substituted, or the actual charge for the alternative procedure.

(2) *Benefits.* The following benefits are defined (subject to the TDP's exclusions, limitations, and benefit determination rules approved by OCHAMPUS) using the American Dental Association's Council on Dental Care Program's Code on Dental Procedures and Nomenclature. The Director, OCHAMPUS, or designee, may modify these services, to the extent determined appropriate based on developments in common dental care practices and standard dental insurance programs.

(i) Diagnostic and preventive services. Benefits may be extended for those dental services described as oral examination, diagnostic, and preventive services when performed directly by dentists and dental hygienists as authorized under paragraph (f) of this section. These include the following categories of service:

(A) Diagnostic services. (*1*) Clinical oral examinations.

(*2*) Radiographs and diagnostic imaging.

(*3*) Tests and laboratory examinations.

(B) Preventive services. (*1*) Dental prophylaxis.

(*2*) Topical fluoride treatment (office procedure).

(*3*) Other preventive services.

(*4*) Space maintenance (passive appliances).

(*5*) Sealants.

(ii) *General services and services ''by report''.* The following categories of services are authorized when performed directly by dentists or dental hygienists, as authorized under paragraph (f) of this section, only in unusual circumstances requiring justification of exceptional conditions directly related to otherwise authorized procedures. Use of the procedures may not result in the fragmentation of services normally included in a single procedure. The dental plan contractor may recognize a ''by report'' condition by providing additional allowance to the primary covered procedure instead of recognizing or permitting a distinct billing for the ''by report'' service. These include the following categories of general services:

(A) Unclassified treatment.

(B) Anesthesia.

(C) Professional consultation.

(D) Professional visits.

(E) Drugs.

(F) Miscellaneous services.

(iii) *Restorative services.* Benefits may be extended for restorative services when performed directly by dentists or dental hygienists, or under orders and supervision by dentists, as authorized under paragraph (f) of this section. These include the following categories of restorative services:

(A) Amalgam restorations.

(B) Resin restorations.

(C) Inlay and onlay restorations.

(D) Crowns.

(E) Other restorative services.

(iv) *Endodontic services.* Benefits may be extended for those dental services involved in treatment of diseases and injuries affecting the dental pulp, tooth root, and periapical tissue when performed directly by dentists as authorized under paragraph (f) of this section. These include the following categories of endodontic services:

(A) Pulp capping.

(B) Pulpotomy and pulpectomy.

(C) Endodontic therapy.

(D) Apexification and recalcification procedures.

(E) Apicoectomy and periradicular services.

(F) Other endodontic procedures.

(v) *Periodontic services.* Benefits may be extended for those dental services involved in prevention and treatment of diseases affecting the supporting structures of the teeth to include periodontal prophylaxis, gingivectomy or gingivoplasty, gingival curettage, etc., when performed directly by dentists as authorized under paragraph (f) of this section. These include the following categories of periodontic services:

(A) Surgical services.

(B) Periodontal services.

(C) Other periodontal services.

(vi) *Prosthodontic services.* Benefits may be extended for those dental services involved in fabrication, insertion adjustment, relinement, and repair of artificial teeth and associated tissues to include removable complete and partial dentures, fixed crowns and bridges when performed directly by dentists as authorized under paragraph (f)(4) of this section. These include the following categories of prosthodontic services:

(A) Prosthodontics (removable).

(*1*) Complete and partial dentures.

(*2*) Adjustments to dentures.

(*3*) Repairs to complete and partial dentures.

(*4*) Denture rebase procedures.

(*5*) Denture reline procedures.

(*6*) Other removable prosthetic services.

(B) Prosthodontics (fixed).

(*1*) Fixed partial denture pontics.

(*2*) Fixed partial denture retainers.

(*3*) Other partial denture services.

(vii) *Orthodontic services.* Benefits may be extended for the supervision, guidance, and correction of growing or mature dentofacial structures, including those conditions that require movement of teeth or correction of malrelationships and malformations through the use of orthodontic procedures and devices when performed directly by dentists as authorized under paragraph (f) of this section to include in-process orthodontics. These include the following categories of orthodontic services:

(A) Limited orthodontic treatment.

(B) Minor treatment to control harmful habits.

(C) Interceptive orthodontic treatment.

(D) Comprehensive orthodontic treatment.

(E) Other orthodontic services.

(viii) *Oral and maxillofacial surgery services.* Benefits may be extended for basic surgical procedure of the extraction, reimplantation, stabilization and repositioning of teeth, alveoloplasties, incision and drainage of abscesses, suturing of wounds, biopsies, etc., when performed directly by dentists as authorized under paragraph (f) of this section. These include the following categories of oral and maxillofacial surgery services:

(A) Extractions.

(B) Surgical extractions.

(C) Other surgical procedures.

(D) Alveoloplasty—surgical preparation of ridge for denture.

(E) Surgical incision.

(F) Repair of traumatic wounds.

(G) Complicated suturing.

(H) Other repair procedures.

(ix) Exclusion of adjunctive dental care. Adjunctive dental care benefits are excluded under the TDP. For further information on adjunctive dental care benefits under TRICARE/CHAMPUS, see §199.4(e)(10).

(x) *Benefit limitations and exclusions.* The Director, OCHAMPUS, or designee, may establish such exclusions and limitations as are consistent with those established by dental insurance and prepayment plans to control utilization and quality of care for the services and items covered by the TDP.

(xi) *Limitation on reduction of benefits.* If a reduction in benefits is planned, the Secretary of Defense, or designee, may not reduce TDP benefits without notifying the appropriate Congressional committees. If a reduction is approved, the Secretary of Defense, or designee, must wait one (1) year from the date of notice before a benefit reduction can be implemented.

(3) *Cost-shares, liability and maximum coverage*—(i) *Cost-shares.* The following table lists maximum active duty, Selected Reserve and Individual Ready Reserve member and dependent cost-shares for covered services for participating and nonparticipating providers of care (see paragraph (f)(6) of this section for additional active duty, Selected Reserve and Individual Ready Reserve costs). These are percentages

of the dental plan contractor's determined allowable amount that the active duty, Selected Reserve and Individual Ready Reserve member or beneficiary must pay to these providers. For care received in the OCONUS service area, the ASD(HA), or designee, may pay certain cost-shares and other portions of a provider's billed charge for enrolled dependents of active duty members (under a call or order that does not specify a period of thirty (30) days or less), and for members of the Selected Reserve (as specified in 10 U.S.C. 10143) and Individual Ready Reserve (as specified in 10 U.S.C. 10144(b)) enrolled on their own behalf.

[In percent]

Covered services	Cost-share for pay grades E-1, E-2, E-3 and E-4	Cost-share for all other pay grades
Diagnostic	0	0
Preventive, except Sealants	0	0
Emergency Services	0	0
Professional Consultations	20	20
Professional Visits	20	20
Post Surgical Services	20	20
Basic Restorative (example: amalgams, resins, stainless steel crowns)	20	20
Endodontic	30	40
Periodontic	30	40
Oral and Maxillofacial Surgery	30	40
General Anesthesia	40	40
Intravenous Sedation	50	50
Other Restorative (example: crowns, onlays, casts)	50	50
Prosthodontics	50	50
Medications	50	50
Orthodontic	50	50
Miscellaneous	50	50

(ii) *Dental plan contractor liability.* When more than twenty-five (25) percent or more than two hundred (200) enrollees in a specific five (5) digit zip code area are unable to obtain a periodic or initial (non-emergency) dentistry appointment with a network provider within twenty-one (21) calendar days and within thirty-five (35) miles of the enrollee's place of residence, then the TRICARE Management Activity (TMA) will designate that area as ''non-compliant with the access standard.'' Once so designated, the dental program contractor will reimburse the beneficiary, or active duty, Selected Reserve or Individual Ready Reserve member, or the nonparticipating provider selected by enrollees in that area (or a subset of the area or nearby zip codes in other five (5) digit zip code areas as determined by TMA) at the level of the provider's usual fees less the applicable enrollee cost-share, if any. TMA shall determine when such area becomes compliant with the access standards. This access standard and associated liability does not apply to care received in the OCONUS service area.

(iii) *Maximum coverage amounts.* Beneficiaries are subject to an annual maximum coverage amount for non-orthodontic dental benefits and a lifetime maximum coverage amount for orthodontics as established by the ASD (HA) or designee.

(f) *Authorized providers*—(1) *General.* Beneficiaries may seek covered services from any provider who is fully licensed and approved to provide dental care or covered anesthesia benefits in the state where the provider is located. This includes licensed dental hygienists, practicing within the scope of their licensure, subject to any restrictions a state licensure or legislative body imposes regarding their status as independent providers of care.

(2) *Authorized provider status does not guarantee payment of benefits.* The fact that a provider is ''authorized'' is not to be construed to mean that the TDP will automatically pay a claim for services or supplies provided by such a provider. The Director, OCHAMPUS, or designee, also must determine if the patient is an eligible beneficiary, whether the services or supplies billed are authorized and medically necessary, and whether any of the authorized exclusions of otherwise qualified providers presented in this section apply.

(3) *Utilization review and quality assurance.* Services and supplies furnished by providers of care shall be subject to utilization review and quality assurance standards, norms, and criteria established under the TDP. Utilization review and quality assurance assessments shall be performed under the TDP consistent with the nature and level of benefits of the plan, and shall include analysis of the data and findings by the dental plan contractor from other dental accounts.

(4) *Provider required.* In order to be considered benefits, all services and

supplies shall be rendered by, prescribed by, or furnished at the direction of, or on the order of a TDP authorized provider practicing within the scope of his or her license.

(5) *Participating provider.* An authorized provider may elect to participate as a network provider in the dental plan contractor's network and any such election will apply to all TDP beneficiaries. The authorized provider may not participate on a claim-by-claim basis. The participating provide must agree to accept, within one (1) day of a request for appointment, beneficiaries in need of emergency palliative treatment. Payment to the participating provider is based on the methodology specified in paragraph (g)(2)(ii) of this section. The fee or charge determinations are binding upon the provider in accordance with the dental plan contractor's procedures for participation in the network. Payment is made directly to the participating provider, and the participating provider may only charge the beneficiary the applicable percent cost-share of the dental plan contractor's allowable charge for those benefit categories as specified in paragraph (e) of this section, in addition to the full charges for any services not authorized as benefits.

(6) *Nonparticipating provider.* An authorized provider may elect to not participate for all TDP beneficiaries and request the beneficiary or active duty, Selected Reserve or Individual Ready Reserve member to pay any amount of the provider's billed charge in excess of the dental plan contractor's determination of allowable charges (to include the appropriate cost-share). Neither the Government nor the dental plan contractor shall have any responsibility for any amounts over the allowable charges as determined by the dental plan contractor, except where the dental plan contractor is unable to identify a participating provider of care within thirty-five (35) miles of the beneficiary's place of residence with appointment availability within twenty-one (21) calendar days. In such instances of the nonavailability of a participating provider and in accordance with the provisions of the dental contract, the nonparticipating provider located within thirty-five (35) miles of the beneficiary's place of residence shall be paid his or her usual fees (either by the beneficiary or the dental plan contractor if the beneficiary elected assignment of benefits), less the percent cost-share as specified in paragraph (e)(3)(i) of this section.

(i) *Assignment of benefits.* A nonparticipating provider may accept assignment of benefits for claims (for beneficiaries certifying their willingness to make such assignment of benefits) by filing the claims completed with the assistance of the beneficiary or active duty, Selected Reserve or Individual Ready Reserve member for direct payment by the dental plan contractor to the provider.

(ii) *No assignment of benefits.* A nonparticipating provider for all beneficiaries may request that the beneficiary or active duty, Selected Reserve or Individual Ready Reserve member file the claim directly with the dental plan contractor, making arrangements with the beneficiary or active duty, Selected Reserve or Individual Ready Reserve member for direct payment by the beneficiary or active duty, Selected Reserve or Individual Ready Reserve member.

(7) *Alternative delivery system*—(i) *General.* Alternative delivery systems may be established by the Director, OCHAMPUS, or designee, as authorized providers. Only dentists, dental hygienists and licensed anesthetists shall be authorized to provide or direct the provision of authorized services and supplies in an approved alternative delivery system.

(ii) *Defined.* An alternative delivery system may be any approved arrangement for a preferred provider organization, capitation plan, dental health maintenance or clinic organization, or other contracted arrangement which is approved by OCHAMPUS in accordance with requirements and guidelines.

(iii) *Elective or exclusive arrangement.* Alternative delivery systems may be established by contract or other arrangement on either an elective or exclusive basis for beneficiary selection of participating and authorized providers in accordance with contractual requirements and guidelines.

(iv) *Provider election of participation.* Otherwise authorized providers must be provided with the opportunity of applying for participation in an alternative delivery system and of achieving participation status based on reasonable criteria for timeliness of application, quality of care, cost containment, geographic location, patient availability, and acceptance of reimbursement allowance.

(v) *Limitation on authorized providers.* Where exclusive alternative delivery systems are established, only providers participating in the alternative delivery system are authorized providers of care. In such instances, the TDP shall continue to pay beneficiary claims for services rendered by otherwise authorized providers in accordance with established rules for reimbursement of nonparticipating providers where the beneficiary has established a patient relationship with the nonparticipating provider prior to the TDP's proposal to subcontract with the alternative delivery system.

(vi) *Charge agreements.* Where the alternative delivery system employs a discounted fee-for-service reimbursement methodology or schedule of charges or rates which includes all or most dental services and procedures recognized by the American Dental Association's Council on Dental Care Program's Code on Dental Procedures and Nomenclature, the discounts or schedule of charges or rates for all dental services and procedures shall be extended by its participating providers to beneficiaries of the TDP as an incentive for beneficiary participation in the alternative delivery system.

(g) *Benefit payment*—(1) *General.* TDP benefits payments are made either directly to the provider or to the beneficiary or active duty, Selected Reserve or Individual Ready Reserve member, depending on the manner in which the claim is submitted or the terms of the subcontract of an alternative delivery system with the dental plan contractor.

(2) *Benefit payment.* Beneficiaries are not required to utilize participating providers. For beneficiaries who do use these participating providers, however, these providers shall not balance bill any amount in excess of the maximum payment allowed by the dental plan contractor for covered services. Beneficiaries using nonparticipating providers may be balance-billed amounts in excess of the dental plan contractor's determination of allowable charges. The following general requirements for the TDP benefit payment methodology shall be met, subject to modifications and exceptions approved by the Director, OCHAMPUS, or designee:

(i) Nonparticipating providers (or the Beneficiaries or active duty, Selected Reserve or Individual Ready Reserve members for unassigned claims) shall be reimbursed at the lesser of the provider's actual charge: Or the network maximum allowable charge for similar services for that same locality (region) or state, whichever is lower, subject to the exception listed in paragraph (e)(3)(ii) of this section, less any cost-share amount due for authorized services. The network maximum allowable charge is the maximum negotiated fee between the dental contractor and any TDP participating provider for similar services covered by the dental plan in that same locality (region) or state.

(ii) Participating providers shall be reimbursed in accordance with the contractor's network agreements, less any cost-share amount due for authorized services.

(3) *Fraud, abuse, and conflict of interest.* The provisions of §199.9 shall apply except for §199.9(e). All references to ''CHAMPUS contractors'', ''CHAMPUS beneficiaries'' and ''CHAMPUS providers'' in §199.9 shall be construed to mean the ''dental plan contractor'', ''TDP beneficiaries'' and ''TPD providers'' respectively for the purposes of this section. Examples of fraud include situations in which ineligible persons not enrolled in the TDP obtain care and file claims for benefits under the name and identification of a beneficiary; or when providers submit claims for services and supplies not rendered to Beneficiaries; or when a participating provider bills the beneficiary for amounts over the dental plan contractor's determination of allowable charges; or when a provider fails to collect the specified patient cost-share amount.

(h) *Appeal and hearing procedures.* The provisions of §199.10 shall apply except where noted in this section. All references to ''CHAMPUS contractors'', ''CHAMPUS beneficiaries'', ''CHAMPUS participating providers'' and ''CHAMPUS Explanation of Benefits'' in §199.10 shall be construed to mean the ''dental plan contractor'', ''TDP beneficiaries'', ''TDP participating providers'' and ''Dental Explanation of Benefits or DEOB'' respectively for the purposes of this section. References to ''OCHAMPUSEUR'' in §199.10 are not applicable to the TDP or this section.

(1) *General.* See §199.10(a).

(i) *Initial determination*—(A) *Notice of initial determination and right to appeal.* See §199.10(a)(1)(i).

(B) *Effect of initial determination.* See §199.10(a)(1)(ii).

(ii) *Participation in an appeal.* Participation in an appeal is limited to any party to the initial determination, including OCHAMPUS, the dental plan contractor, and authorized representatives of the parties. Any party to the initial determination, except OCHAMPUS and the dental plan contractor, may appeal an adverse determination. The appealing party is the party who actually files the appeal.

(A) *Parties to the initial determination.* See §§199.10(a)(2)(i) and 199.10(a)(2)(i)(A), (B), (C) and (E). In addition, a third party other than the dental plan contractor, such as an insurance company, is not a party to the initial determination and is not entitled to appeal, even though it may have an indirect interest in the initial determination.

(B) *Representative.* See §199.10(a)(2)(ii).

(iii) *Burden of proof.* See §199.10(a)(3).

(iv) *Evidence in appeal and hearing cases.* See §199.10(a)(4).

(v) *Late filing.* If a request for reconsideration, formal review, or hearing is filed after the time permitted in this section, written notice shall be issued denying the request. Late filing may be permitted only if the appealing party reasonably can demonstrate to the satisfaction of the dental plan contractor, or the Director, OCHAMPUS, or designee, that timely filing of the request was not feasible due to extraordinary circumstances over which the appealing party had no practical control. Each request for an exception to the filing requirement will be considered on its own merits. The decision of the Director, OCHAMPUS, or a designee, on the request for an exception to the filing requirement shall be final.

(vi) *Appealable issue.* See §§199.10(a)(6), 199.10(a)(6)(i), 199.10(a)(6)(iv), including §§199.10(a)(6)(iv) (A) and (C), and 199.10(a)(6)(v) for an explanation and examples of non-appealable issues. Other examples of issues that are not appealable under this section include:

(A) The amount of the dental plan contractor-determined allowable charge since the methodology constitutes a limitation on benefits under the provisions of this section.

(B) Certain other issues on the basis that the authority for the initial determination is not vested in OCHAMPUS. Such issues include but are not limited to the following examples:

(*1*) A determination of a person's enrollment in the TDP is the responsibility of the dental plan contractor and ultimate responsibility for resolving a beneficiary's enrollment rests with the dental plan contractor. Accordingly, a disputed question of fact concerning a beneficiary's enrollment will not be considered an appealable issue under the provisions of this section, but shall be resolved in accordance with paragraph (c) of this section and the dental plan contractor's enrollment policies and procedures.

(*2*) Decisions relating to the issuance of a nonavailability statement (NAS) in each case are made by the Uniformed Services. Disputes over the need for an NAS or a refusal to issue an NAS are not appealable under this section. The one exception is when a dispute arises over whether the facts of the case demonstrate a dental emergency for which an NAS is not required. Denial of payment in this one situation is an appealable issue.

(*3*) Any decision or action on the part of the dental plan contractor to include a provider in their network or to designate a provider as participating is not appealable under this section. Similarly, any decision or action on the part of the dental plan contractor

to exclude a provider from their network or to deny participating provider status is not appealable under this section.

(vii) *Amount in dispute*—(A) *General.* An amount in dispute is required for an adverse determination to be appealed under the provisions of this section, except as set forth or further explained in §199.10(a)(7)(ii), (iii) and (iv).

(B) *Calculated amount.* The amount in dispute is calculated as the amount of money the dental plan contractor would pay if the services involved in the dispute were determined to be authorized benefits of the TDP. Examples of amounts of money that are excluded by this section from payments for authorized benefits include, but are not limited to:

(*1*) Amounts in excess of the dental plan contractor's—determined allowable charge.

(*2*) The beneficiary's cost-share amounts.

(*3*) Amounts that the beneficiary, or parent, guardian, or other responsible person has no legal obligation to pay.

(*4*) Amounts excluded under the provisions of §199.8 of this part.

(viii) *Levels of appeal.* See §199.10(a)(8)(i). Initial determinations involving the sanctioning (exclusion, suspension, or termination) of TDP providers shall be appealed directly to the hearing level.

(ix) *Appeal decision.* See §199.10(a)(9).

(2) *Reconsideration.* See §199.10(b).

(3) *Formal review.* See §199.10(c).

(4) *Hearing*—(i) *General.* See §§1.99.10(d) and 199.10(d)(1) through (d)(5) and (d0(7) through (d)(12) for information on the hearing process.

(ii) *Authority of the hearing officer.* The hearing officer, in exercising the authority to conduct a hearing under this part, will be bound by 10 U.S.C., chapter 55, and this part. The hearing officer in addressing substantive, appealable issues shall be bound by the dental benefits brochure applicable for the date(s) of service, policies, procedures, instructions and other guidelines issued by the ASD(HA), or a designee, or by the Director, OCHAMPUS, or a designee, in effect for the period in which the matter in dispute arose. A hearing officer may not establish or amend the dental benefits brochure, policy, procedures, instructions, or guidelines. However, the hearing officer may recommend reconsideration of the policy, procedures, instructions or guidelines by the ASD (HA), or a designee, when the final decisions is issued in the case.

(5) *Final decision.* See §§199.10(e)(1) and 199.10(e)(1)(i) for information on final decisions in the appeal and hearing process, with the exception that no recommended decision shall be referred for review by ASD(HA).

(i) *Implementing Instructions.* The Director, TRICARE Management Activity or designee may issue TRICARE Dental Program policies, standards, and criteria as may be necessary to implement the intent of this section.

[66 FR 12860, Mar. 1, 2001; 66 FR 16400, Mar. 26, 2001, as amended at 68 FR 65174, Nov. 19, 2003; 69 FR 55359, Sept. 14, 2004; 70 FR 55252, Sept. 21, 2005; 71 FR 1696, Jan. 11, 2006; 71 FR 66872, Nov. 17, 2006; 72 FR 53685, Sept. 20, 2007; 76 FR 57643, Sept. 16, 2011; 76 FR 81367, Dec. 28, 2011; 80 FR 55254, Sept. 15, 2015; 81 FR 11667, Mar. 7, 2016]

§199.14 Provider reimbursement methods.

(a) *Hospitals.* The CHAMPUS-determined allowable cost for reimbursement of a hospital shall be determined on the basis of one of the following methodologies.

(1) *CHAMPUS Diagnosis Related Group (DRG)-based payment system.* Under the CHAMPUS DRG-based payment system, payment for the operating costs of inpatient hospital services furnished by hospitals subject to the system is made on the basis of prospectively-determined rates and applied on a per discharge basis using DRGs. Payments under this system will include a differentiation for urban (using large urban and other urban areas) and rural hospitals and an adjustment for area wage differences and indirect medical education costs. Additional payments will be made for capital costs, direct medical education costs, and outlier cases.

(i) *General*—(A) *DRGs used.* The CHAMPUS DRG-based payment system will use the same DRGs used in the most recently available grouper for the Medicare Prospective Payment System, except as necessary to recognize distinct characteristics of CHAMPUS

beneficiaries and as described in instructions issued by the Director, OCHAMPUS.

(B) *Assignment of discharges to DRGs.* (*1*) The classification of a particular discharge shall be based on the patient's age, sex, principal diagnosis (that is, the diagnosis established, after study, to be chiefly responsible for causing the patient's admission to the hospital), secondary diagnoses, procedures performed and discharge status. In addition, for neonatal cases (other than normal newborns) the classification shall also account for birthweight, surgery and the presence of multiple, major and other neonatal problems, and shall incorporate annual updates to these classification features.

(*2*) Each discharge shall be assigned to only one DRG regardless of the number of conditions treated or services furnished during the patient's stay.

(C) *Basis of payment—*(*1*) *Hospital billing.* Under the CHAMPUS DRG-based payment system, hospitals are required to submit claims (including itemized charges) in accordance with §199.7(b). The CHAMPUS fiscal intermediary will assign the appropriate DRG to the claim based on the information contained in the claim. Any request from a hospital for reclassification of a claim to a higher weighted DRG must be submitted, within 60 days from the date of the initial payment, in a manner prescribed by the Director, OCHAMPUS.

(*2*) *Payment on a per discharge basis.* Under the CHAMPUS DRG-based payment system, hospitals are paid a predetermined amount per discharge for inpatient hospital services furnished to CHAMPUS beneficiaries.

(*3*) *Pricing of claims.* All final claims with discharge dates of September 30, 2014, or earlier that are reimbursed under the CHAMPUS DRG-based payment system are to be priced as of the date of admission, regardless of when the claim is submitted. All final claims with discharge dates of October 1, 2014, or later that are reimbursed under the CHAMPUS DRG-based payment system are to be priced as of the date of discharge.

(*4*) *Payment in full.* The DRG-based amount paid for inpatient hospital services is the total CHAMPUS payment for the inpatient operating costs (as described in paragraph (a)(1)(i)(C)(*5*) of this section) incurred in furnishing services covered by the CHAMPUS. The full prospective payment amount is payable for each stay during which there is at least one covered day of care, except as provided in paragraph (a)(1)(iii)(E)(*1*)(*i*)(*A*) of this section.

(*5*) *Inpatient operating costs.* The CHAMPUS DRG-based payment system provides a payment amount for inpatient operating costs, including:

(*i*) Operating costs for routine services, such as the costs of room, board, and routine nursing services;

(*ii*) Operating costs for ancillary services, such as hospital radiology and laboratory services (other than physicians' services) furnished to hospital inpatients;

(*iii*) Special care unit operating costs; and

(*iv*) Malpractice insurance costs related to services furnished to inpatients.

(*6*) *Discharges and transfers—*(*i*) *Discharges.* A hospital inpatient is discharged when:

(*A*) The patient is formally released from the hospital (release of the patient to another hospital as described in paragraph (a)(1)(i)(C)(*6*)(*ii*) of this section, or a leave of absence from the hospital, will not be recognized as a discharge for the purpose of determining payment under the CHAMPUS DRG-based payment system);

(*B*) The patient dies in the hospital; or

(*C*) The patient is transferred from the care of a hospital included under the CHAMPUS DRG-based payment system to a hospital or unit that is excluded from the prospective payment system.

(*ii*) *Transfers.* Except as provided under paragraph (a)(1)(i)(C)(*6*)(*i*) of this section, a discharge of a hospital inpatient is not counted for purposes of the CHAMPUS DRG-based payment system when the patient is transferred:

(*A*) From one inpatient area or unit of the hospital to another area or unit of the same hospital;

(*B*) From the care of a hospital included under the CHAMPUS DRG-based payment system to the care of

another hospital paid under this system;

(*C*) From the care of a hospital included under the CHAMPUS DRG-based payment system to the care of another hospital that is excluded from the CHAMPUS DRG-based payment system because of participation in a statewide cost control program which is exempt from the CHAMPUS DRG-based payment system under paragraph (a)(1)(ii)(A) of this section; or

(*D*) From the care of a hospital included under the CHAMPUS DRG-based payment system to the care of a uniformed services treatment facility.

(*iii*) *Payment in full to the discharging hospital.* The hospital discharging an inpatient shall be paid in full under the CHAMPUS DRG-based payment system.

(*iv*) *Payment to a hospital transferring an inpatient to another hospital.* If a hospital subject to the CHAMPUS DRG-based payment system transfers an inpatient to another such hospital, the transferring hospital shall be paid a per diem rate (except that in neonatal cases, other than normal newborns, the hospital will be paid at 125 percent of that per diem rate), as determined under instructions issued by TSO, for each day of the patient's stay in that hospital, not to exceed the DRG-based payment that would have been paid if the patient had been discharged to another setting. For admissions occurring on or after October 1, 1995, the transferring hospital shall be paid twice the per diem rate for the first day of any transfer stay, and the per diem amount for each subsequent day, up to the limit described in this paragraph.

(*v*) *Additional payments to transferring hospitals.* A transferring hospital may qualify for an additional payment for extraordinary cases that meet the criteria for long-stay or cost outliers.

(D) *DRG system updates.* The CHAMPUS DRG-based payment system is modeled on the Medicare Prospective Payment System (PPS) and uses annually updated items and numbers from the Medicare PPS as provided for in this part and in instructions issued by the Director, DHA. The effective date of these items and numbers shall not correspond to that under Medicare PPS but shall be delayed until January 1, to align with TRICARE's program year reporting. This allows for an administrative simplicity that optimizes healthcare delivery by reducing existing administrative burden and costs.

(ii) *Applicability of the DRG system*—(A) *Areas affected.* The CHAMPUS DRG-based payment system shall apply to hospitals' services in the fifty states, the District of Columbia, and Puerto Rico, except that any state which has implemented a separate DRG-based payment system or similar payment system in order to control costs and is exempt from the Medicare Prospective Payment System may be exempt from the CHAMPUS DRG-based payment system if it requests exemption in writing, and provided payment under such system does not exceed payment which would otherwise be made under the CHAMPUS DRG-based payment system.

(B) *Services subject to the DRG-based payment system.* All normally covered inpatient hospital services furnished to CHAMPUS beneficiaries by hospitals are subject to the CHAMPUS DRG-based payment system.

(C) *Services exempt from the DRG-based payment system.* The following hospital services, even when provided in a hospital subject to the CHAMPUS DRG-based payment system, are exempt from the CHAMPUS DRG-based payment system. The services in paragraphs (a)(1)(ii)(C)(*1*) through (a)(1)(ii)(C)(*4*) and (a)(1)(ii)(C)(*7*) through (a)(1)(ii)(C)(*9*) of this section shall be reimbursed under the procedures in paragraph (a)(4) of this section, and the services in paragraphs (a)(1)(ii)(C)(*5*) and (a)(1)(ii)(C)(*6*) of this section shall be reimbursed under the procedures in paragraph (j) of this section.

(*1*) Services provided by hospitals exempt from the DRG-based payment system.

(*2*) All services related to solid organ acquisition for CHAMPUS covered transplants by CHAMPUS-authorized transplantation centers.

(*3*) All services related to heart and liver transplantation for admissions prior to October 1, 1998, which would otherwise be paid under the respective DRG.

(*4*) All services related to CHAMPUS covered solid organ transplantations for which there is no DRG assignment.

(*5*) All professional services provided by hospital-based physicians.

(*6*) All services provided by nurse anesthetists.

(*7*) All services related to discharges involving pediatric bone marrow transplants (patient under 18 at admission).

(*8*) All services related to discharges involving children who have been determined to be HIV seropositive (patient under 18 at admission).

(*9*) All services related to discharges involving pediatric cystic fibrosis (patient under 18 at admission).

(*10*) For admissions occurring on or after October 1, 1990, and before October 1, 1994, and for discharges occurring on or after October 1, 1997, the costs of blood clotting factor for hemophilia inpatients. An additional payment shall be made to a hospital for each unit of blood clotting factor furnished to a CHAMPUS inpatient who is hemophiliac in accordance with the amounts established under the Medicare Prospective Payment System (42 CFR 412.115).

(D) *Hospitals subject to the CHAMPUS DRG-based payment system.* All hospitals within the fifty states, the District of Columbia, and Puerto Rico which are certified to provide services to CHAMPUS beneficiaries are subject to the DRG-based payment system except for the following hospitals or hospital units which are exempt.

(*1*) *Psychiatric hospitals.* A psychiatric hospital which is exempt from the Medicare Prospective Payment System is also exempt from the CHAMPUS DRG-based payment system. In order for a psychiatric hospital which does not participate in Medicare to be exempt from the CHAMPUS DRG-based payment system, it must meet the same criteria (as determined by the Director, OCHAMPUS, or a designee) as required for exemption from the Medicare Prospective Payment System as contained in 42 CFR 412.23.

(*2*) *Inpatient Rehabilitation Facilities (IRF).* Prior to implementation of the IRF PPS methodology described in paragraph (a)(10) of this section, an inpatient rehabilitation facility which is exempt from the Medicare prospective payment system is also exempt from the TRICARE DRG-based payment system.

(*3*) *Psychiatric and rehabilitation units (distinct parts).* Prior to implementation of the IRF PPS methodology described in paragraph (a)(10) of this section, a rehabilitation unit which is exempt from the Medicare prospective payment system is also exempt from the TRICARE DRG-based payment system. A psychiatric unit which is exempt from the Medicare prospective payment system is also exempt from the TRICARE DRG-based payment system.

(*4*) *Long Term Care Hospitals.* Prior to implementation of the LTCH PPS methodology described in paragraph (a)(9) of this section, a long-term care hospital which is exempt from the Medicare prospective payment system is also exempt from the CHAMPUS DRG-based payment system.

(*5*) *Hospitals within hospitals.* A hospital within a hospital which is exempt from the Medicare prospective payment system is also exempt from the CHAMPUS DRG-based payment system. In order for a hospital within a hospital which does not participate in Medicare to be exempt from the CHAMPUS DRG-based payment system, it must meet the same criteria (as determined by the Director, TSO, or a designee) as required for exemption from the Medicare Prospective Payment System as contained in 42 CFR 412.22 and the criteria for one or more of the excluded hospital classifications described in § 412.23 of Title 42 CFR.

(*6*) *Sole community hospitals (SCHs).* Prior to implementation of the SCH reimbursement method described in paragraph (a)(7) of this section, any hospital that has qualified for special treatment under the Medicare prospective payment system as an SCH (see subpart G of 42 CFR part 412) and has not given up that classification is exempt from the CHAMPUS DRG-based payment system.

(*7*) *Christian Science sanitoriums.* All Christian Science sanitoriums (as defined in paragraph (b)(4)(viii) of § 199.6) are exempt from the CHAMPUS DRG-based payment system.

(*8*) *Cancer hospitals.* Any hospital which qualifies as a cancer hospital

under the Medicare standards and has elected to be exempt from the Medicare prospective payment system is exempt from the CHAMPUS DRG-based payment system. (See 42 CFR 412.94.)

(*9*) *Hospitals outside the 50 states, the District of Columbia, and Puerto Rico.* A hospital is excluded from the CHAMPUS DRG-based payment system if it is not located in one of the fifty States, the District of Colubmia, or Puerto Rico.

(*10*) *CAHs.* Effective December 1, 2009, any facility which has been designated and certified as a CAH as contained in 42 CFR Part 485.606 is exempt from the CHAMPUS DRG-based payment system.

(E) *Hospitals which do not participate in Medicare.* Any hospital which is subject to the CHAMPUS DRG-based payment system and which otherwise meets CHAMPUS requirements but which is not a Medicare-participating provider (having completed a form HCA–1514, Hospital Request for Certification in the Medicare/Medicaid Program and a form HCFA–1561, Health Insurance Benefit Agreement) must complete a participation agreement with TRICARE. By completing the participation agreement, the hospital agrees to participate on all CHAMPUS inpatient claims and to accept the CHAMPUS-determined allowable amount as payment in full for these claims. Any hospital which does not participate in Medicare and does not complete a participation agreement with TRICARE will not be authorized to provide services to TRICARE beneficiaries.

(F) *Substance Use Disorder Rehabilitation facilities.* With admissions on or after July 1, 1995, substance use disorder rehabilitation facilities, authorized under §199.6(b)(4)(xiv), are subject to the DRG-based payment system.

(iii) *Determination of payment amounts.* The actual payment for an individual claim under the CHAMPUS DRG-based payment system is calculated by multiplying the appropriate adjusted standardized amount (adjusted to account for area wage differences using the wage indexes used in the Medicare program) by a weighting factor specific to each DRG.

(A) *Calculation of DRG weights—*(*1*) *Grouping of charges.* All discharge records in the database shall be grouped by DRG.

(*2*) Remove DRGs. Those DRGs that represent discharges with invalid data or diagnoses insufficient for DRG assignment purposes are removed from the database.

(*3*) *Indirect medical education standardization.* To standardize the charges for the cost effects of indirect medical education factors, each teaching hospital's charges will be divided by 1.0 plus the following ratio on a hospital-specific basis:

$$1.43 \times \left[\left(1.0 + \frac{\text{number of interns + residents}}{\text{number of beds}} \right) .5795 - 1.0 \right]$$

(*4*) *Wage level standardization.* To standardize the charge records for area wage differences, each charge record will be divided into labor-related and nonlabor-related portions, and the labor-related portion shall be divided by the most recently available Medicare wage index for the area. The labor-related and nonlabor-related portions will then be added together.

(*5*) *Elimination of statistical outliers.* All unusually high or low charges shall be removed from the database.

(*6*) *Calculation of DRG average charge.* After the standardization for indirect medical education, and area wage differences, an average charge for each DRG shall be computed by summing charges in a DRG and dividing that sum by the number of records in the DRG.

(*7*) *Calculation of national average charge per discharge.* A national average charge per discharge shall be calculated by summing all charges and dividing that sum by the total number of records from all DRG categories.

(*8*) *DRG relative weights.* DRG relative weights shall be calculated for each DRG category by dividing each DRG average charge by the national average charge.

(B) *Empty and low-volume DRGs.* For any DRG with less than ten (10) occurrences in the CHAMPUS database, the Director, TSO, or designee, has the authority to consider alternative methods for estimating CHAMPUS weights in these low-volume DRG categories.

(C) *Updating DRG weights.* The CHAMPUS DRG weights shall be updated or adjusted as follows:

(*1*) DRG weights shall be recalculated annually using CHAMPUS charge data and the methodology described in paragraph (a)(1)(iii)(A) of this section.

(*2*) When a new DRG is created, CHAMPUS will, if practical, calculate a weight for it using an appropriate charge sample (if available) and the methodology described in paragraph (a)(1)(iii)(A) of this section.

(*3*) In the case of any other change under Medicare to an existing DRG weight (such as in connection with technology changes), CHAMPUS shall adjust its weight for that DRG in a manner comparable to the change made by Medicare.

(D) *Calculation of the adjusted standardized amounts.* The following procedures shall be followed in calculating the CHAMPUS adjusted standardized amounts. (*1*) Differentiate large urban and other area charges. All charges in the database shall be sorted into large urban and other area groups (using the same definitions for these categories used in the Medicare program. The following procedures will be applied to each group.

(*2*) *Indirect medical education standardization.* To standardize the charges for the cost effects of indirect medical education factors, each teaching hospital's charges will be divided by 1.0 plus the following ratio on a hospital-specific basis:

$$1.43 \times \left[\left(1.0 + \frac{\text{number of interns + residents}}{\text{number of beds}} \right) .5795 - 1.0 \right]$$

(*3*) *Wage level standardization.* To standardize the charge records for area wage differences, each charge record will be divided into labor-related and nonlabor-related portions, and the labor-related portion shall be divided by the most recently available Medicare wage index for the area. The labor-related and nonlabor-related portions will then be added together.

(*4*) *Apply the cost to charge ratio.* Each charge is to be reduced to a representative cost by using the Medicare cost to charge ratio. This amount shall be increased by 1 percentage point in order to reimburse hospitals for bad debt expenses attributable to CHAMPUS beneficiaries.

(*5*) Preliminary base year standardized amount. A preliminary base year standardized amount shall be calculated by summing all costs in the database applicable to the large urban or other area group and dividing by the total number of discharges in the respective group.

(*6*) *Update for inflation.* The preliminary base year standardized amounts shall be updated using an annual update factor equal to 1.07 to produce fiscal year 1988 preliminary standardized amounts. Therefore, any development of a new standardized amount will use an inflation factor equal to the hospital market basket index used by the Health Care Financing Administration in their Prospective Payment System.

(*7*) The preliminary standardized amounts, updated for inflation, shall be divided by a system standardization factor so that total DRG outlays, given the database distribution across hospitals and diagnosis, are equal to the total charges reduced to costs.

(*8*) *Labor and nonlabor portions of the adjusted standardized amounts.* The adjusted standardized amounts shall be

divided into labor and nonlabor portions in accordance with the Medicare division of labor and nonlabor portions.

(E) *Adjustments to the DRG-based payments amounts.* The following adjustments to the DRG-based amounts (the weight multiplied by the adjusted standardized amount) will be made. Additional adjustments to DRG amounts are included in paragraph (a)(1)(iv) of this section.

(*1*) *Outliers.* The DRG-based payment to a hospital shall be adjusted for atypical cases. These outliers are those cases that have either an unusually short length-of-stay or extremely long length-of-stay or that involve extraordinarily high costs when compared to most discharges classified in the same DRG. Cases which qualify as both a length-of-stay outlier and a cost outlier shall be paid at the rate which results in the greater payment.

(*i*) *Length-of-stay outliers.* Length-of-stay outliers shall be identified and paid by the fiscal intermediary when the claims are processed.

(*A*) *Short-stay outliers.* Any discharge with a length-of-stay (LOS) less than 1.94 standard deviations from the DRG's arithmetic LOS shall be classified as a short-stay outlier. Short-stay outliers shall be reimbursed at 200 percent of the per diem rate for the DRG for each covered day of the hospital stay, not to exceed the DRG amount. The per diem rate shall equal the DRG amount divided by the arithmetic mean length-of-stay for the DRG.

(*B*) *Long-stay outliers.* Any discharge (except for neonatal services and services in children's hospitals) which has a length-of-stay (LOS) exceeding a threshold established in accordance with the criteria used for the Medicare Prospective Payment System as contained in 42 CFR 412.82 shall be classified as a long-stay outlier. Any discharge for neonatal services or for services in a children's hospital which has a LOS exceeding the lesser of 1.94 standard deviations or 17 days from the DRG's arithmetic mean LOS also shall be classified as a long-stay outlier. Long-stay outliers shall be reimbursed the DRG-based amount plus a percentage (as established for the Medicare Prospective Payment System) of the per diem rate for the DRG for each covered day of care beyond the long-stay outlier threshold. The per diem rate shall equal the DRG amount divided by the arithmetic mean LOS for the DRG. For admissions on or after October 1, 1997, the long stay outlier has been eliminated for all cases except children's hospitals and neonates. For admissions on or after October 1, 1998, the long stay outlier has been eliminated for children's hospitals and neonates.

(*ii*) *Cost outliers.* Additional payment for cost outliers shall be made only upon request by the hospital.

(*A*) Cost outliers except those in children's hospitals or for neonatal services. Any discharge which has standardized costs that exceed a threshold established in accordance with the criteria used for the Medicare Prospective Payment System as contained in 42 CFR 412.84 shall qualify as a cost outlier. The standardized costs shall be calculated by multiplying the total charges by the factor described in paragraph (a)(1)(iii)(D)(*4*) of this section and adjusting this amount for indirect medical education costs. Cost outliers shall be reimbursed the DRG-based amount plus a percentage (as established for the Medicare Prospective Payment System) of all costs exceeding the threshold. Effective with admissions occurring on or after October 1, 1997, the standardized costs are no longer adjusted for indirect medical education costs.

(*B*) Cost outliers in children's hospitals for neonatal services. Any discharge for services in a children's hospital or for neonatal services which has standardized costs that exceed a threshold of the greater of two times the DRG-based amount or $13,500 shall qualify as a cost outlier. The standardized costs shall be calculated by multiplying the total charges by the factor described in paragraph (a)(1) (iii) (D) (*4*) of this section (adjusted to include average capital and direct medical education costs) and adjusting this amount for indirect medical education costs. Cost outliers for services in children's hospitals and for neonatal services shall be reimbursed the DRG-based amount plus a percentage (as established for the Medicare Prospective

Payment System) of all costs exceeding the threshold. Effective with admissions occurring on or after October 1, 1998, standardized costs are no longer adjusted for indirect medical education costs. In addition, CHAMPUS will calculate the outlier payments that would have occurred at each of the 59 Children's hospitals under the FY99 outlier policy for all cases that would have been outliers under the FY94 policies using the most accurate data available in September 1998. A ratio will be calculated which equals the level of outlier payments that would have been made under the FY94 outlier policies and the outlier payments that would be made if the FY99 outlier policies had applied to each of these potential outlier cases for these hospitals. The ratio will be calculated across all outlier claims for the 59 hospitals and will not be hospital specific. The ratio will be used to increase cost outlier payments in FY 1999 and FY 2000, unless the hospital has a negotiated agreement with a managed care support contractor which would affect this payment. For hospitals with managed care support agreements which affect these payments, CHAMPUS will apply these payments if the increased payments would be consistent with the agreements. In FY 2000 the ratio of outlier payments (long stay and cost) that would have occurred under the FY 94 policy and actual cost outlier payments made under the FY 99 policy will be recalculated. If the ratio has changed significantly, the ratio will be revised for use in FY 2001 and thereafter. In FY 2002, the actual cost outlier cases in FY 2000 and 2001 will be reexamined. The ratio of outlier payments that would have occurred under the FY94 policy and the actual cost outlier payments made under the FY 2000 and FY 2001 policies. If the ratio has changed significantly, the ratio will be revised for use in FY 2003.

(*C*) *Cost outliers for burn cases.* All cost outliers for DRGs related to burn cases shall be reimbursed the DRG-based amount plus a percentage (as established for the Medicare Prospective Payment System) of all costs exceeding the threshold. The standardized costs and thresholds for these cases shall be calculated in accordance with §199.14(a)(1)(iii)(E)(*1*)(*ii*)(*A*) and §199.14(a)(1)(iii)(E)(*1*)(*ii*)(*B*).

(*2*) *Wage adjustment.* CHAMPUS will adjust the labor portion of the standardized amounts according to the hospital's area wage index. The wage adjusted DRG payment will also be multiplied by 1.2 for an individual diagnosed with COVID–19 and/or Coronavirus discharged during the Secretary of Health and Human Services' declared public health emergency (PHE).

(*3*) *Indirect medical education adjustment.* The wage adjusted DRG payment will also be multiplied by 1.0 plus the hospital's indirect medical education ratio.

(*4*) *Children's hospital differential.* With respect to claims from children's hospitals, the appropriate adjusted standardized amount shall also be adjusted by a children's hospital differential.

(*i*) *Qualifying children's hospitals.* Hospitals qualifying for the children's hospital differential are hospitals that are exempt from the Medicare Prospective Payment System, or, in the case of hospitals that do not participate in Medicare, that meet the same criteria (as determined by the Director, OCHAMPUS, or a designee) as required for exemption from the Medicare Prospective Payment System as contained in 42 CFR 412.23.

(*ii*) *Calculation of differential.* The differential shall be equal to the difference between a specially calculated children's hospital adjusted standardized amount and the adjusted standardized amount for fiscal year 1988. The specially calculated children's hospital adjusted standardized amount shall be calculated in the same manner as set forth in §199.14(a)(1)(iii)(D), except that:

(*A*) The base period shall be fiscal year 1988 and shall represent total estimated charges for discharges that occurred during fiscal year 1988.

(*B*) No cost to charge ratio shall be applied.

(*C*) Capital costs and direct medical education costs will be included in the calculation.

(*D*) The factor used to update the database for inflation to produce the fiscal year 1988 base period amount

shall be the applicable Medicare inpatient hospital market basket rate.

(*iii*) *Transition rule.* Until March 1, 1992, separate differentials shall be used for each higher volume children's hospital (individually) and for all other children's hospitals (in the aggregate). For this purpose, a higher volume hospital is a hospital that had 50 or more CHAMPUS discharges in fiscal year 1988.

(*iv*) *Hold harmless provision.* At such time as the weights initially assigned to neonatal DRGs are recalibrated based on sufficient volume of CHAMPUS claims records, children's hospital differentials shall be recalculated and appropriate retrospective and prospective adjustments shall be made. To the extent practicable, the recalculation shall also include reestimated values of other factors (including but not limited to direct education and capital costs and indirect education factors) for which more accurate data became available.

(*v*) *No update for inflation.* The children's hospital differential, calculated (and later recalculated under the hold harmless provision) for the base period of fiscal year 1988, shall not be updated for subsequent fiscal years.

(*vi*) *Administrative corrections.* In connection with determinations pursuant to paragraph (a)(1)(iii) (E)(*4*)(*iii*) of this section, any children's hospital that believes OCHAMPUS erroneously failed to classify the hospital as a high volume hospital or incorrectly calculated (in the case of a high volume hospital) the hospital's differential may obtain administrative corrections by submitting appropriate documentation to the Director, OCHAMPUS (or a designee).

(F) *Updating the adjusted standardized amounts.* Beginning in FY 1989, the adjusted standardized amounts will be updated by the Medicare annual update factor, unless the adjusted standardized amounts are recalculated.

(G) *Annual cost pass-throughs*—(*1*) *Capital costs.* When requested in writing by a hospital, CHAMPUS shall reimburse the hospital its share of actual capital costs as reported annually to the CHAMPUS fiscal intermediary. Payment for capital costs shall be made annually based on the ratio of CHAMPUS inpatient days for those beneficiaries subject to the CHAMPUS DRG-based payment system to total inpatient days applied to the hospital's total allowable capital costs. Reductions in payments for capital costs which are required under Medicare shall also be applied to payments for capital costs under CHAMPUS.

(*i*) *Costs included as capital costs.* Allowable capital costs are those specified in Medicare Regulation § 413.130, as modified by § 412.72.

(*ii*) *Services, facilities, or supplies provided by supplying organizations.* If services, facilities, or supplies are provided to the hospital by a supplying organization related to the hospital within the meaning of Medicare Regulation § 413.17, then the hospital must include in its capital-related costs, the capital-related costs of the supplying organization. However, if the supplying organization is not related to the provider within the meaning of § 413.17, no part of the change to the provider may be considered a capital-related cost unless the services, facilities, or supplies are capital-related in nature and:

(*A*) The capital-related equipment is leased or rented by the provider;

(*B*) The capital-related equipment is located on the provider's premises; and

(*C*) The capital-related portion of the charge is separately specified in the charge to the provider.

(*2*) *Direct medical education costs.* When requested in writing by a hospital, CHAMPUS shall reimburse the hospital its actual direct medical education costs as reported annually to the CHAMPUS fiscal intermediary. Such teaching costs must be for a teaching program approved under Medicare Regulation § 413.85. Payment for direct medical education costs shall be made annually based on the ratio of CHAMPUS inpatient days for those beneficiaries subject to the CHAMPUS DRG-based payment system to total inpatient days applied to the hospital's total allowable direct medical education costs. Allowable direct medical education costs are those specified in Medicare Regulation § 413.85.

(*3*) Information necessary for payment of capital and direct medical education costs. All hospitals subject to the CHAMPUS DRG-based payment system, except for children's hospitals,

may be reimbursed for allowed capital and direct medical education costs by submitting a request to the CHAMPUS contractor. Beginning October 1, 1998, such request shall be filed with CHAMPUS on or before the last day of the twelfth month following the close of the hospitals' cost reporting period, and shall cover the one-year period corresponding to the hospital's Medicare cost-reporting period. The first such request may cover a period of less than a full year—from the effective date of the CHAMPUS DRG-based payment system to the end of the hospital's Medicare cost-reporting period. All costs reported to the CHAMPUS contractor must correspond to the costs reported on the hospital's Medicare cost report. An extension of the due date for filing the request may only be granted if an extension has been granted by HCFA due to a provider's operations being significantly adversely affected due to extraordinary circumstances over which the provider has no control, such as flood or fire. (If these costs change as a result of a subsequent audit by Medicare, the revised costs are to be reported to the hospital's CHAMPUS contractor within 30 days of the date the hospital is notified of the change). The request must be signed by the hospital official responsible for verifying the amounts and shall contain the following information.

(*i*) The hospital's name.

(*ii*) The hospital's address.

(*iii*) The hospital's CHAMPUS provider number.

(*iv*) The hospital's Medicare provider number.

(*v*) The period covered—this must correspond to the hospital's Medicare cost-reporting period.

(*vi*) Total inpatient days provided to all patients in units subject to DRG-based payment.

(*vii*) Total allowed CHAMPUS inpatient days provided in units subject to DRG-based payment.

(*viii*) Total allowable capital costs.

(*ix*) Total allowable direct medical education costs.

(*x*) Total full-time equivalents for:

(*A*) Residents.

(*B*) Interns.

(*xi*) Total inpatient beds as of the end of the cost-reporting period. If this has changed during the reporting period, an explanation of the change must be provided.

(*xii*) Title of official signing the report.

(*xiii*) Reporting date.

(*xiv*) The report shall contain a certification statement that any changes to the items in paragraphs (a)(1)(iii)(G)(*3*)(*vi*), (*vii*), (*viii*), (*ix*), or (*x*), which are a result of an audit of the hospital's Medicare cost-report, shall be reported to CHAMPUS within thirty (30) days of the date the hospital is notified of the change.

(iv) *Special Programs and Incentive Payments.* (A) *Additional payment for new medical services and technologies.* TRICARE will make New Technology Add On Payments (NTAPs) adjustments to DRGs as provided in paragraphs (a)(1)(iv)(A)(*1*) through (a)(1)(iv)(A)(*11*) of this section. The Director, Defense Health Agency (DHA), shall provide notice of the issuance of policies and guidelines adopting such adjustments together with any variations deemed necessary to address unique issues involving the beneficiary population or program administration.

(*1*) *Adoption of Medicare NTAPs.* For TRICARE covered services and supplies, TRICARE will adopt Medicare NTAPs as implemented under 42 CFR 412.87 under the same conditions as published by the Centers for Medicare & Medicaid Services, except for pediatric cases.

(*2*) *Pediatric cases.* For pediatric NTAP DRGs, the TRICARE NTAP adjustment shall be modified to be set at 100 percent of the costs in excess of the Medicare Severity-Diagnosis Related Group (MS–DRG) payment. As used in this paragraph, pediatric is defined as services and supplies provided to individuals under the age of 18, or who are being treated in a children's hospital or in a pediatric ward.

(*3*) *TRICARE designated NTAP adjustments.* For categories of TRICARE covered services and supplies for which Medicare has not established an NTAP adjustment for DRGs, the Director, DHA may designate a TRICARE NTAP adjustment through a process using criteria to identify and select such new

technology services/supplies similar to that utilized by Medicare under 42 CFR 412.87. The Director, DHA may then designate a TRICARE NTAP reimbursement adjustment through a process using a methodology similar to the Medicare methodology outlined in 42 CFR 412.88. This discretionary authority to designate TRICARE NTAP adjustments shall apply to services and supplies typically provided to TRICARE beneficiaries age 64 or younger when Medicare has not established an NTAP adjustment for such services/supplies. As with other discretionary authority under this part, a decision to designate a TRICARE category of services/supplies for an NTAP adjustment to DRGs and the amount of such an adjustment are not subject to the appeal and hearing procedures of §199.10. The Director, DHA, shall select which new technologies may be designated as TRICARE NTAPs and will publish this list based on the eligibility criteria and reimbursement methodology provided in paragraphs (a)(1)(iv)(A)(*4*) through (a)(1)(iv)(A)(*11*) of this section.

(*4*) *Eligibility requirements and reimbursement methodology for TRICARE designated NTAP adjustments.* A new medical service or technology represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of TRICARE beneficiaries. The totality of the circumstances is considered when making a determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of TRICARE beneficiaries.

(*5*) *Criteria for improvement.* A determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of TRICARE beneficiaries means one or more of the following:

(*i*) The new medical service or technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.

(*ii*) The new medical service or technology offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable, or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods and there must also be evidence that use of the new medical service or technology to make a diagnosis affects the management of the patient.

(*iii*) The use of the new medical service or technology significantly improves clinical outcomes relative to services or technologies previously available as demonstrated by one or more of the following seven outcomes: A reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication; A decreased rate of at least one subsequent diagnostic or therapeutic intervention; A decreased number of future hospitalizations or physician visits; A more rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time; An improvement in one or more activities of daily living; An improved quality of life; or A demonstrated greater medication adherence or compliance.

(*iv*) The totality of the information otherwise demonstrates that the new medical service or technology substantially improves, relative to technologies previously available, the diagnosis or treatment of TRICARE beneficiaries.

(*6*) *Evidence.* Evidence from scientific literature may be sufficient to establish that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of TRICARE beneficiaries.

(*7*) *Prevalence.* The medical condition diagnosed or treated by the new medical service or technology may have a low prevalence among TRICARE beneficiaries.

(*8*) *Subpopulation.* The new medical service or technology may represent an advance that substantially improves, relative to services or technologies previously available, the diagnosis or

treatment of a subpopulation of patients with the medical condition diagnosed or treated by the new medical service or technology.

(*9*) *Newness criteria*. A medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the inpatient hospital code assigned to the new service or technology (depending on when a new code is assigned and data on the new service or technology becomes available for DRG recalibration). After TRICARE has recalibrated the DRGs, based on available data, to reflect the costs of an otherwise new medical service or technology, the medical service or technology will no longer be considered ''new'' under the criterion of this section.

(*10*) *Payment methodology*. For discharges involving new medical services or technologies that meet the criteria specified in paragraphs (a)(1)(iv)(A)(*4*) through (a)(1)(iv)(A)(*9*) and that are approved as TRICARE NTAPs per paragraph (a)(1)(iv)(A)(*11*) of this section, TRICARE payment will be the lesser of:

(*i*) The CMS designated percentage of the estimated costs of the new technology or medical service, as published in 42 CFR 412.88; or

(*ii*) The CMS designated percentage of the difference between the full DRG payment and the hospital's estimated cost for the case, as published in 42 CFR 412.88.

(*11*) *Publication and timing*. TRICARE may consider whether a new medical service or technology meets the eligibility criteria specified in paragraphs (a)(1)(iv)(A)(*4*) through (a)(1)(iv)(A)(*9*) of this section and announce the results on the NTAP website. In doing so, TRICARE only considers, for add-on payments for a particular fiscal year, an application for which the new medical device or product has received FDA marketing authorization by July 1 prior to the particular fiscal year; or the application is submitted under an alternative pathway to the FDA for which conditional NTAP approval for FDA marketing authorization is granted before July 1 of the fiscal year for which the applicant applied for new technology add-on payments.

(B) *Hospital Value Based Purchasing*. TRICARE will adopt the Medicare Hospital Value Based Purchasing (HVBP) Program adjustments to DRGs to incentivize hospitals as implemented under 42 CFR 412.160, when determined by the ASD(HA), as practicable. The Director, DHA, shall provide notice of the issuance of policies and guidelines adopting such adjustments together with any variations deemed necessary to address unique issues involving the beneficiary population or program administration.

(C) *Additional payment for new COVID–19 Treatments*. TRICARE will adopt the Medicare New COVID–19 Treatments Add-On Payments (NCTAP) adjustment to DRGs. New COVID–19 treatments shall be reimbursed the lesser of (1) 65 percent of the operating outlier threshold for the claim or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment for an individual treated using new COVID–19 treatments discharged during the Secretary of Health and Human Services' declared public health emergency (PHE) through the end of the FY in which the PHE terminates.

(2) *CHAMPUS mental health per diem payment system*. The CHAMPUS mental health per diem payment system shall be used to reimburse for inpatient mental health hospital care in specialty psychiatric hospitals and units. Payment is made on the basis of prospectively determined rates and paid on a per diem basis. The system uses two sets of per diems. One set of per diems applies to hospitals and units that have a relatively higher number of CHAMPUS discharges. For these hospitals and units, the system uses hospital-specific per diem rates. The other set of per diems applies to hospitals and units with a relatively lower number of CHAMPUS discharges. For these hospitals and units, the system uses regional per diems, and further provides for adjustments for area wage differences and indirect medical education costs and additional pass-through payments for direct medical education costs.

(i) *Applicability of the mental health per diem payment system*—(A) *Hospitals*

and units covered. The CHAMPUS mental health per diem payment system applies to services covered (see paragraph (a)(2)(i)(B) of this section) that are provided in Medicare prospective payment system (PPS) exempt psychiatric specialty hospitals and all Medicare PPS exempt psychiatric specialty units of other hospitals. In addition, any psychiatric hospital that does not participate in Medicare, or any other hospital that has a psychiatric specialty unit that has not been so designated for exemption from the Medicare prospective payment system because the hospital does not participate in Medicare, may be designated as a psychiatric hospital or psychiatric specialty unit for purposes of the CHAMPUS mental health per diem payment system upon demonstrating that it meets the same criteria (as determined by the Director, OCHAMPUS) as required for the Medicare exemption. The CHAMPUS mental health per diem payment system does not apply to mental health services provided in other hospitals.

(B) *Services covered.* Unless specifically exempted, all covered hospitals' and units' inpatient claims which are classified into a mental health DRG (DRG categories 425–432, but not DRG 424) or an alcohol/drug abuse DRG (DRG categories 433–437) shall be subject to the mental health per diem payment system.

(ii) *Hospital-specific per diems for higher volume hospitals and units.* This paragraph describes the per diem payment amounts for hospitals and units with a higher volume of CHAMPUS discharges.

(A)(*1*) *Per diem amount.* A hospital-specific per diem amount shall be calculated for each hospital and unit with a higher volume of CHAMPUS discharges. The base period per diem amount shall be equal to the hospital's average daily charge in the base period. The base period amount, however, may not exceed the cap described in paragraph (a)(2)(ii)(B) of this section. The base period amount shall be updated in accordance with paragraph (a)(2)(iv) of this section.

(*2*) In states that have implemented a payment system in connection with which hospitals in that state have been exempted from the CHAMPUS DRG-based payment system pursuant to paragraph (a)(1)(ii)(A) of this section, psychiatric hospitals and units may have per diem amounts established based on the payment system applicable to such hospitals and units in the state. The per diem amount, however, may not exceed the cap amount applicable to other higher volume hospitals.

(B) *Cap*—(*1*) As it affects payment for care provided to patients prior to April 6, 1995, the base period per diem amount may not exceed the 80th percentile of the average daily charge weighted for all discharges throughout the United States from all higher volume hospitals.

(*2*) Applicable to payments for care provided to patients on or after April 6, 1996, the base period per diem amount may not exceed the 70th percentile of the average daily charge weighted for all discharges throughout the United States from all higher volume hospitals. For this purpose, base year charges shall be deemed to be charges during the period of July 1, 1991 to June 30, 1992, adjusted to correspond to base year (FY 1988) charges by the percentage change in average daily charges for all higher volume hospitals and units between the period of July 1, 1991 to June 30, 1992 and the base year.

(C) *Review of per diem.* Any hospital or unit which believes OCHAMPUS calculated a hospital-specific per diem which differs by more than $5.00 from that calculated by the hospital or unit may apply to the Director, OCHAMPUS, or a designee, for a recalculation. The burden of proof shall be on the hospital.

(iii) *Regional per diems for lower volume hospitals and units.* This paragraph describes the per diem amounts for hospitals and units with a lower volume of CHAMPUS discharges.

(A) *Per diem amounts.* Hospitals and units with a lower volume of CHAMPUS patients shall be paid on the basis of a regional per diem amount, adjusted for area wages and indirect medical education. Base period regional per diems shall be calculated based upon all CHAMPUS lower volume hospitals' claims paid during the base period. Each regional per diem

amount shall be the quotient of all covered charges divided by all covered days of care, reported on all CHAMPUS claims from lower volume hospitals in the region paid during the base period, after having standardized for indirect medical education costs and area wage indexes and subtracted direct medical education costs. Regional per diem amounts are adjusted in accordance with paragraph (a)(2)(iii)(C) of this section. Additional pass-through payments to lower volume hospitals are made in accordance with paragraph (a)(2)(iii)(D) of this section. The regions shall be the same as the Federal census regions.

(B) *Review of per diem amount.* Any hospital that believes the regional per diem amount applicable to that hospital has been erroneously calculated by OCHAMPUS by more than $5.00 may submit to the Director, OCHAMPUS, or a designee, evidence supporting a different regional per diem. The burden of proof shall be on the hospital.

(C) *Adjustments to regional per diems.* Two adjustments shall be made to the regional per diem rates.

(*1*) *Area wage index.* The same area wage indexes used for the CHAMPUS DRG-based payment system (see paragraph (a)(1)(iii)(E)(*2*) of this section) shall be applied to the wage portion of the applicable regional per diem rate for each day of the admission. The wage portion shall be the same as that used for the CHAMPUS DRG-based payment system.

(*2*) *Indirect medical education.* The indirect medical education adjustment factors shall be calculated for teaching hospitals in the same manner as is used in the CHAMPUS DRG-based payment system (see paragraph (a)(1)(iii)(E)(*3*) of this section) and applied to the applicable regional per diem rate for each day of the admission.

(D) *Annual cost pass-through for direct medical education.* In addition to payments made to lower volume hospitals under paragraph (a)(2)(iii) of this section, CHAMPUS shall annually reimburse hospitals for actual direct medical education costs associated with services to CHAMPUS beneficiaries. This reimbursement shall be done pursuant to the same procedures as are applicable to the CHAMPUS DRG-based payment system (see paragraph (a)(1)(iii)(G) of this section).

(iv) *Base period and update factors*—(A) *Base period.* The base period for calculating the hospital-specific and regional per diems, as described in paragraphs (a)(2)(ii) and (a)(2)(iii) of this section, is Federal fiscal year 1988. Base period calculations shall be based on actual claims paid during the period July 1, 1987 through May 31, 1988, trended forward to represent the 12-month period ending September 30, 1988 on the basis of the Medicare inpatient hospital market basket rate.

(B) *Alternative hospital-specific data base.* Upon application of a higher volume hospital or unit to the Director, OCHAMPUS, or a designee, the hospital or unit may have its hospital-specific base period calculations based on claims with a date of discharge (rather than date of payment) between July 1, 1987 through May 31, 1988 if it has generally experienced unusual delays in claims payments and if the use of such an alternative data base would result in a difference in the per diem amount of at least $5.00. For this purpose, the unusual delays means that the hospital's or unit's average time period between date of discharge and date of payment is more than two standard deviations longer than the national average.

(C) *Update factors*—(*1*) The hospital-specific per diems and the regional per diems calculated for the base period pursuant to paragraphs (a)(2)(ii) of this section shall remain in effect for federal fiscal year 1989; there will be no additional update for fiscal year 1989.

(*2*) Except as provided in paragraph (a)(2)(iv)(C)(*3*) of this section, for subsequent federal fiscal years, each per diem shall be updated by the Medicare Inpatient Prospective Payment System update factor.

(*3*) As an exception to the update required by paragraph (a)(2)(iv)(C)(*2*) of this section, all per diems in effect at the end of fiscal year 1995 shall remain in effect, with no additional update, throughout fiscal years 1996 and 1997. For fiscal year 1998 and thereafter, the per diems in effect at the end of fiscal year 1997 will be updated in accordance with paragraph (a)(2)(iv)(C)(*2*).

(*4*) Hospitals and units with hospital-specific rates will be notified of their respective rates prior to the beginning of each Federal fiscal year. New hospitals shall be notified at such time as the hospital rate is determined. The actual amount of each regional per diem that will apply in any Federal fiscal year shall be posted to the Agency's official Web site at the start of that fiscal year.

(v) *Higher volume hospitals.* This paragraph describes the classification of and other provisions pertinent to hospitals with a higher volume of CHAMPUS patients.

(A) *In general.* Any hospital or unit that had an annual rate of 25 or more CHAMPUS discharges of CHAMPUS patients during the period July 1, 1987 through May 31, 1988 shall be considered a higher volume hospital has 25 or more CHAMPUS discharges, that hospital shall be considered to be a higher volume hospital during Federal fiscal year 1989 and all subsequent fiscal years. All other hospitals and units covered by the CHAMPUS mental health per diem payment system shall be considered lower volume hospitals.

(B) *Hospitals that subsequently become higher volume hospitals.* In any Federal fiscal year in which a hospital, including a new hospital (see paragraph (a)(2)(v)(C) of this section), not previously classified as a higher volume hospital has 25 or more CHAMPUS discharges, that hospital shall be considered to be a higher volume hospital during the next Federal fiscal year and all subsequent fiscal years. The hospital specific per diem amount shall be calculated in accordance with the provisions of paragraph (a)(2)(ii) of this section, except that the base period average daily charge shall be deemed to be the hospital's average daily charge in the year in which the hospital had 25 or more discharges, adjusted by the percentage change in average daily charges for all higher volume hospitals and units between the year in which the hospital had 25 or more CHAMPUS discharges and the base period. The base period amount, however, may not exceed the cap described in paragraph (a)(2)(ii)(B) of this section.

(C) *Special retrospective payment provision for new hospitals.* For purposes of this paragraph, a new hospital is a hospital that qualifies for the Medicare exemption from the rate of increase ceiling applicable to new hospitals which are PPS-exempt psychiatric hospitals. Any new hospital that becomes a higher volume hospital, in addition to qualifying prospectively as a higher volume hospital for purposes of paragraph (a)(2)(v)(B) of this section, may additionally, upon application to the Director, OCHAMPUS, receive a retrospective adjustment. The retrospective adjustment shall be calculated so that the hospital receives the same government share payments it would have received had it been designated a higher volume hospital for the federal fiscal year in which it first had 25 or more CHAMPUS discharges and the preceding fiscal year (if it had any CHAMPUS patients during the preceding fiscal year). Such new hospitals must agree not to bill CHAMPUS beneficiaries for any additional costs beyond that determined initially.

(D) *Review of classification.* Any hospital or unit which OCHAMPUS erroneously fails to classify as a higher volume hospital may apply to the Director, OCHAMPUS, or a designee, for such a classification. The hospital shall have the burden of proof.

(vi) *Payment for hospital based professional services.* Lower volume hospitals and units may not bill separately for hospital based professional mental health services; payment for those services is included in the per diems. Higher volume hospitals and units, whether they billed CHAMPUS separately for hospital based professional mental health services or included those services in the hospital's billing to CHAMPUS, shall continue the practice in effect during the period July 1, 1987 to May 31, 1988 (or other data base period used for calculating the hospital's or unit's per diem), except that any such hospital or unit may change its prior practice (and obtain an appropriate revision in its per diem) by providing to OCHAMPUS notice in accordance with procedures established by the Director, OCHAMPUS, or a designee.

(vii) *Leave days.* CHAMPUS shall not pay for days where the patient is absent on leave from the specialty psychiatric hospital or unit. The hospital must identify these days when claiming reimbursement. CHAMPUS shall not count a patients's leave of absence as a discharge in determining whether a facility should be classified as a higher volume hospital pursuant to paragraph (a)(2)(v) of this section.

(viii) *Exemptions from the CHAMPUS mental health per diem payment system.* The following providers and procedures are exempt from the CHAMPUS mental health per diem payment system.

(A) *Non-specialty providers.* Providers of inpatient care which are not either psychiatric hospitals or psychiatric specialty units as described in paragraph (a)(2)(i)(A) of this section are exempt from the CHAMPUS mental health per diem payment system. Such providers should refer to paragraph (a)(1) of this section for provisions pertinent to the CHAMPUS DRG-based payment system.

(B) *DRG 424.* Admissions for operating room procedures involving a principal diagnosis of mental illness (services which group into DRG 424) are exempt from the per diem payment system. They will be reimbursed pursuant to the provisions of paragraph (a)(3) of this section.

(C) *Non-mental health services.* Admissions for non-mental health procedures in specialty psychiatric hospitals and units are exempt from the per diem payment system. They will be reimbursed pursuant to the provisions of paragraph (a)(3) of this section.

(D) *Sole community hospitals (SCHs).* Prior to implementation of the SCH reimbursement method described in paragraph (a)(7) of this section, any hospital that has qualified for special treatment under the Medicare prospective payment system as an SCH and has not given up that classification is exempt.

(E) *Hospitals outside the U.S.* A hospital is exempt if it is not located in one of the 50 states, the District of Columbia or Puerto Rico.

(ix) *Payment for psychiatric and substance use disorder rehabilitation partial hospitalization services, intensive outpatient psychiatric and substance use disorder services and opioid treatment services*—(A) *Per diem payments.* Psychiatric and substance use disorder partial hospitalization services, intensive outpatient psychiatric and substance use disorder services and opioid treatment services authorized by §199.4(b)(9), (b)(10), and (b)(11), respectively, and provided by institutional providers authorized under §199.6(b)(4)(xii), (b)(4)(xviii) and (b)(4)(xix), respectively, are reimbursed on the basis of prospectively determined, all-inclusive per diem rates pursuant to the provisions of paragraphs (a)(2)(ix)(A)(*1*) through (*3*) of this section, with the exception of hospital-based psychiatric and substance use disorder and opioid services which are reimbursed in accordance with provisions of paragraph (a)(6)(ii) of this section and free-standing opioid treatment programs when reimbursed on a fee-for-service basis as specified in paragraph (a)(2)(ix)(A)(*3*)(*ii*) of this section. The per diem payment amount must be accepted as payment in full, subject to the outpatient cost-sharing provisions under §199.4(f), for institutional services provided, including board, routine nursing services, group therapy, ancillary services (*e.g.*, music, dance, and occupational and other such therapies), psychological testing and assessment, overhead and any other services for which the customary practice among similar providers is included in the institutional charges, except for those services which may be billed separately under paragraph (a)(2)(ix)(B) of this section. Per diem payment will not be allowed for leave days during which treatment is not provided.

(*1*) *Partial hospitalization programs.* For any full-day partial hospitalization program (minimum of 6 hours), the maximum per diem payment amount is 40 percent of the average inpatient per diem amount per case established under the TRICARE mental health per diem reimbursement system during the fiscal year for both high and low volume psychiatric hospitals and units [as defined in paragraph (a)(2) of this section]. Intensive outpatient services provided in a PHP setting lasting less than 6 hours, with a minimum of 2 hours, will be paid as provided in paragraph (a)(2)(ix)(A)(2) of this section.

PHP per diem rates will be updated annually by the Medicare update factor used for their Inpatient Prospective Payment System.

(*2*) *Intensive outpatient programs.* For intensive outpatient programs (IOPs) (minimum of 2 hours), the maximum per diem amount is 75 percent of the rate for a full-day partial hospitalization program as established in paragraph (a)(2)(ix)(A)(1) of this section. IOP per diem rates will be updated annually by the Medicare update factor used for their Inpatient Prospective Payment System.

(*3*) *Opioid treatment programs.* Opioid treatment programs (OTPs) authorized by §199.4(b)(11) and provided by providers authorized under §199.6(b)(4)(xix) will be reimbursed based on the variability in the dosage and frequency of the drug being administered and in related supportive services.

(*i*) *Weekly all-inclusive per diem rate.* Methadone OTPs will be reimbursed the lower of the billed charge or the weekly all-inclusive per diem rate (the weekly national all-inclusive rate adjusted for locality), including the cost of the drug and related services (*i.e.*, the costs related to the initial intake/assessment, drug dispensing and screening and integrated psychosocial and medical treatment and support services). The bundled weekly per diem payments will be accepted as payment in full, subject to the outpatient cost-sharing provisions under §199.4(f). The methadone per diem rate for OTPs will be updated annually by the Medicare update factor used for their Inpatient Prospective Payment System.

(*ii*) *Exceptions to per diem reimbursement.* When providing other medications which are more likely to be prescribed and administered in an office-based opioid treatment setting, but which are still available for treatment of substance use disorders in an outpatient treatment program setting, OTPs will be reimbursed on a fee-for-service basis (*i.e.*, separate payments will be allowed for both the medication and accompanying support services), subject to the outpatient cost-sharing provisions under §199.4(f). OTPs' rates will be updated annually by the Medicare update factor used for their Inpatient Prospective Payment System.

(*iii*) *Discretionary authority.* The Director, TRICARE, will have discretionary authority in establishing the reimbursement methodologies for new drugs and biologicals that may become available for the treatment of substance use disorders in OTPs. The type of reimbursement (*e.g.*, fee-for-service versus bundled per diem payments) will be dependent on the variability of the dosage and frequency of the medication being administered, as well as the support services.

(B) *Services which may be billed separately.* Psychotherapy sessions and non-mental health related medical services not normally included in the evaluation and assessment of PHP, IOP or OTPs, provided by authorized independent professional providers who are not employed by, or under contract with, PHP, IOP or OTPs for the purposes of providing clinical patient care are not included in the per diem rate and may be billed separately. This includes ambulance services when medically necessary for emergency transport.

(3) *Reimbursement for inpatient services provided by a CAH.* (i) For admissions on or after December 1, 2009, inpatient services provided by a CAH, other than services provided in psychiatric and rehabilitation distinct part units, shall be reimbursed at allowable cost (*i.e.*, 101 percent of reasonable cost) under procedures, guidelines, and instructions issued by the Director, DHA, or designee. This does not include any costs of physicians' services or other professional services provided to CAH inpatients. Inpatient services provided in psychiatric distinct part units would be subject to the TRICARE mental health payment system. Inpatient services provided in rehabilitation distinct part units would be subject to billed charges. Upon implementation of TRICARE's IRF PPS, inpatient services provided in rehabilitation distinct part units would be subject to the TRICARE IRF PPS methodology in paragraph (a)(10) of this section.

(ii) The percentage amount stated in paragraph (a)(3)(i) of this section is subject to possible upward adjustment based on a inpatient GTMCPA for TRICARE network hospitals deemed essential for military readiness and

support during contingency operations under paragraph (a)(8) of this section.

(4) The allowable cost for authorized care in all hospitals not subject to the TRICARE DRG-based payment system, the TRICARE mental health per-diem system, the TRICARE reasonable cost method for CAHs, the TRICARE reimbursement rules for SCHs, the TRICARE LTCH–PPS, or the TRICARE IRF PPS shall be determined on the basis of billed charges or set rates.

(i) The actual charge for such service made to the general public; or

(ii) The allowed charge applicable to the policyholders or subscribers of the CHAMPUS fiscal intermediary for comparable services under comparable circumstances, when extended to CHAMPUS beneficiaries by consent or agreement; or

(iii) The allowed charge applicable to the citizens of the community or state as established by local or state regulatory authority, excluding title XIX of the Social Security Act or other welfare program, when extended to CHAMPUS beneficiaries by consent or agreement.

(5) *CHAMPUS discount rates.* The CHAMPUS-determined allowable cost for authorized care in any hospital may be based on discount rates established under paragraph (l) of this section.

(6) *Hospital outpatient services.* This paragraph (a)(6) identifies and clarifies payment methods for certain outpatient services, including emergency services, provided by hospitals.

(i) *Outpatient Services Not Subject to Hospital Outpatient Prospective Payment System (OPPS).* The following are payment methods for outpatient services that are either provided in an OPPS exempt hospital or paid outside the OPPS payment methodology under existing fee schedules or other prospectively determined rates in a hospital subject to OPPS reimbursement.

(A) *Laboratory services.* TRICARE payments for hospital outpatient laboratory services including clinical laboratory services are based on the allowable charge method under paragraph (j)(1) of the section. In the case of laboratory services for which the CMAC rates are established under that paragraph, a payment rate for the technical component of the laboratory services is provided. Hospital charges for an outpatient laboratory service are reimbursed using the CMAC technical component rate.

(B) *Rehabilitation therapy services.* Rehabilitation therapy services provided on an outpatient basis by hospitals are paid on the same basis as rehabilitation therapy services covered by the allowable charge method under paragraph (j)(1) of this section.

(C) *Venipuncture.* Routine venipuncture services provided on an outpatient basis by hospitals are paid on the same basis as such services covered by the allowable charge method under paragraph (j)(1) of this section. Routine venipuncture services provided on an outpatient basis by institutional providers other than hospitals are also paid on this basis.

(D) *Radiology services.* TRICARE payments for hospital outpatient radiology services are based on the allowable charge method under paragraph (j)(1) of the section. In the case of radiology services for which the CMAC rates are established under that paragraph, a payment rate for the technical component of the radiology services is provided. Hospital charges for an outpatient radiology service are reimbursed using the CMAC technical component rate.

(E) *Diagnostic services.* TRICARE payments for hospital outpatient diagnostic services are based on the allowable charge method under paragraph (j)(1) of the section. In the case of diagnostic services for which the CMAC rates are established under that paragraph, a payment rate for the technical component of the diagnostic services is provided. Hospital charges for an outpatient diagnostic service are reimbursed using the CMAC technical component rate.

(F) *Ambulance services.* Ambulance services provided on an outpatient basis by hospitals are paid on the same basis as ambulance services covered by the allowable charge method under paragraph (j)(1) of this section.

(G) *Durable medical equipment (DME) and supplies.* Durable medical equipment and supplies provided on an outpatient basis by hospitals are paid on the same basis as durable medical equipment and supplies covered by the

allowable charge method under paragraph (j)(1) of this section.

(H) *Oxygen and related supplies.* Oxygen and related supplies provided on an outpatient basis by hospitals are paid on the same basis as oxygen and related supplies covered by the allowable charge method under paragraph (j)(1) of this section.

(I) *Drugs administered other than by oral method.* Drugs administered other than by oral method provided on an outpatient basis by hospitals are paid on the same basis as drugs administered other than by oral method covered by the allowable charge method under paragraph (j)(1) of this section.

(J) *Professional provider services.* TRICARE payments for hospital outpatient professional provider services rendered in an emergency room, clinic, or hospital outpatient department, etc., are based on the allowable charge method under paragraph (j)(1) of the section. In the case of professional services for which the CMAC rates are established under that paragraph, a payment rate for the professional component of the services is provided. Hospital charges for an outpatient professional service are reimbursed using the CMAC professional component rate. If the professional outpatient hospital services are billed by a professional provider group, not by the hospital, no payment shall be made to the hospital for these services.

(K) *Facility charges.* TRICARE payments for hospital outpatient facility charges that would include the overhead costs of providing the outpatient service would be paid as billed. For the definition of facility charge, see §199.2(b).

(L) *Ambulatory surgery services.* Hospital outpatient ambulatory surgery services shall be paid in accordance with §199.14(d).

(ii) *Outpatient services subject to OPPS*—(A) *General.* Outpatient services provided in hospitals subject to Medicare OPPS as specified in 42 CFR 413.65 and 42 CFR 419.20 will be paid in accordance with the provisions outlined in sections 1833t of the Social Security Act and its implementing Medicare regulation (42 CFR part 419) subject to exceptions as authorized by this paragraph (a)(6)(ii).

(B) Under the above governing provisions, TRICARE will recognize to the extent practicable, in accordance with 10 U.S.C. 1089(j)(2), Medicare's OPPS reimbursement methodology to include specific coding requirements, ambulatory payment classifications (APCs), nationally established APC amounts and associated adjustments (*e.g.*, discounting across geographical regions and outlier calculations).

(C) While TRICARE intends to remain as true as possible to Medicare's basic OPPS methodology, there will be some deviations required to accommodate TRICARE's unique benefit structure and beneficiary population as authorized under the provisions of 10 U.S.C. 1079(j)(2).

(D) TRICARE is also authorized to deviate from Medicare's basic OPPS methodology to establish special reimbursement methods, amounts, and procedures to encourage use of high-value products and discourage use of low-value products with respect to pharmaceutical agents provided as part of medical services from authorized providers. Therefore, drugs administered other than oral method provided on an outpatient basis by hospitals are paid on the same basis as drugs administered other than oral method covered by the allowable charge method under paragraph (j)(1) of this section.

(E) *Temporary transitional payment adjustments (TTPAs).* Temporary transitional payment adjustments will be in place for all hospitals, both network and non-network, in order to buffer the initial decline in payments upon implementation of TRICARE's OPPS.

(*1*) *For network hospitals.* The temporary transitional payment adjustments will cover a four-year period. The four-year transition will set higher payment percentages for the ten Ambulatory Payment Classification (APC) codes 604–609 and 613–616, with reductions in each of the transition years. For non-network hospitals, the adjustments will cover a three year period, with reductions in each of the transition years. For network hospitals, under the TTPAs, the APC payment level for the five clinic visit APCs would be set at 175 percent of the Medicare APC level, while the five ER visit APCs would be increased by 200 percent

in the first year of OPPS implementation. In the second year, the APC payment levels would be set at 150 percent of the Medicare APC level for clinic visits and 175 percent for ER APCs. In the third year, the APC visit amounts would be set at 130 percent of the Medicare APC level for clinic visits and 150 percent for ER APCs. In the fourth year, the APC visit amounts would be set at 115 percent of the Medicare APC level for clinic visits and 130 percent for ER APCs. In the fifth year, the TRICARE and Medicare payment levels for the 10 APC visit codes would be identical.

(*2*) *For non-network hospitals.* Under the TTPAs, the APC payment level for the five clinic and ER visit APCs would be set at 140 percent of the Medicare APC level in the first year of OPPS implementation. In the second year, the APC payment levels would be set at 125 percent of the Medicare APC level for clinic and ER visits. In the third year, the APC visit amounts would be set at 110 percent of the Medicare APC level for clinic and ER visits. In the fourth year, the TRICARE and Medicare payment levels for the 10 APC visit codes would be identical.

(*3*) An additional temporary military contingency payment adjustment (TMCPA) will also be available at the discretion of the Director, Defense Health Agency (DHA), or a designee, at any time after implementation to adopt, modify and/or extend temporary adjustments to OPPS payments for TRICARE network hospitals deemed essential for military readiness and deployment in time of contingency operations. Any TMCPAs to OPPS payments shall be made only on the basis of a determination that it is impracticable to support military readiness or contingency operations by making OPPS payments in accordance with the same reimbursement rules implemented by Medicare. The criteria for adopting, modifying, and/or extending deviations and/or adjustments to OPPS payments shall be issued through TRICARE policies, instructions, procedures and guidelines as deemed appropriate by the Director, DHA, or a designee. TMCPAs may also be extended to non-network hospitals on a case-by-case basis for specific procedures where it is determined that the procedures cannot be obtained timely enough from a network hospital. For such case-by-case extensions, ''Temporary'' might be less than three years at the discretion of the DHA Director, or designee.

(iii) *Outpatient Services Subject to CAH Reasonable Cost Method.* For services on or after December 1, 2009, outpatient services provided by a CAH, shall be reimbursed at 101 percent of reasonable cost. This does not include any costs of physician services or other professional services provided to CAH outpatients.

(iv) *CAH Ambulance Services.* Effective for services provided on or after December 1, 2009, payment for ambulance services furnished by a CAH or an entity that is owned and operated by a CAH is the reasonable costs of the CAH or the entity in furnishing those services, but only if the CAH or the entity is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH or the entity as specified under 42 CFR part 413.70(b)(5)(ii).

(7) *Reimbursement for inpatient services provided by an SCH.* (i) In accordance with 10 U.S.C. 1079(j)(2), TRICARE payment methods for institutional care shall be determined, to the extent practicable, in accordance with the same reimbursement rules as those that apply to payments to providers of services of the same type under Medicare. TRICARE's SCH reimbursements approximate Medicare's for SCHs. Inpatient services provided by an SCH, other than services provided in psychiatric and rehabilitation distinct part units, shall be reimbursed through a two-step process.

(ii) The first step referred to in paragraph (a)(7)(i) of this section will be to calculate the TRICARE allowable cost by multiplying the applicable TRICARE percentage by the billed charge amount on each institutional inpatient claim. The applicable TRICARE percentage is the greater of: the SCH's most recently available cost-to-charge ratio (CCR) from the Centers for Medicare and Medicaid Services' (CMS') inpatient Provider Specific File (after the ratio has been converted to a percentage), or the TRICARE allowed-to-billed ratio, defined as the ratio of

the TRICARE allowed amounts (including discounts) to the amount of billed charges for TRICARE inpatient admissions at the SCH in FY 2012 (after it has been converted to a percentage). The TRICARE allowed-to-billed ratio in FY 2012 shall be reduced as follows (after the ratio has been converted to a percentage):

(A) In the first year of implementation, 10 percentage points for network SCHs and 15 percentage points for non-network SCHs.

(B) In the second year of implementation, 20 percentage points for network SCHs and 30 percentage points for non-network SCHs.

(C) In the third year of implementation, 30 percentage points for network SCHs and 45 percentage points for non-network SCHs.

(D) In the fourth year of implementation, 40 percentage points for network SCHs and 60 percentage points for non-network SCHs.

(E) In the fifth year of implementation, 50 percentage points for network SCHs and 75 percentage points for non-network SCHs.

(F) In the sixth year of implementation, 60 percentage points for network SCHs and 90 percentage points for non-network SCHs.

(G) In the seventh year of implementation, 70 percentage points for network SCHs and 100 percentage points for non-network SCHs.

(H) In the eighth year of implementation, 80 percentage points for network SCHs and 100 percentage points for non-network SCHs.

(I) In the ninth year of implementation, 90 percentage points for network SCHs and 100 percentage points for non-network SCHs.

(J) In the tenth year of implementation, 100 percentage points for network SCHs and 100 percentage points for non-network SCHs.

(iii) The second step referred to in paragraph (a)(7)(i) of this section is a year-end adjustment. The year-end adjustment will compare the aggregate allowable costs over a 12-month period under paragraph (a)(7)(ii) of this section to the aggregate amount that would have been allowed for the same care using the TRICARE DRG-method (under paragraph (a)(1) of this section). In the event that the DRG method amount is the greater, the year-end adjustment will be the amount by which it exceeds the aggregate allowable costs. In addition, the year-end adjustment also may incorporate a possible upward adjustment for inpatient services based on a GTMCPA for TRICARE network hospitals under paragraph (a)(8) of this section.

(iv) At the end of an SCH's transition period, when the SCH reaches its Medicare CCR, a special allowable cost shall be applicable for discharges that group to inpatient nursery and labor/delivery DRGs. For these discharges, instead of using the percentage of the SCH's Medicare cost-to-charge ratio (as described in paragraph (a)(7)(ii) of this section), the percentage will be 130 percent of the Medicare CCR.

(v) The SCH reimbursement provisions of paragraphs (a)(7)(i) through (iv) of this section do not apply to any costs of physician services or other professional services provided to SCH inpatients (which are subject to individual provider payment provisions of this section), inpatient services provided in psychiatric distinct part units (which are subject to the CHAMPUS mental health per-diem payment system), or inpatient services provided in rehabilitation distinct part units (which are reimbursed on the basis of billed charges or set rates).

(vi) The SCH payment system under this paragraph (a)(7) applies to hospitals classified by CMS as Essential Access Community Hospitals (EACHs).

(vii) The SCH payment system under this paragraph (a)(7) does not apply to hospitals in States that are paid by Medicare and TRICARE under a cost containment waiver.

(8) *General temporary military contingency payment adjustment for SCHs and CAHs.* (i) Payments under paragraph (a) of this section for inpatient services provided by SCHs and CAHs may be supplemented by a GTMCPA. This is a year-end discretionary, temporary adjustment that the TMA Director may approve based on all the following criteria:

(A) The hospital serves a disproportionate share of ADSMs and ADDs;

(B) The hospital is a TRICARE network hospital;

(C) The hospital's actual costs for inpatient services exceed TRICARE payments or other extraordinary economic circumstance exists; and,

(D) Without the GTMCPA, DoD's ability to meet military contingency mission requirements will be significantly compromised.

(ii) Policy and procedural instructions implementing the GTMCPA will be issued as deemed appropriate by the Director, TMA, or a designee. As with other discretionary authority under this Part, a decision to allow or deny a GTMCPA to a hospital is not subject to the appeal and hearing procedures of §199.10.

(9) *Reimbursement for inpatient services provided by a Long Term Care Hospital (LTCH).* (i) In accordance with 10 U.S.C. 1079(i)(2), TRICARE payment methods for institutional care shall be determined, to the extent practicable, in accordance with the same reimbursement rules as those that apply to payments to providers of services of the same type under Medicare. The TRICARE–LTC–DRG reimbursement methodology shall be in accordance with Medicare's Medicare Severity Long Term Care Diagnosis Related Groups (MS–LTC–DRGs) as found in regulation at 42 CFR part 412, subpart O. Inpatient services provided in hospitals subject to the Medicare LTCH Prospective Payment System (PPS) and classified as LTCHs and also as specified in 42 CFR parts 412 and 413 will be paid in accordance with the provisions outlined in sections 1886(d)(1)(B)(IV) and 1886(m)(6) of the Social Security Act and its implementing Medicare regulation (42 CFR parts 412, 413, and 170) to the extent practicable. Under the above governing provisions, TRICARE will recognize, to the extent practicable, in accordance with 10 U.S.C. 1079(i)(2), Medicare's LTCH PPS methodology to include the relative weights, inpatient operating and capital costs of furnishing covered services (including routine and ancillary services), interrupted stay policy, short-stay and high cost outlier payments, site-neutral payments, wage adjustments for variations in labor-related costs across geographical regions, cost-of-living adjustments, payment adjustments associated with the quality reporting program, method of payment for preadmission services, and updates to the system. TRICARE will not be adopting Medicare's 25 percent threshold payment adjustment.

NOTE TO PARAGRAPH (A)(9)(I): LTCH admissions that are in response to the COVID–19 declared PHE and occur during the COVID–19 PHE period will be reimbursed the LTCH PPS standard Federal rate.

(ii) Implementation of the TRICARE LTCH PPS will include a gradual transition to full implementation of the Medicare LTCH PPS rates as follows:

(A) For the first 12 months following implementation, the TRICARE LTCH PPS allowable cost will be 135 percent of Medicare LTCH PPS amounts.

(B) For the second 12 months of implementation, TRICARE LTCH PPS allowable cost will be 115 percent of the Medicare LTCH PPS amounts.

(C) For the third 12 months of implementation, and subsequent years, TRICARE LTCH PPS allowable cost will be 100 percent of the Medicare LTCH PPS amounts.

(iii) *Exemption.* The TRICARE LTCH PPS methodology under this paragraph does not apply to hospitals in States that are reimbursed by Medicare and TRICARE under a waiver that exempts them from Medicare's inpatient prospective payment system or the TRICARE DRG-based payment system, to Children's Hospitals, or to Neoplastic Disease Care Hospitals, respectively.

(10) *Reimbursement for inpatient services provided by Inpatient Rehabilitation Facilities (IRF).* (i) In accordance with 10 U.S.C. 1079(i)(2), TRICARE payment methods for institutional care shall be determined to the extent practicable, in accordance with the same reimbursement rules as those that apply to payments to providers of services of the same type under Medicare. The TRICARE IRF PPS reimbursement methodology shall be in accordance with Medicare's IRF PPS as found in 42 CFR part 412. Inpatient services provided in IRFs subject to the Medicare IRF prospective payment system (PPS) and classified as IRFs and also as specified in 42 CFR 412.604 will be paid in accordance with the provisions outlined in section 1886(j) of the Social Security Act and its implementing Medicare regulation found at 42 CFR part 412, subpart P to the extent practicable.

Under the above governing provisions, TRICARE will recognize, to the extent practicable, in accordance with 10 U.S.C. 1079(i)(2), Medicare's IRF PPS methodology to include the relative weights, payment rates covering all operating and capitals costs of furnishing rehabilitative services adjusted for wage variations in labor-related costs across geographical regions, adjustments for the 60 percent compliance threshold, teaching adjustment, rural adjustment, high-cost outlier payments, low income payment adjustment, payment adjustments associated with the quality reporting program, and updates to the system.

(ii) Implementation of the TRICARE IRF PPS will include a gradual transition to full implementation of the Medicare IRF PPS rates as follows:

(A) For the first 12 months of implementation, the TRICARE IRF PPS allowable cost will be 135 percent of Medicare IRF PPS amounts.

(B) For the second 12 months of implementation, the TRICARE IRF PPS allowable cost will be 115 percent of the Medicare IRF PPS amounts.

(C) For the third 12 months of implementation, and subsequent years, the TRICARE IRF PPS allowable cost will be 100 percent of the Medicare IRF PPS amounts.

(iii) The IRF PPS allowable cost in paragraph (a)(10)(ii) of this section may be supplemented by an inpatient general temporary military contingency payment adjustment (GTMCPA) for TRICARE authorized IRFs.

(A) This is a year-end discretionary, temporary adjustment that the Director, DHA (or designee) may approve based on the following criteria:

(*1*) The IRF serves a disproportionate share of ADSMs and ADDs;

(*2*) The IRF is a TRICARE network hospital;

(*3*) The IRF's actual costs for inpatient services exceed TRICARE payments or other extraordinary economic circumstance exists; and

(*4*) Without the GTMCPA, DoD's ability to meet military contingency mission requirements will be significantly compromised.

(B) Policy and procedural instructions implementing the GTMCPA will be issued as deemed appropriate by the Director, DHA (or designee). As with other discretionary authority under this part, a decision to allow or deny a GTMCPA to an IRF is not subject to the appeal and hearing procedures of §199.10.

(iv) *Exemption.* The TRICARE IRF PPS methodology under this paragraph does not apply to hospitals in States that are reimbursed by Medicare and TRICARE under a waiver that exempts them from Medicare's inpatient prospective payment system or the TRICARE DRG-based payment system, to Children's hospitals, or to VA hospitals, respectively.

(b) *Skilled nursing facilities (SNFs)*—(1) *Use of Medicare prospective payment system and rates.* TRICARE payments to SNFs are determined using the same methods and rates used under the Medicare prospective payment system for SNFs under 42 CFR part 413, subpart J, except for children under age ten. SNFs receive a per diem payment of a predetermined Federal payment rate appropriate for the case based on patient classification (using the RUG classification system), urban or rural location of the facility, and area wage index.

(2) *Payment in full.* The SNF payment rates represent payment in full (subject to any applicable beneficiary cost shares) for all costs (routine, ancillary, and capital-related) associated with furnishing inpatient SNF services to TRICARE beneficiaries other than costs associated with operating approved educational activities.

(3) *Education costs.* Costs for approved educational activities shall be subject to separate payment under procedures established by the Director, TRICARE Management Activity. Such procedures shall be similar to procedures for payments for direct medical education costs of hospitals under paragraph (a)(1)(iii)(G)(*2*) of this section.

(4) *Resident assessment data.* SNFs are required to submit the same resident assessment data as is required under the Medicare program. (The residential assessment is addressed in the Medicare regulations at 42 CFR 483.20.) SNFs must submit assessments according to an assessment schedule. This schedule must include performance of patient assessments on the 5th, 14th,

and 30th days of SNF care and at each successive 30 day interval of SNF admissions that are longer than 30 days. It must also include such other assessments that are necessary to account for changes in patient care needs. TRICARE pays a default rate for the days of a patient's care for which the SNF has failed to comply with the assessment schedule.

(c) *Reimbursement of Freestanding End Stage Renal Disease (ESRD) facilities.* (1) This paragraph (c)(1) establishes payment methods for dialysis provided by TRICARE authorized freestanding ESRD facilities. TRICARE shall reimburse a single, flat, per-session fee to TRICARE authorized freestanding ESRD facilities rendering hemodialysis or peritoneal dialysis for treatment of ESRD or AKI. The flat, per-session fee will apply to renal dialysis services furnished in the ESRD facility or in a patient's home. All renal dialysis items and services furnished in the ESRD facility or in a patient's home are included in the flat per-session rate, except for those items and services listed in paragraph (c)(1)(ii) of this section.

(i) Services included in the flat per-session rate must be furnished by an authorized TRICARE ESRD institutional provider:

(A) Institutional charges (e.g., charges for facility use, use or treatment rooms, and general nursing services);

(B) Routine laboratory services related to the dialysis session;

(C) Pharmaceuticals and supplies related to the dialysis;

(D) Home dialysis support services identified at 42 CFR 494.100;

(E) Purchase and delivery of all necessary home dialysis supplies; and

(F) Dialysis training for days 1–120.

(ii) Services which may be billed separately:

(A) Evaluation and management services provided by authorized individual professional providers. These services will continue to be reimbursed using existing reimbursement systems (e.g., CMAC).

(B) Drugs, supplies, and devices listed by Medicare as eligible for Transitional Drug Add-on Payment Adjustment and Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies under the Medicare ESRD PPS. These services will continue to be reimbursed using existing reimbursement systems (e.g., CMAC).

(C) Professional services, supplies, and pharmaceuticals unrelated to dialysis care (e.g., if a flu shot is administered at the same time as dialysis treatment). These services will continue to be reimbursed using existing reimbursement systems (e.g., CMAC).

(iii) Establishment of the flat rate:

(A) *Per session rate for treatment days 1–120.* The flat, per-session rate shall be equal to the current Medicare base rate, multiplied by the current Medicare adjustment factor applied to individuals aged 44–69 (7% for CY 22), and further multiplied by the current Medicare adjustment factor for the date of onset (32.7% for CY 2022). The Medicare factors utilized in subsequent years will be based on modifications made under 42 CFR part 413, subpart H, Medicare ESRD PPS.

(B) *Per session rate for treatment day 121 and beyond.* The flat, per-session rate shall be equal to the Medicare base rate, multiplied by the Medicare adjustment factor applied to individuals aged 44–69. The Medicare factors utilized in subsequent years will be based on modifications made under 42 CFR part 413, subpart H, Medicare ESRD PPS.

(C) *Wage adjustment.* The per-session rates in paragraphs (c)(1)(iii)(A) and (B) of this section shall be wage adjusted using the wage adjustment factors and labor-related shares published in the most recent Medicare ESRD Final Rule at the time the annual per-session rates are posted.

(D) *Annual updates.* The per session rates will be updated within 90 days of publication of new Medicare base rates, and published to the TRICARE website at *www.health.mil.*

(E) *Dialysis training.* To account for training services and supplies, dialysis training sessions will receive a home dialysis training add-on payment for day treatment days 121 and after. The training add-on payment will not apply to treatment days 1–120, as the onset adjustment factor of 32.7% is applied to the per-session rate for treatment days 1–120.

(2) The reimbursement methods established in paragraph (c)(1) of this section applies to freestanding ESRD facilities meeting the requirements established for TRICARE authorized freestanding ESRD facilities in §199.6. For purposes of cost-sharing and copayments, treatment provided by freestanding ESRD facilities are considered outpatient specialty visits. The applicable copayments and cost-shares described in §§199.4 and 199.17(k)(2)(iii) shall apply. Hospital-based ESRD facilities are not subject to the provisions of this paragraph, and will continue to be reimbursed utilizing other applicable reimbursement systems (e.g., the Outpatient Prospective Payment System).

(d) *Payment of institutional facility costs for ambulatory surgery*—(1) *In general.* CHAMPUS pays institutional facility costs for ambulatory surgery on the basis of prospectively determined amounts, as provided in this paragraph, with the exception of ambulatory surgery procedures performed in hospital outpatient departments or in CAHs, which are to be reimbursed in accordance with the provisions of paragraph (a)(6)(ii) or (a)(6)(iii) respectively, of this section. This payment method is similar to that used by the Medicare program for ambulatory surgery. This paragraph applies to payment for freestanding ambulatory surgical centers. It does not apply to professional services. A list of ambulatory surgery procedures subject to the payment method set forth in the paragraph shall be published periodically by the Director, TRICARE Management Activity (TMA). Payment to freestanding ambulatory surgery centers is limited to these procedures.

(2) *Payment in full.* The payment provided for under this paragraph is the payment in full for services covered by this paragraph. Facilities may not charge beneficiaries for amounts, if any, in excess of the payment amounts determined pursuant to this paragraph.

(3) *Calculation of standard payment rates.* Standard payment rates are calculated for groups of procedures under the following steps:

(i) *Step 1: Calculate a median standardized cost for each procedure.* For each ambulatory surgery procedure, a median standardized cost will be calculated on the basis of all ambulatory surgery charges nationally under CHAMPUS during a recent one-year base period. The steps in this calculation include standardizing for local labor costs by reference to the same wage index and labor/non-labor-related cost ratio as applies to the facility under Medicare, applying a cost-to-charge ratio, calculating a median cost for each procedure, and updating to the year for which the payment rates will be in effect by the Consumer Price Index-Urban. In applying a cost-to-charge ratio, the Medicare cost-to-charge ratio for freestanding ambulatory surgery centers (FASCs) will be used for all charges from FASCs, and the Medicare cost-to-charge ratio for hospital outpatient settings will be used for all charges from hospitals.

(ii) *Step 2: Grouping procedures.* Procedures will then be placed into one of ten groups by their median per procedure cost, starting with $0 to $299 for group 1 and ending with $1000 to $1299 for group 9 and $1300 and above for group 10, with groups 2 through 8 set on the basis of $100 fixed intervals.

(iii) *Step 3: Adjustments to groups.* The Director, OCHAMPUS may make adjustments to the groupings resulting from step 2 to account for any ambulatory surgery procedures for which there were insufficient data to allow a grouping or to correct for any anomalies resulting from data or statistical factors or other special factors that fairness requires be specially recognized. In making any such adjustments, the Director may take into consideration the placing of particular procedures in the ambulatory surgery groups under Medicare.

(iv) *Step 4*: standard payment amount per group. The standard payment amount per group will be the volume weighted median per procedure cost for the procedures in that group. For cases in which the standard payment amount per group exceeds the CHAMPUS-determined inpatient allowable amount, the Director, TSO or his designee, may make adjustments.

(v) *Step 5: Actual payments.* Actual payment for a procedure will be the standard payment amount for the

group which covers that procedure, adjusted for local labor costs by reference to the same labor/non-labor- related cost ratio and hospital wage index as used for ambulatory surgery centers by Medicare.

(4) *Multiple procedures.* In cases in which authorized multiple procedures are performed during the same operative session, payment shall be based on 100 percent of the payment amount for the procedure with the highest ambulatory surgery payment amount, plus, for each other procedure performed during the session, 50 percent of its payment amount.

(5) *Annual updates.* The standard payment amounts will be updated annually by the same update factor as is used in the Medicare annual updates for ambulatory surgery center payments.

(6) *Recalculation of rates.* The Director, OCHAMPUS may periodically recalculate standard payment rates for ambulatory surgery using the steps set forth in paragraph (d)(3) of this section.

(e) *Reimbursement of Birthing Centers.* (1) Reimbursement for maternity care and childbirth services furnished by an authorized birthing center shall be limited to the lower of the CHAMPUS established all-inclusive rate or the center's most-favored all-inclusive rate.

(2) The all-inclusive rate shall include the following to the extent that they are usually associated with a normal pregnancy and childbirth: Laboratory studies, prenatal management, labor management, delivery, postpartum management, newborn care, birth assistant, certified nurse-midwife professional services, physician professional services, and the use of the facility.

(3) The CHAMPUS established all-inclusive rate is equal to the sum of the CHAMPUS area prevailing professional charge for total obstetrical care for a normal pregnancy and delivery and the sum of the average CHAMPUS allowable institutional charges for supplies, laboratory, and delivery room for a hospital inpatient normal delivery. The CHAMPUS established all-inclusive rate areas will coincide with those established for prevailing professional charges and will be updated concurrently with the CHAMPUS area prevailing professional charge database.

(4) Extraordinary maternity care services, when otherwise authorized, may be reimbursed at the lesser of the billed charge or the CHAMPUS allowable charge.

(5) Reimbursement for an incomplete course of care will be limited to claims for professional services and tests where the beneficiary has been screened but rejected for admission into the birthing center program, or where the woman has been admitted but is discharged from the birthing center program prior to delivery, adjudicated as individual professional services and items.

(6) The beneficiary's share of the total reimbursement to a birthing center is limited to the cost-share amount plus the amount billed for non-covered services and supplies.

(f) *Reimbursement of Residential Treatment Centers.* The CHAMPUS rate is the per diem rate that CHAMPUS will authorize for all mental health services rendered to a patient and the patient's family as part of the total treatment plan submitted by a CHAMPUS-approved RTC, and approved by the Director, OCHAMPUS, or designee.

(1) The all-inclusive per diem rate for RTCs operating or participating in CHAMPUS during the base period of July 1, 1987, through June 30, 1988, will be the lowest of the following conditions:

(i) The CHAMPUS rate paid to the RTC for all-inclusive services as of June 30, 1988, adjusted by the Consumer Price Index—Urban (CPI-U) for medical care as determined applicable by the Director, OCHAMPUS, or designee; or

(ii) The per diem rate accepted by the RTC from any other agency or organization (public or private) that is high enough to cover one-third of the total patient days during the 12-month period ending June 30, 1988, adjusted by the CPI-U; or

NOTE: The per diem rate accepted by the RTC from any other agency or organization includes the rates accepted from entities such as Government contractors in CHAMPUS demonstration projects.

(iii) An OCHAMPUS determined capped per diem amount not to exceed the 80th percentile of all established

CHAMPUS RTC rates nationally, weighted by total CHAMPUS days provided at each rate during the base period discussed in paragraph (f)(1) of this section.

(2) The all-inclusive per diem rates for RTCs which began operation after June 30, 1988, or began operation before July 1, 1988, but had less than 6 months of operation by June 30, 1988, will be calculated based on the lower of the per diem rate accepted by the RTC that is high enough to cover one-third of the total patient days during its first 6 to 12 consecutive months of operation, or the CHAMPUS determined capped amount. Rates for RTCs beginning operation prior to July 1, 1988, will be adjusted by an appropriate CPI-U inflation factor for the period ending June 30, 1988. A period of less than 12 months will be used only when the RTC has been in operation for less than 12 months. Once a full 12 months is available, the rate will be recalculated.

(3) For care on or after April 6, 1995, the per diem amount may not exceed a cap of the 70th percentile of all established Federal fiscal year 1994 RTC rates nationally, weighted by total CHAMPUS days provided at each rate during the first half of Federal fiscal year 1994, and updated to FY95. For Federal fiscal years 1996 and 1997, the cap shall remain unchanged. For Federal fiscal years after fiscal year 1997, the cap shall be adjusted by the Medicare update factor for hospitals and units exempt from the Medicare prospective payment system.

(4) All educational costs, whether they include routine education or special education costs, are excluded from reimbursement except when appropriate education is not available from, or not payable by, a cognizant public entity.

(i) The RTC shall exclude educational costs from its daily costs.

(ii) The RTC's accounting system must be adequate to assure CHAMPUS is not billed for educational costs.

(iii) The RTC may request payment of educational costs on an individual case basis from the Director, OCHAMPUS, or designee, when appropriate education is not available from, or not payable by, a cognizant public entity. To qualify for reimbursement of educational costs in individual cases, the RTC shall comply with the application procedures established by the Director, OCHAMPUS, or designee, including, but not limited to, the following:

(A) As part of its admission procedures, the RTC must counsel and assist the beneficiary and the beneficiary's family in the necessary procedures for assuring their rights to a free and appropriate public education.

(B) The RTC must document any reasons why an individual beneficiary cannot attend public educational facilities and, in such a case, why alternative educational arrangements have not been provided by the cognizant public entity.

(C) If reimbursement of educational costs is approved for an individual beneficiary by the Director, OCHAMPUS, or designee, such educational costs shall be shown separately from the RTC's daily costs on the CHAMPUS claim. The amount paid shall not exceed the RTC's most-favorable rate to any other patient, agency, or organization for special or general educational services whichever is appropriate.

(D) If the RTC fails to request CHAMPUS approval of the educational costs on an individual case, the RTC agrees not to bill the beneficiary or the beneficiary's family for any amounts disallowed by CHAMPUS. Requests for payment of educational costs must be referred to the Director, OCHAMPUS, or designee for review and a determination of the applicability of CHAMPUS benefits.

(5) Subject to the applicable RTC cap, adjustments to the RTC rates may be made annually.

(i) For Federal fiscal years through 1995, the adjustment shall be based on the Consumer Price Index-Urban (CPI-U) for medical care as determined applicable by the Director, OCHAMPUS.

(ii) For purposes of rates for Federal fiscal years 1996 and 1997:

(A) For any RTC whose 1995 rate was at or above the thirtieth percentile of all established Federal fiscal year 1995 RTC rates normally, weighted by total CHAMPUS days provided at each rate during the first half of Federal fiscal year 1994, that rate shall remain in effect, with no additional update,

throughout fiscal years 1996 and 1997; and

(B) For any RTC whose 1995 rate was below the 30th percentile level determined under paragraph (f)(5)(ii)(A) of this section, the rate shall be adjusted by the lesser of: the CPI-U for medical care, or the amount that brings the rate up to that 30th percentile level.

(iii) For subsequent Federal fiscal years after fiscal year 1997, RTC rates shall be updated by the Medicare update factor for hospitals and units exempt from the Medicare prospective payment system.

(6) For care provided on or after July 1, 1995, CHAMPUS will not pay for days in which the patient is absent on leave from the RTC. The RTC must identify these days when claiming reimbursement.

(g) *Reimbursement of hospice programs.* Hospice care will be reimbursed at one of four predetermined national CHAMPUS rates based on the type and intensity of services furnished to the beneficiary. A single rate is applicable for each day of care except for continuous home care where payment is based on the number of hours of care furnished during a 24-hour period. These rates will be adjusted for regional differences in wages using wage indices for hospice care.

(1) *National hospice rates.* CHAMPUS will use the national hospice rates for reimbursement of each of the following levels of care provided by or under arrangement with a CHAMPUS approved hospice program:

(i) *Routine home care.* The hospice will be paid the routine home care rate for each day the patient is at home, under the care of the hospice, and not receiving continuous home care. This rate is paid without regard to the volume or intensity of routine home care services provided on any given day.

(ii) *Continuous home care.* The hospice will be paid the continuous home care rate when continuous home care is provided. The continuous home care rate is divided by 24 hours in order to arrive at an hourly rate.

(A) A minimum of 8 hours of care must be provided within a 24-hour day starting and ending at midnight.

(B) More than half of the total actual hours being billed for each 24-hour period must be provided by either a registered or licensed practical nurse.

(C) Homemaker and home health aide services may be provided to supplement the nursing care to enable the beneficiary to remain at home.

(D) For every hour or part of an hour of continuous care furnished, the hourly rate will be reimbursed to the hospice up to 24 hours a day.

(iii) *Inpatient respite care.* The hospice will be paid at the inpatient respite care rate for each day on which the beneficiary is in an approved inpatient facility and is receiving respite care.

(A) Payment for respite care may be made for a maximum of 5 days at a time, including the date of admission but not counting the date of discharge. The necessity and frequency of respite care will be determined by the hospice interdisciplinary group with input from the patient's attending physician and the hospice's medical director.

(B) Payment for the sixth and any subsequent days is to be made at the routine home care rate.

(iv) *General inpatient care.* Payment at the inpatient rate will be made when general inpatient care is provided for pain control or acute or chronic symptom management which cannot be managed in other settings. None of the other fixed payment rates (i.e., routine home care) will be applicable for a day on which the patient receives general inpatient care except on the date of discharge.

(v) *Date of discharge.* For the day of discharge from an inpatient unit, the appropriate home care rate is to be paid unless the patient dies as an inpatient. When the patient is discharged deceased, the inpatient rate (general or respite) is to be paid for the discharge date.

(2) *Use of Medicare rates.* CHAMPUS will use the most current Medicare rates to reimburse hospice programs for services provided to CHAMPUS beneficiaries. It is CHAMPUS' intent to adopt changes in the Medicare reimbursement methodology as they occur; e.g., Medicare's adoption of an updated, more accurate wage index.

(3) *Physician reimbursement.* Payment is dependent on the physician's relationship with both the beneficiary and the hospice program.

(i) *Physicians employed by, or contracted with, the hospice.* (A) Administrative and supervisory activities (i.e., establishment, review and updating of plans of care, supervising care and services, and establishing governing policies) are included in the adjusted national payment rate.

(B) Direct patient care services are paid in addition to the adjusted national payment rate.

(*1*) Physician services will be reimbursed an amount equivalent to 100 percent of the CHAMPUS' allowable charge; i.e., there will be no cost-sharing and/or deductibles for hospice physician services.

(*2*) Physician payments will be counted toward the hospice cap limitation.

(ii) *Independent attending physician.* Patient care services rendered by an independent attending physician (a physician who is not considered employed by or under contract with the hospice) are not part of the hospice benefit.

(A) Attending physician may bill in his/her own right.

(B) Services will be subject to the appropriate allowable charge methodology.

(C) Reimbursement is not counted toward the hospice cap limitation.

(D) Services provided by an independent attending physician must be coordinated with any direct care services provided by hospice physicians.

(E) The hospice must notify the CHAMPUS contractor of the name of the physician whenever the attending physician is not a hospice employee.

(iii) *Voluntary physician services.* No payment will be allowed for physician services furnished voluntarily (both physicians employed by, and under contract with, the hospice and independent attending physicians). Physicians may not discriminate against CHAMPUS beneficiaries; e.g., designate all services rendered to non-CHAMPUS patients as volunteer and at the same time bill for CHAMPUS patients.

(4) *Unrelated medical treatment.* Any covered CHAMPUS services not related to the treatment of the terminal condition for which hospice care was elected will be paid in accordance with standard reimbursement methodologies; i.e., payment for these services will be subject to standard deductible and cost-sharing provisions under the CHAMPUS. A determination must be made whether or not services provided are related to the individual's terminal illness. Many illnesses may occur when an individual is terminally ill which are brought on by the underlying condition of the ill patient. For example, it is not unusual for a terminally ill patient to develop pneumonia or some other illness as a result of his or her weakened condition. Similarly, the setting of bones after fractures occur in a bone cancer patient would be treatment of a related condition. Thus, if the treatment or control of an upper respiratory tract infection is due to the weakened state of the terminal patient, it will be considered a related condition, and as such, will be included in the hospice daily rates.

(5) *Cap amount.* Each CHAMPUS-approved hospice program will be subject to a cap on aggregate CHAMPUS payments from November 1 through October 31 of each year, hereafter known as ''the cap period.''

(i) The cap amount will be adjusted annually by the percent of increase or decrease in the medical expenditure category of the Consumer Price Index for all urban consumers (CPI-U).

(ii) The aggregate cap amount (i.e., the statutory cap amount times the number of CHAMPUS beneficiaries electing hospice care during the cap period) will be compared with total actual CHAMPUS payments made during the same cap period.

(iii) Payments in excess of the cap amount must be refunded by the hospice program. The adjusted cap amount will be obtained from the Health Care Financing Administration (HCFA) prior to the end of each cap period.

(iv) Calculation of the cap amount for a hospice which has not participated in the program for an entire cap year (November 1 through October 31) will be based on a period of at least 12 months but no more than 23 months. For example, the first cap period for a hospice entering the program on October 1, 1994, would run from October 1, 1994 through October 31, 1995. Similarly, the first cap period for hospice providers entering the program after

November 1, 1993 but before November 1, 1994 would end October 31, 1995.

(6) *Inpatient limitation.* During the 12-month period beginning November 1 of each year and ending October 31, the aggregate number of inpatient days, both for general inpatient care and respite care, may not exceed 20 percent of the aggregate total number of days of hospice care provided to all CHAMPUS beneficiaries during the same period.

(i) If the number of days of inpatient care furnished to CHAMPUS beneficiaries exceeds 20 percent of the total days of hospice care to CHAMPUS beneficiaries, the total payment for inpatient care is determined follows:

(A) Calculate the ratio of the maximum number of allowable inpatient days of the actual number of inpatient care days furnished by the hospice to Medicare patients.

(B) Multiply this ratio by the total reimbursement for inpatient care made by the CHAMPUS contractor.

(C) Multiply the number of actual inpatient days in excess of the limitation by the routine home care rate.

(D) Add the amounts calculated in paragraphs (g)(6)(i) (B) and (C) of this section.

(ii) Compare the total payment for inpatient care calculated in paragraph (g)(6)(i)(D) of this section to actual payments made to the hospice for inpatient care during the cap period.

(iii) Payments in excess of the inpatient limitation must be refunded by the hospice program.

(7) *Hospice reporting responsibilities.* The hospice is responsible for reporting the following data within 30 days after the end of the cap period:

(i) Total reimbursement received and receivable for services furnished CHAMPUS beneficiaries during the cap period, including physician's services not of an administrative or general supervisory nature.

(ii) Total reimbursement received and receivable for general inpatient care and inpatient respite care furnished to CHAMPUS beneficiaries during the cap period.

(iii) Total number of inpatient days furnished to CHAMPUS hospice patients (both general inpatient and inpatient respite days) during the cap period.

(iv) Total number of CHAMPUS hospice days (both inpatient and home care) during the cap period.

(v) Total number of beneficiaries electing hospice care. The following rules must be adhered to by the hospice in determining the number of CHAMPUS beneficiaries who have elected hospice care during the period:

(A) The beneficiary must not have been counted previously in either another hospice's cap or another reporting year.

(B) The beneficiary must file an initial election statement during the period beginning September 28 of the previous cap year through September 27 of the current cap year in order to be counted as an electing CHAMPUS beneficiary during the current cap year.

(C) Once a beneficiary has been included in the calculation of a hospice cap amount, he or she may not be included in the cap for that hospice again, even if the number of covered days in a subsequent reporting period exceeds that of the period where the beneficiary was included.

(D) There will be proportional application of the cap amount when a beneficiary elects to receive hospice benefits from two or more different CHAMPUS-certified hospices. A calculation must be made to determine the percentage of the patient's length of stay in each hospice relative to the total length of hospice stay.

(8) *Reconsideration of cap amount and inpatient limit.* A hospice dissatisfied with the contractor's calculation and application of its cap amount and/or inpatient limitation may request and obtain a contractor review if the amount of program reimbursement in controversy—with respect to matters which the hospice has a right to review—is at least $1000. The administrative review by the contractor of the calculation and application of the cap amount and inpatient limitation is the only administrative review available. These calculations are not subject to the appeal procedures set forth in §199.10. The methods and standards for calculation of the hospice payment rates established by CHAMPUS, as well as questions as to the validity of the applicable law, regulations or CHAMPUS decisions, are not subject to

administrative review, including the appeal procedures of § 199.10.

(9) *Beneficiary cost-sharing.* There are no deductibles under the CHAMPUS hospice benefit. CHAMPUS pays the full cost of all covered services for the terminal illness, except for small cost-share amounts which *may be* collected by the individual hospice for outpatient drugs and biologicals and inpatient respite care.

(i) The patient is responsible for 5 percent of the cost of outpatient drugs or $5 toward each prescription, whichever is less. Additionally, the cost of prescription drugs (drugs or biologicals) may not exceed that which a prudent buyer would pay in similar circumstances; that is, a buyer who refuses to pay more than the going price for an item or service and also seeks to economize by minimizing costs.

(ii) For inpatient respite care, the cost-share for each respite care day is equal to 5 percent of the amount CHAMPUS has estimated to be the cost of respite care, after adjusting the national rate for local wage differences.

(iii) The amount of the individual cost-share liability for respite care during a hospice cost-share period may not exceed the Medicare inpatient hospital deductible applicable for the year in which the hospice cost-share period began. The individual hospice cost-share period begins on the first day an election is in effect for the beneficiary and ends with the close of the first period of 14 consecutive days on each of which an election is not in effect for the beneficiary.

(h) *Reimbursement of Home Health Agencies (HHAs).* HHAs will be reimbursed using the same methods and rates as used under the Medicare HHA prospective payment system under Section 1895 of the Social Security Act (42 U.S.C. 1395fff) and 42 CFR Part 484, Subpart E except as otherwise necessary to recognize distinct characteristics of TRICARE beneficiaries and as described in instructions issued by the Director, TMA. Under this methodology, an HHA will receive a fixed case-mix and wage-adjusted national 60-day episode payment amount as payment in full for all costs associated with furnishing home health services to TRICARE-eligible beneficiaries with the exception of osteoporosis drugs and DME. The full case-mix and wage-adjusted 60-day episode amount will be payment in full subject to the following adjustments and additional payments:

(1) *Split percentage payments.* The initial percentage payment for initial episodes is paid to an HHA at 60 percent of the case-mix and wage adjusted 60-day episode rate. The residual final payment for initial episodes is paid at 40 percent of the case-mix and wage adjusted 60-day episode rate subject to appropriate adjustments. The initial percentage payment for subsequent episodes is paid at 50 percent of the case-mix and wage-adjusted 60-day episode rate. The residual final payment for subsequent episodes is paid at 50 percent of the case-mix and wage-adjusted 60-day episode rate subject to appropriate adjustments.

(2) *Low-utilization payment.* A low utilization payment is applied when a HHA furnishes four or fewer visits to a beneficiary during the 60-day episode. The visits are paid at the national per-visit amount by discipline updated annually by the applicable market basket for each visit type.

(3) *Partial episode payment (PEP).* A PEP adjustment is used for payment of an episode of less than 60 days resulting from a beneficiary's elected transfer to another HHA prior to the end of the 60-day episode or discharge and readmission of a beneficiary to the same HHA before the end of the 60-day episode. The PEP payment is calculated by multiplying the proportion of the 60-day episode during which the beneficiary remained under the care of the original HHA by the beneficiary's assigned 60-day episode payment.

(4) *Significant change in condition (SCIC).* The full-episode payment amount is adjusted if a beneficiary experiences a significant change in condition during the 60-day episode that was not envisioned in the initial treatment plan. The total significant change in condition payment adjustment is a proportional payment adjustment reflecting the time both prior to and after the patient experienced a significant change in condition during the 60-day episode. The initial percentage payment provided at the start of the 60-

day episode will be adjusted at the end of the episode to reflect the first and second parts of the total SCIC adjustment determined at the end of the 60-day episode. The SCIC payment adjustment is calculated in two parts:

(i) The first part of the SCIC payment adjustment reflects the adjustment to the level of payment prior to the significant change in the patient's condition during the 60-day episode.

(ii) The second part of the SCIC payment adjustment reflects the adjustment to the level of payment after the significant change in the patient's condition occurs during the 60-day episode.

(5) *Outlier payment.* Outlier payments are allowed in addition to regular 60-day episode payments for beneficiaries generating excessively high treatment costs. The following methodology is used for calculation of the outlier payment:

(i) TRICARE makes an outlier payment for an episode whose estimated cost exceeds a threshold amount for each case-mix group.

(ii) The outlier threshold for each case-mix group is the episode payment amount for that group, the PEP adjustment amount for the episode or the total significant change in condition adjustment amount for the episode plus a fixed dollar loss amount that is the same for all case-mix groups.

(iii) The outlier payment is a proportion of the amount of estimated cost beyond the threshold.

(iv) TRICARE imputes the cost for each episode by multiplying the national per-visit amount of each discipline by the number of visits in the discipline and computing the total imputed cost for all disciplines.

(v) The fixed dollar loss amount and the loss sharing proportion are chosen so that the estimated total outlier payment is no more than the predetermined percentage of total payment under the home health PPS as set by the Centers for Medicare & Medicaid Services (CMS).

(6) *Services paid outside the HHA prospective payment system.* The following are services that receive a separate payment amount in addition to the prospective payment amount for home health services:

(i) *Durable medical equipment (DME).* Reimbursement of DME is based on the same amounts established under the Medicare Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) fee schedule under 42 CFR part 414, subpart D.

(ii) *Osteoporosis drugs.* Although osteoporosis drugs are subject to home health consolidated billing, they continue to be paid on a cost basis, in addition to episode payments.

(7) *Accelerated payments.* Upon request, an accelerated payment may be made to an HHA that is receiving payment under the home health prospective payment system if the HHA is experiencing financial difficulties because there is a delay by the contractor in making payment to the HHA. The following are criteria for making accelerated payments:

(i) *Approval of payment.* An HHA's request for an accelerated payment must be approved by the contractor and TRICARE Management Activity (TMA).

(ii) *Amount of payment.* The amount of the accelerated payment is computed as a percentage of the net payment for unbilled or unpaid covered services.

(iii) *Recovery of payment.* Recovery of the accelerated payment is made by recoupment as HHA bills are processed or by direct payment by the HHA.

(8) *Assessment data.* Beneficiary assessment data, incorporating the use of the current version of the OASIS items, must be submitted to the contractor for payment under the HHA prospective payment system.

(9) *Administrative review.* An HHA is not entitled to judicial or administrative review with regard to:

(i) Establishment of the payment unit, including the national 60-day prospective episode payment rate, adjustments and outlier payment.

(ii) Establishment of transition period, definition and application of the unit of payment.

(iii) Computation of the initial standard prospective payment amounts.

(iv) Establishment of case-mix and area wage adjustment factors.

(i) *Changes in Federal Law affecting Medicare.* With regard to paragraph (b) and (h) of this section, the Department

of Defense must, within the time frame specified in law and to the extent it is practicable, bring the TRICARE program into compliance with any changes in Federal Law affecting the Medicare program that occur after the effective date of the DoD rule to implement the prospective payment systems for skilled nursing facilities and home health agencies.

(j) Reimbursement of individual health care professionals and other non-institutional, non-professional providers. The CHAMPUS-determined reasonable charge (the amount allowed by CHAMPUS) for the service of an individual health care professional or other non-institutional, non-professional provider (even if employed by or under contract to an institutional provider) shall be determined by one of the following methodologies, that is, whichever is in effect in the specific geographic location at the time covered services and supplies are provided to a CHAMPUS beneficiary.

(1) *Allowable charge method*—(i) *Introduction*—(A) *In general.* The allowable charge method is the preferred and primary method for reimbursement of individual health care professionals and other non-institutional health care providers (covered by 10 U.S.C. 1079(h)(1)). The allowable charge for authorized care shall be the lower of the billed charge or the local CHAMPUS Maximum Allowable Charge (CMAC).

(B) *CHAMPUS Maximum Allowable Charge.* Beginning in calendar year 1992, prevailing charge levels and appropriate charge levels will be calculated on a national level. There will then be calculated a national CHAMPUS Maximum Allowable Charge (CMAC) level for each procedure, which shall be the lesser of the national prevailing charge level or the national appropriate charge level. The national CMAC will then be adjusted for localities in accordance with paragraph (j)(1)(iv) of this section.

(C) *Limits on balance billing by nonparticipating providers.* Nonparticipating providers may not balance bill a beneficiary an amount which exceeds the applicable balance billing limit. The balance billing limit shall be the same percentage as the Medicare limiting charge percentage for nonparticipating physicians. The balance billing limit may be waived by the Director, OCHAMPUS on a case-by-case basis if requested by the CHAMPUS beneficiary (or sponsor) involved. A decision by the Director to waive or not waive the limit in any particular case is not subject to the appeal and hearing procedures of § 199.10.

(D) *Special rule for TRICARE Prime Enrollees.* In the case of a TRICARE Prime enrollee (see section 199.17) who receives authorized care from a nonparticipating provider, the CHAMPUS determined reasonable charge will be the CMAC level as established in paragraph (j)(1)(i)(B) of this section plus any balance billing amount up to the balance billing limit as referred to in paragraph (j)(1)(i)(C) of this section. The authorization for such care shall be pursuant to the procedures established by the Director, OCHAMPUS (also referred to as the TRICARE Support Office).

(E) *Special rule for certain TRICARE Standard Beneficiaries.* In the case of dependent spouse or child, as defined in paragraphs (b)(2)(ii)(A) through (F) and (b)(2)(ii)(H)(1), (2), and (4) of § 199.3, of a Reserve Component member serving on active duty pursuant to a call or order to active duty for a period of more than 30 days in support of a contingency operation under a provision of law referred to in section 101(a)(13)(B) of title 10, United States Code, the Director, TRICARE Management Activity, may authorize non-participating providers the allowable charge to be the CMAC level as established in paragraph (j)(l)(i)(B) of this section plus any balance billing amount up to the balance billing limit as referred to in paragraph (j)(l)(i)(C) of this section.

(ii) *Prevailing charge level.* (A) Beginning in calendar year 1992, the prevailing charge level shall be calculated on a national basis.

(B) The national prevailing charge level referred to in paragraph (j)(1)(ii)(A) of this section is the level that does not exceed the amount equivalent to the 80th percentile of billed charges made for similar services during the base period. The 80th percentile of charges shall be determined on the

basis of statistical data and methodology acceptable to the Director, OCHAMPUS (or a designee).

(C) For purposes of paragraph (j)(1)(ii)(B) of this section, the base period shall be a period of 12 calendar months and shall be adjusted once a year, unless the Director, OCHAMPUS, determines that a different period for adjustment is appropriate and publishes a notice to that effect in the FEDERAL REGISTER.

(iii) *Appropriate charge level.* Beginning in calendar year 1992, the appropriate charge level shall be calculated on a national basis. The appropriate charge level for each procedure is the product of the two-step process set forth in paragraphs (j)(1)(iii) (A) and (B) of this section. This process involves comparing the prior year's CMAC with the fully phased in Medicare fee. For years after the Medicare fee has been fully phased in, the comparison shall be to the current year Medicare fee. For any particular procedure for which comparable Medicare fee and CHAMPUS data are unavailable, but for which alternative data are available that the Director, OCHAMPUS (or designee) determines provide a reasonable approximation of relative value or price, the comparison may be based on such alternative data.

(A) *Step 1: Procedures classified.* All procedures are classified into one of three categories, as follows:

(*1*) *Overpriced procedures.* These are the procedures for which the prior year's national CMAC exceeds the Medicare fee.

(*2*) *Other procedures.* These are procedures subject to the allowable charge method that are not included in either the overpriced procedures group or the underpriced procedures group.

(*3*) *Underpriced procedures.* These are the procedures for which the prior year's national CMAC is less than the Medicare fee.

(B) *Step 2: Calculating appropriate charge levels.* For each year, appropriate charge levels will be calculated by adjusting the prior year's CMAC as follows:

(*1*) For overpriced procedures, the appropriate charge level for each procedure shall be the prior year's CMAC, reduced by the lesser of: the percentage by which it exceeds the Medicare fee or fifteen percent.

(*2*) For other procedures, the appropriate charge level for each procedure shall be the same as the prior year's CMAC.

(*3*) For underpriced procedures, the appropriate charge level for each procedure shall be the prior year's CMAC, increased by the lesser of: the percentage by which it is exceeded by the Medicare fee or the Medicare Economic Index.

(C) *Special rule for cases in which the CHAMPUS appropriate charge was prematurely reduced.* In any case in which a recalculation of the Medicare fee results in a Medicare rate higher than the CHAMPUS appropriate charge for a procedure that had been considered an overpriced procedure, the reduction in the CHAMPUS appropriate charge shall be restored up to the level of the recalculated Medicare rate.

(D) *Special rule for cases in which the national CMAC is less than the Medicare rate.*

NOTE: This paragraph will be implemented when CMAC rates are published.

In any case in which the national CMAC calculated in accordance with paragraphs (j)(1)(i) through (iii) of this section is less than the Medicare rate, the Director, TSO, may determine that the use of the Medicare Economic Index under paragraph (j)(1)(iii)(B) of this section will result in a CMAC rate below the level necessary to assure that beneficiaries will retain adequate access to health care services. Upon making such a determination, the Director, TSO, may increase the national CMAC to a level not greater than the Medicare rate.

(iv) *Calculating CHAMPUS Maximum Allowable Charge levels for localities*—(A) *In general.* The national CHAMPUS Maximum Allowable Charge level for each procedure will be adjusted for localities using the same (or similar) geographical areas and the same geographic adjustment factors as are used for determining allowable charges under Medicare.

(B) *Special locality-based phase-in provision*—(*1*) *In general.* Beginning with the recalculation of CMACS for calendar year 1993, the CMAC in a locality

will not be less than 72.25 percent of the maximum charge level in effect for that locality on December 31, 1991. For recalculations of CMACs for calendar years after 1993, the CMAC in a locality will not be less than 85 percent of the CMAC in effect for that locality at the end of the prior calendar year.

(*2*) *Exception*. The special locality-based phase-in provision established by paragraph (j)(1)(iv)(B)(*1*) of this section shall not be applicable in the case of any procedure code for which there were not CHAMPUS claims in the locality accounting for at least 50 services.

(C) *Special locality-based waivers of reductions to assure adequate access to care*. Beginning with the recalculation of CMACs for calendar year 1993, in the case of any procedure classified as an overpriced procedure pursuant to paragraph (j)(1)(iii)(A)(*1*) of this section, a reduction in the CMAC in a locality below the level in effect at the end of the previous calendar year that would otherwise occur pursuant to paragraphs (j)(1)(iii) and (j)(1)(iv) of this section may be waived pursuant to paragraph (j)(1)(iii)(C) of this section.

(*1*) *Waiver based on balanced billing rates*. Except as provided in paragraph (j)(1)(iv)(C)(*2*) of this section such a reduction will be waived if there has been excessive balance billing in the locality for the procedure involved. For this purpose, the extent of balance billing will be determined based on a review of all services under the procedure code involved in the prior year (or most recent period for which data are available). If the number of services for which balance billing was not required was less than 60 percent of all services provided, the Director will determine that there was excessive balance billing with respect to that procedure in that locality and will waive the reduction in the CMAC that would otherwise occur. A decision by the Director to waive or not waive the reduction is not subject to the appeal and hearing procedures of § 199.10.

(*2*) *Exception*. As an exception to the paragraph (j)(1)(iv)(C)(*1*) of this section, the waiver required by that paragraph shall not be applicable in the case of any procedure code for which there were not CHAMPUS claims in the locality accounting for at least 50 services. A waiver may, however, be granted in such cases pursuant to paragraph (j)(1)(iv)(C)(*3*) of this section.

(*3*) *Waiver based on other evidence that adequate access to care would be impaired*. The Director, OCHAMPUS may waive a reduction that would otherwise occur (or restore a reduction that was already taken) if the Director determines that available evidence shows that the reduction would impair adequate access. For this purpose, such evidence may include consideration of the number of providers in the locality who provide the affected services, the number of such providers who are CHAMPUS Participating Providers, the number of CHAMPUS beneficiaries in the area, and other relevant factors. Providers or beneficiaries in a locality may submit to the Director, OCHAMPUS a petition, together with appropriate documentation regarding relevant factors, for a determination that adequate access would be impaired. The Director, OCHAMPUS will consider and respond to all such petitions. Petitions may be filed at any time. Any petition received by the date which is 120 days prior to the implementation of a recalculation of CMACs will be assured of consideration prior to that implementation. The Director, OCHAMPUS may establish procedures for handling petitions. A decision by the Director to waive or not waive a reduction is not subject to the appeal and hearing procedures of § 199.10.

(D) *Special locality-based exception to applicable CMACs to assure adequate beneficiary access to care*. In addition to the authority to waive reductions under paragraph (j)(1)(iv)(C) of this section, the Director may authorize establishment of higher payment rates for specific services than would otherwise be allowable, under paragraph (j)(1) of this section, if the Director determines that available evidence shows that access to health care services is severely impaired. For this purpose, such evidence may include consideration of the number of providers in the locality who provide the affected services, the number of providers who are CHAMPUS participating providers, the number of

CHAMPUS beneficiaries in the locality, the availability of military providers in the location or nearby, and any other factors the Director determines relevant.

(*1) Procedure*. Providers or beneficiaries in a locality may submit to the Director, a petition, together with appropriate documentation regarding relevant factors, for a determination that adequate access to health care services is severely impaired. The Director, will consider and respond to all petitions. A decision to authorize a higher payment amount is subject to review and determination or modification by the Director at any time if circumstances change so that adequate access to health care services would no longer be severely impaired. A decision by the Director, to authorize, not authorize, terminate, or modify authorization of higher payment amounts is not subject to the appeal and hearing procedures of §199.10 of the part.

(*2) Establishing the higher payment rate(s)*. When the Director, determines that beneficiary access to health care services in a locality is severely impaired, the Director may establish the higher payment rate(s) as he or she deems appropriate and cost-effective through one of the following methodologies to assure adequate access:

(*i*) A percent factor may be added to the otherwise applicable payment amount allowable under paragraph (j)(1) of this section;

(*ii*) A prevailing charge may be calculated, by applying the prevailing charge methodology of paragraph (j)(1)(ii) of this section to a specific locality (which need not be the same as the localities used for purposes of paragraph (j)(1)(iv)(A) of this section; or another government payment rate may be adopted, for example, an applicable state Medicaid rate).

(*3) Application of higher payment rates*. Higher payment rates defined under paragraph (j)(1)(iv)(D) of this section may be applied to all similar services performed in a locality, or, if circumstances warrant, a new locality may be defined for application of the higher payments. Establishment of a new locality may be undertaken where access impairment is localized and not pervasive across the existing locality. Generally, establishment of a new, more specific locality will occur when the area is remote so that geographical characteristics and other factors significantly impair transportation through normal means to health care services routinely available within the existing locality.

(E) *Special locality-based exception to applicable CMACs to ensure an adequate TRICARE Prime preferred network*. The Director, may authorize reimbursements to health care providers participating in a TRICARE preferred provider network under §199.17(p) of this part at rates higher than would otherwise be allowable under paragraph (j)(1) of this section, if the Director, determines that application of the higher rates is necessary to ensure the availability of an adequate number and mix of qualified health care providers in a network in a specific locality. This authority may only be used to ensure adequate networks in those localities designated by the Director, as requiring TRICAR preferred provider networks, not in localities in which preferred provider networks have been suggested or established but are not determined by the Director to be necessary. Appropriate evidence for determining that higher rates are necessary may include consideration of the number of available primary care and specialist providers in the network locality, availability (including reassignment) of military providers in the location or nearby, the appropriate mix of primary care and specialists needed to satisfy demand and meet appropriate patient access standards (appointment/waiting time, travel distance, etc.), the efforts that have been made to create an adequate network, other cost-effective alternatives, and other relevant factors. The Director, may establish procedures by which exceptions to applicable CMACs are requested and approved or denied under paragraph (j)(1)(iv)(E) of this section. A decision by the Director, to authorize or deny an exception is not subject to the appeal and hearing procedures of §199.10. When the Director, determines that it is necessary and cost-effective to approve a higher rate or rates in order to ensure the availability of an adequate

number of qualified health care providers in a network in a specific locality, the higher rate may not exceed the lesser of the following:

(*1*) The amount equal to the local fee for service charge for the service in the service area in which the service is provided as determined by the Director, based on one or more of the following payment rates:

(*i*) Usual, customary, and reasonable;

(*ii*) The Health Care Financing Administration's Resource Based Relative Value Scale;

(*iii*) Negotiated fee schedules;

(*iv*) Global fees; or

(*v*) Sliding scale individual fee allowances.

(*2*) The amount equal to 115 percent of the otherwise allowable charge under paragraph (j)(1) of the section for the service.

(v) *Special rules for 1991.* (A) Appropriate charge levels for care provided on or after January 1, 1991, and before the 1992 appropriate levels take effect shall be the same as those in effect on December 31, 1990, except that appropriate charge levels for care provided on or after October 7, 1991, shall be those established pursuant to this paragraph (j)(1)(v) of this section.

(B) Appropriate charge levels will be established for each locality for which an appropriate charge level was in effect immediately prior to October 7, 1991. For each procedure, the appropriate charge level shall be the prevailing charge level in effect immediately prior to October 7, 1991, adjusted as provided in (j)(1)(v)(B) (*1*) through (*3*) of this section.

(*1*) For each overpriced procedure, the level shall be reduced by fifteen percent. For this purpose, overpriced procedures are the procedures determined by the Physician Payment Review Commission to be overvalued pursuant to the process established under the Medicare program, other procedures considered overvalued in the Medicare program (for which Congress directed reductions in Medicare allowable levels for 1991), radiology procedures and pathology procedures.

(*2*) For each other procedure, the level shall remain unchanged. For this purpose, other procedures are procedures which are not overpriced procedures or primary care procedures.

(*3*) For each primary care procedure, the level shall be adjusted by the MEI, as the MEI is applied to Medicare prevailing charge levels. For this purpose, primary care procedures include maternity care and delivery services and well baby care services.

(C) For purposes of this paragraph (j)(i)(v), ''appropriate charge levels'' in effect at any time prior to October 7, 1991 shall mean the lesser of:

(*1*) The prevailing charge levels then in effect, or

(*2*) The fiscal year 1988 prevailing charge levels adjusted by the Medicare Economic Index (MEI), as the MEI was applied beginning in the fiscal year 1989.

(vi) *Special transition rule for 1992.* (A) For purposes of calculating the national appropriate charge levels for 1992, the prior year's appropriate charge level for each service will be considered to be the level that does not exceed the amount equivalent to the 80th percentile of billed charges made for similar services during the base period of July 1, 1986 to June 30, 1987 (determined as under paragraph (j)(1)(ii)(B) of this section), adjusted to calendar year 1991 based on the adjustments made for maximum CHAMPUS allowable charge levels through 1990 and the application of paragraph (j)(1)(v) of this section for 1991.

(B) The adjustment to calendar year 1991 of the product of paragraph (j)(1)(vi)(A) of this section shall be as follows:

(*1*) For procedures other than those described in paragraph (j)(1)(vi)(B)(*2*) of this section, the adjustment to 1991 shall be on the same basis as that provided under paragraph (j)(1)(v) of this section.

(*2*) For any procedure that was considered an overpriced procedure for purposes of the 1991 appropriate charge levels under paragraph (j)(1)(v) of this section for which the resulting 1991 appropriate charge level was less than 150 percent of the Medicare converted relative value unit, the adjustment to 1991 for purposes of the special transition rule for 1992 shall be as if the procedure had been treated under paragraph

(j)(1)(v)(B)(*2*) of this section for purposes of the 1991 appropriate charge level.

(vii) *Adjustments and procedural rules.* (A) The Director, OCHAMPUS may make adjustments to the appropriate charge levels calculated pursuant to paragraphs (j)(1)(iii) and (j)(1)(v) of this section to correct any anomalies resulting from data or statistical factors, significant differences between Medicare-relevant information and CHAMPUS-relevant considerations or other special factors that fairness requires be specially recognized. However, no such adjustment may result in reducing an appropriate charge level.

(B) The Director, OCHAMPUS will issue procedural instructions for administration of the allowable charge method.

(viii) *Clinical laboratory services.* The allowable charge for clinical diagnostic laboratory test services shall be calculated in the same manner as allowable charges for other individual health care providers are calculated pursuant to paragraphs (j)(1)(i) through (j)(1)(iv) of this section, with the following exceptions and clarifications.

(A) The calculation of national prevailing charge levels, national appropriate charge levels and national CMACs for laboratory service shall begin in calendar year 1993. For purposes of the 1993 calculation, the prior year's national appropriate charge level or national prevailing charge level shall be the level that does not exceed the amount equivalent to the 80th percentile of billed charges made for similar services during the period July 1, 1991, through June 30, 1992 (referred to in this paragraph (j)(1)(viii) of this section as the ''base period'').

(B) For purposes of comparison to Medicare allowable payment amounts pursuant to paragraph (j)(1)(iii) of this section, the Medicare national laboratory payment limitation amounts shall be used.

(C) For purposes of establishing laboratory service local CMACs pursuant to paragraph (j)(1)(iv) of this section, the adjustment factor shall equal the ratio of the local average charge (standardized for the distribution of clinical laboratory services) to the national average charge for all clinical laboratory services during the base period.

(D) For purposes of a special locality-based phase-in provision similar to that established by paragraph (j)(1)(iv)(B) of this section, the CMAC in a locality will not be less than 85 percent of the maximum charge level in effect for that locality during the base period.

(ix) The allowable charge for physician assistant services other than assistant-at-surgery shall be at the same percentage, used by Medicare, of the allowable charge for a comparable service rendered by a physician performing the service in a similar location. For cases in which the physician assistant and the physician perform component services of a procedure other than assistant-at-surgery (e.g., home, office, or hospital visit), the combined allowable charge for the procedure may not exceed the allowable charge for the procedure rendered by a physician alone. The allowable charge for physician assistant services performed as an assistant-at-surgery shall be at the same percentage, used by Medicare, of the allowable charge for a physician serving as an assistant surgeon when authorized as CHAMPUS benefits in accordance with the provisions of §199.4(c)(3)(iii). Physician assistant services must be billed through the employing physician who must be an authorized CHAMPUS provider.

(x) A charge that exceeds the CHAMPUS Maximum Allowable Charge can be determined to be allowable only when unusual circumstances or medical complications justify the higher charge. The allowable charge may not exceed the billed charge under any circumstances.

(xi) *Pharmaceutical agents utilized as part of medically necessary medical services.* In general, the TRICARE-determined allowed amount shall be equal to an amount determined to be appropriate, to the extent practicable, in accordance with the same reimbursement rules as apply to payments for similar services under Medicare. Under the authority of 10 U.S.C. 1079(q), in the case of any pharmaceutical agent utilized as part of medically necessary medical services, the Director may adopt special reimbursement methods, amounts,

and procedures to encourage the use of high-value products and discourage the use of low-value products, as determined by the Director. For this purpose, the Director may obtain recommendations from the Pharmaceutical and Therapeutics Committee under §199.21 or other entities as the Director, DHA deems appropriate with respect to the relative value of products in a class of products subject to this paragraph (j)(1)(xi). Among the special reimbursement methods the Director may choose to adopt under this paragraph (j)(1)(xi) is to reimburse the average sales price of a product plus six percent of the median of the average sales prices of products in the product class or category. The Director shall issue guidance regarding the special reimbursement methods adopted and the appropriate reimbursement rates.

(2) *Bonus payments in medically underserved areas.* A bonus payment, in addition to the amount normally paid under the allowable charge methodology, may be made to physicians in medically underserved areas. For purposes of this paragraph, medically underserved areas are the same as those determined by the Secretary of Health and Human Services for the Medicare program. Such bonus payments shall be equal to the bonus payments authorized by Medicare, except as necessary to recognize any unique or distinct characteristics or requirements of the TRICARE program, and as described in instructions issued by the Executive Director, TRICARE Management Activity. If the Department of Health and Human Services acts to amend or remove the provision for bonus payments under Medicare, TRICARE likewise may follow Medicare in amending or removing provision for such payments.

(3) *All-inclusive rate.* Claims from individual health-care professional providers for services rendered to CHAMPUS beneficiaries residing in an RTC that is either being reimbursed on an all-inclusive per diem rate, or is billing an all-inclusive per diem rate, shall be denied; with the exception of independent health-care professionals providing geographically distant family therapy to a family member residing a minimum of 250 miles from the RTC or covered medical services related to a nonmental health condition rendered outside the RTC. Reimbursement for individual professional services is included in the rate paid the institutional provider.

(4) *Alternative method.* The Director, OCHAMPUS, or a designee, may, subject to the approval of the ASD(HA), establish an alternative method of reimbursement designed to produce reasonable control over health care costs and to ensure a high level of acceptance of the CHAMPUS-determined charge by the individual health-care professionals or other noninstitutional health-care providers furnishing services and supplies to CHAMPUS beneficiaries. Alternative methods may not result in reimbursement greater than the allowable charge method above.

(k) *Reimbursement of Durable Medical Equipment, Prosthetics, orthotics and Supplies 9DMEPOS).* Reimbursement of DMEPOS may be based on the same amounts established under the Centers for Medicare and Medicaid Services (CMS) DMEPOS fee schedule under 42 CFR part 414, subpart D.

(l) *Reimbursement Under the Military-Civilian Health Services Partnership Program.* The Military-Civilian Health Services Partnership Program, as authorized by section 1096, chapter 55, title 10, provides for the sharing of staff, equipment, and resources between the civilian and military health care system in order to achieve more effective, efficient, or economical health care for authorized beneficiaries. Military treatment facility commanders, based upon the authority provided by their respective Surgeons General of the military departments, are responsible for entering into individual partnership agreements only when they have determined specifically that use of the Partnership Program is more economical overall to the Government than referring the need for health care services to the civilian community under the normal operation of the CHAMPUS Program. (See paragraph (p) of §199.1 for general requirements of the Partnership Program.)

(1) *Reimbursement of institutional health care providers.* Reimbursement of institutional health care providers

under the Partnership Program shall be on the same basis as non-Partnership providers.

(2) *Reimbursement of individual health-care professionals and other non-institutional health care providers.* Reimbursement of individual health care professionals and other non-institutional health care providers shall be on the same basis as non-Partnership providers as detailed in paragraph (j) of this section.

(m) *Accommodation of Discounts Under Provider Reimbursement Methods*—(1) *General rule.* The Director. OCHAMPUS (or designee) has authority to reimburse a provider at an amount below the amount usually paid pursuant to this section when, under a program approved by the Director, the provider has agreed to the lower amount.

(2) *Special applications.* The following are examples of applications of the general rule; they are not all inclusive.

(i) In the case and individual health care professionals and other non-institutional providers, if the discounted fee is below the provider's normal billed charge and the prevailing charge level (see paragraph (g) of this section), the discounted fee shall be the provider's actual billed charge and the CHAMPUS allowable charge.

(ii) In the case of institutional providers normally paid on the basis of a pre-set amount (such as DRG-based amount under paragraph (a)(1) of this section or per-diem amount under paragraph (a)(2) of this section), if the discount rate is lower than the pre-set rate, the discounted rate shall be the CHAMPUS-determined allowable cost. This is an exception to the usual rule that the pre-set rate is paid regardless of the institutional provider's billed charges or other factors.

(3) *Procedures.* (i) This paragraph applies only when both the provider and the Director have agreed to the discounted payment rate. The Director's agreement may be in the context of approval of a program that allows for such discounts.

(ii) The Director of OCHAMPUS may establish uniform terms, conditions and limitations for this payment method in order to avoid administrative complexity.

(n) *Outside the United States.* The Director, OCHAMPUS, or a designee, shall determine the appropriate reimbursement method or methods to be used in the extension of CHAMPUS benefits for otherwise covered medical services or supplies provided by hospitals or other institutional providers, physicians or other individual professional providers, or other providers outside the United States.

(o) *Implementing Instructions.* The Director, OCHAMPUS, or a designee, shall issue CHAMPUS policies, instructions, procedures, and guidelines, as may be necessary to implement the intent of this section.

[55 FR 13266, Apr. 10, 1990]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §199.14, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

EFFECTIVE DATE NOTE: At 88 FR 19855, Apr. 4, 2023, §199.14 was amended by revising paragraphs (a)(6)(ii)(A), (a)(6)(ii)(E) introductory text, and (a)(6)(ii)(E)(*3*), adding paragraph (a)(6)(ii)(E)(*4*), and revising paragraph (d), effective Oct. 1, 2023. For the convenience of the user, the added and revised text is set forth as follows:

§ 199.14 Provider reimbursement methods.

(a) * * *

(6) * * *

(ii) * * *

(A) *General.* Outpatient services provided in hospitals subject to Medicare OPPS as specified in 42 CFR 413.65 and 42 CFR 419.20, to include cancer and children's hospitals, will be paid in accordance with the provisions outlined in sections 1833t of the Social Security Act and its implementing Medicare regulation (42 CFR part 419) subject to exceptions as authorized by this paragraph (a)(6)(ii).

* * * * *

(E) *Temporary transitional payment adjustments (TTPAs).* Temporary transitional payment adjustments will be in place for all hospitals, both network and non-network, except for cancer and children's hospitals, in order to buffer the initial decline in payments upon implementation of TRICARE's OPPS.

* * * * *

(*3*) An additional general temporary military contingency payment adjustment

(GTMCPA) will also be available at the discretion of the Director, or a designee, at any time after implementation to adopt, modify and/or extend temporary adjustments to OPPS payments for TRICARE network hospitals deemed essential for military readiness and deployment in time of contingency operations. Any GTMCPAs to OPPS payments shall be made only on the basis of a determination that it is impracticable to support military readiness or contingency operations by making OPPS payments in accordance with the same reimbursement rules implemented by Medicare. For cancer and children's hospitals to qualify for the GTMCPA, they must meet the criteria in paragraphs (a)(6)(ii)(E)(*3*)(*i*) through (*iii*) of this section. Cancer and children's hospitals that meet these criteria will be eligible to receive up to 115 percent of the hospital's costs for OPPS services. The criteria for adopting, modifying, and/or extending deviations and/or adjustments to OPPS payments shall be issued through CHAMPUS policies, instructions, procedures and guidelines as deemed appropriate by the Director, or a designee. GTMCPAs may also be extended to non-network hospitals on a case-by-case basis for specific procedures where it is determined that the procedures cannot be obtained timely enough from a network hospital. For such case-by-case extensions, ''Temporary'' might be less than three years at the discretion of the Director, or designee. The GTMCPA qualification criteria for cancer and children's hospitals follow:

(*i*) Have 10 percent or more of its revenue come from TRICARE for care of ADSMs and ADDs;

(*ii*) Have 10,000 or more of its TRICARE visits paid under the OPPS for ADSMs and ADDs annually; and

(*iii*) Be deemed as essential for TRICARE operations.

(*4*) *For cancer and children's hospitals.* There are no temporary transitional payment adjustments in place. Reimbursement will be on the basis of OPPS, however, payments shall be adjusted so that these providers receive 100 percent of their costs. Adjustments shall be made on an annual basis, and within 180 days of the end of the OPPS year (OPPS Year is defined as April 1 through March 30) DHA will calculate the hospital's costs, utilizing the hospital-specific outpatient cost-to-charge ratio (CCR). The costs shall be calculated by multiplying the hospital's billed charges for OPPS services by the CCR. If the hospital's costs, as calculated by DHA, exceeded the payment that had been made under OPPS, the hospital shall receive an annual payment adjustment so that the hospital receives 100% of their costs.

* * * * *

(d) *Payment of institutional facility costs for ambulatory surgery.* In general, TRICARE pays for institutional facility costs for ambulatory surgery on the basis of prospectively determined amounts, as provided in this paragraph, with the exception of ambulatory surgery procedures performed in hospital outpatient departments or CAHs, which are to be reimbursed in accordance with the provisions of paragraph (a)(6)(ii) or (iii) of this section. Surgical services provided in Ambulatory Surgery Centers (ASCs) as defined in §199.2(b) will be paid in accordance with the provisions outlined in section 1833(t) of the Social Security Act and its implementing Medicare regulation (42 CFR part 416). TRICARE will recognize, to the extent practicable, in accordance with 10 U.S.C. 1079(i)(2), Medicare's ASC reimbursement methodology to include specific coding requirements, prospectively determined rates, discounts for multiple surgical procedures, the scope of ASC services, covered surgical procedures, and the basis of payment as described in 42 CFR part 416 with the exception that TRICARE will implement no transitional payments. Payments to ASCs for covered procedures and services will be based on the lesser of the billed charge or the ASC payment rate. Payment for ambulatory surgery procedures is limited to those procedures that are reimbursed by Medicare in ASCs, with the exception of dental procedures that are covered by the TRICARE program, as described in §199.4. In the absence of a Medicare ASC fee schedule rate, the payment for a covered dental procedure in ASCs will be based on the same rate under TRICARE's OPPS.

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§ 199.15 Quality and utilization review peer review organization program.

(a) *General*—(1) *Purpose.* The purpose of this section is to establish rules and procedures for the CHAMPUS Quality and Utilization Review Peer Review Organization program.

(2) *Applicability of program.* All claims submitted for health services under CHAMPUS are subject to review for quality of care and appropriate utilization. The Director, OCHAMPUS shall establish generally accepted standards, norms and criteria as are necessary for this program of utilization and quality review. These standards, norms and criteria shall include, but not be limited to, need for inpatient admission or inpatient or outpatient service, length of inpatient stay, intensity of care, appropriateness of treatment, and level of

institutional care required. The Director, OCHAMPUS may issue implementing instructions, procedures and guidelines for retrospective, concurrent and prospective review.

(3) *Contractor implementation.* The CHAMPUS Quality and Utilization Review Peer Review Organization program may be implemented through contracts administered by the Director, OCHAMPUS. These contractors may include contractors that have exclusive functions in the area of utilization and quality review, fiscal intermediary contractors (which perform these functions along with a broad range of administrative services), and managed care contractors (which perform a range of functions concerning management of the delivery and financing of health care services under CHAMPUS). Regardless of the contractors involved, utilization and quality review activities follow the same standards, rules and procedures set forth in this section, unless otherwise specifically provided in this section or elsewhere in this part.

(4) *Medical issues affected.* The CHAMPUS Quality and Utilization Review Peer Review Organization program is distinguishable in purpose and impact from other activities relating to the administration and management of CHAMPUS in that the Peer Review Organization program is concerned primarily with medical judgments regarding the quality and appropriateness of health care services. Issues regarding such matters as benefit limitations are similar, but, if not determined on the basis of medical judgments, are governed by CHAMPUS rules and procedures other than those provided in this section. (See, for example, §199.7 regarding claims submission, review and payment.) Based on this purpose, a major attribute of the Peer Review Organization program is that medical judgments are made by (directly or pursuant to guidelines and subject to direct review) reviewers who are peers of the health care providers providing the services under review.

(5) *Provider responsibilities.* Because of the dominance of medical judgments in the quality and utilization review program, principal responsibility for complying with program rules and procedures rests with health care providers. For this reason, there are limitations, set forth in this section and in §199.4(h), on the extent to which beneficiaries may be held financially liable for health care services not provided in conformity with rules and procedures of the quality and utilization review program concerning medical necessity of care.

(6) *Medicare rules used as model.* The CHAMPUS Quality and Utilization Review Peer Review Organization program, based on specific statutory authority, follows many of the quality and utilization review requirements and procedures in effect for the Medicare Peer Review Organization program, subject to adaptations appropriate for the CHAMPUS program. In recognition of the similarity of purpose and design between the Medicare and CHAMPUS PRO programs, and to avoid unnecessary duplication of effort, the CHAMPUS Quality and Utilization Review Peer Review Organization program will have special procedures applicable to supplies and services furnished to Medicare-eligible CHAMPUS beneficiaries. These procedures will enable CHAMPUS normally to rely upon Medicare determinations of medical necessity and appropriateness in the processing of CHAMPUS claims as a second payer to Medicare. As a general rule, only in cases involving Medicare-eligible CHAMPUS beneficiaries where Medicare payment for services and supplies is denied for reasons other than medical necessity and appropriateness will the CHAMPUS claim be subject to review for quality of care and appropriate utilization under the CHAMPUS PRO program. TRICARE will continue to perform a medical necessity and appropriateness review for quality of care and appropriate utilization under the CHAMPUS PRO program where required by statute.

(b) *Objectives and general requirements of review system*—(1) *In general.* Broadly, the program of quality and utilization review has as its objective to review the quality, completeness and adequacy of care provided, as well as its necessity, appropriateness and reasonableness.

(2) *Payment exclusion for services provided contrary to utilization and quality*

standards. (i) In any case in which health care services are provided in a manner determined to be contrary to quality or necessity standards established under the quality and utilization review program, payment may be wholly or partially excluded.

(ii) In any case in which payment is excluded pursuant to paragraph (b)(2)(i) of this section, the patient (or the patient's family) may not be billed for the excluded services.

(iii) Limited exceptions and other special provisions pertaining to the requirements established in paragraphs (b)(2) (i) and (ii) of this section, are set forth in §199.4(h).

(3) *Review of services covered by DRG-based payment system.* Application of these objectives in the context of hospital services covered by the DRG-based payment system also includes a validation of diagnosis and procedural information that determines CHAMPUS reimbursement, and a review of the necessity and appropriateness of care for which payment is sought on an outlier basis.

(4) *Preauthorization and other utilization review procedures*—(i) *In general.* all health care services for which payment is sought under TRICARE are subject to review for appropriateness of utilization as determined by the Director, TRICARE Management Activity, or a designee.

(A) The procedures for this review may be prospective (before the care is provided), concurrent (while the care is in process), or retrospective (after the care has been provided). Regardless of the procedures of this utilization review, the same generally accepted standards, norms and criteria for evaluating the medical necessity, appropriateness and reasonableness of the care involved shall apply. The Director, TRICARE Management Activity, or a designee, shall establish procedures for conducting reviews, including types of health care services for which preauthorization or concurrent review shall be required. Preauthorization or concurrent review may be required for categories of health care services. Except where required by law, the categories of health care services for which preauthorization or concurrent review is required may vary in different geographical locations or for different types of providers.

(B) For healthcare services provided under TRICARE contracts entered into by the Department of Defense after October 30, 2000, medical necessity preauthorization will not be required for referrals for specialty consultation appointment services requested by primary care providers or specialty providers when referring TRICARE Prime beneficiaries for specialty consultation appointment services within the TRICARE contractor's network. However, the lack of medical necessity preauthorization requirements for consultative appointment services does not mean that non-emergent admissions or invasive diagnostic or therapeutic procedures which in and of themselves constitute categories of health care services related to, but beyond the level of the consultation appointment service, are not subject to medical necessity prior authorization. In fact many such health care services may continue to require medical necessity prior authorization as determined by the Director, TRICARE Management Activity, or a designee. TRICARE Prime beneficiaries are also required to obtain preauthorization before seeking health care services from a non-network provider.

(ii) *Preauthorization procedures.* With respect to categories of health care (inpatient or outpatient) for which preauthorization is required, the following procedures shall apply:

(A) The requirement for preauthorization shall be widely publicized to beneficiaries and providers.

(B) All requests for preauthorization shall be responded to in writing. Notification of approval or denial shall be sent to the beneficiary. Approvals shall specify the health care services and supplies approved and identify any special limits or further requirements applicable to the particular case.

(C) An approved preauthorization shall state the number of days, appropriate for the type of care involved, for which it is valid. In general, preauthorizations will be valid for 30 days. If the services or supplies are not obtained within the number of days specified, a new preauthorization request is required. For organ and stem

cell transplants, the preauthorization shall remain in effect as long as the beneficiary continues to meet the specific transplant criteria set forth in the TRICARE/CHAMPUS Policy Manual, or until the approved transplant occurs.

(D) For healthcare services provided under TRICARE contracts entered into by the Department of Defense after October 30, 2000, medical necessity preauthorization for specialty consultation appointment services within the TRICARE contractor's network will not be required. However, the Director, TRICARE Management Activity, or designee, may continue to require or waive medical necessity prior (or pre) authorization for other categories of other health care services based on best business practice.

(iii) *Payment reduction for noncompliance with required utilization review procedures.* (A) Paragraph (b)(4)(iii) of this section applies to any case in which:

(*1*) A provider was required to obtain preauthorization or continued stay (in connection with required concurrent review procedures) approval.

(*2*) The provider failed to obtain the necessary approval; and

(*3*) The health care services have not been disallowed on the basis of necessity, appropriateness or reasonableness.

In such a case, reimbursement will be reduced, unless such reduction is waived based on special circumstances.

(B) In a case described in paragraph (b)(4)(iii)(A) of this section, reimbursement will be reduced, unless such reduction is waived based on special circumstances. The amount of this reduction shall be at least ten percent of the amount otherwise allowable for services for which preauthorization (including preauthorization for continued stays in connection with concurrent review requirements) approval should have been obtained, but was not obtained.

(C) The payment reduction set forth in paragraph (b)(4)(iii)(B) of this section may be waived by the Director, OCHAMPUS when the provider could not reasonably have been expected to know of the preauthorization requirement or some other special circumstance justifies the waiver.

(D) Services for which payment is disallowed under paragraph (b)(4)(iii) of this section may not be billed to the patient (or the patient's family).

(c) *Hospital cooperation.* All hospitals which participate in CHAMPUS and submit CHAMPUS claims are required to provide all information necessary for CHAMPUS to properly process the claims. In order for CHAMPUS to be assured that services for which claims are submitted meet quality of care standards, hospitals are required to provide the Peer Review Organization (PRO) responsible for quality review with all the information, within timeframes to be established by OCHAMPUS, necessary to perform the review functions required by this paragraph. Additionally, all participating hospitals shall provide CHAMPUS beneficiaries, upon admission, with information about the admission and quality review system including their appeal rights. A hospital which does not cooperate in this activity shall be subject to termination as a CHAMPUS-authorized provider.

(1) Documentation that the beneficiary has received the required information about the CHAMPUS PRO program must be maintained in the same manner as is the notice required for the Medicare program by 42 CFR 466.78(b).

(2) The physician acknowledgment required for Medicare under 42 CFR 412.46 is also required for CHAMPUS as a condition for payment and may be satisfied by the same statement as required for Medicare, with substitution or addition of ''CHAMPUS'' when the word ''Medicare'' is used.

(3) Participating hospitals must execute a memorandum of understanding with the PRO providing appropriate procedures for implementation of the PRO program.

(4) Participating hospitals may not charge a CHAMPUS beneficiary for inpatient hospital services excluded on the basis of §199.4(g)(1) (not medically necessary), §199.4(g)(3) (inappropriate level), or §199.4(g)(7) (custodial care) unless all of the conditions established by 42 CFR 412.42(c) with respect to Medicare beneficiaries have been met

with respect to the CHAMPUS beneficiary. In such cases in which the patient requests a PRO review while the patient is still an inpatient in the hospital, the hospital shall provide to the PRO the records required for the review by the close of business of the day the patient requests review, if such request was made before noon. If the hospital fails to provide the records by the close of business, that day and any subsequent working day during which the hospital continues to fail to provide the records shall not be counted for purposes of the two-day period of 42 CFR 412.42(c)(3)(ii).

(d) *Areas of review*—(1) *Admissions.* The following areas shall be subject to review to determine whether inpatient care was medically appropriate and necessary, was delivered in the most appropriate setting and met acceptable standards of quality. This review may include preadmission or prepayment review when appropriate.

(i) Transfers of CHAMPUS beneficiaries from a hospital or hospital unit subject to the CHAMPUS DRG-based payment system to another hospital or hospital unit.

(ii) CHAMPUS admissions to a hospital or hospital unit subject to the CHAMPUS DRG-based payment system which occur within a certain period (specified by OCHAMPUS) of discharge from a hospital or hospital unit subject to the CHAMPUS DRG-based payment system.

(iii) A random sample of other CHAMPUS admissions for each hospital subject to the CHAMPUS DRG-based payment system.

(iv) CHAMPUS admissions in any DRGs which have been specifically identified by OCHAMPUS for review or which are under review for any other reason.

(2) *DRG validation.* The review organization responsible for quality of care reviews shall be responsible for ensuring that the diagnostic and procedural information reported by hospitals on CHAMPUS claims which is used by the fiscal intermediary to assign claims to DRGs is correct and matches the information contained in the medical records. In order to accomplish this, the following review activities shall be done.

(i) Perform DRG validation reviews of each case under review.

(ii) Review of claim adjustments submitted by hospitals which result in the assignment of a higher weighted DRG.

(iii) Review for physician's acknowledgement of annual receipt of the penalty statement as contained in the Medicare regulation at 42 CFR 412.46.

(iv) Review of a sample of claims for each hospital reimbursed under the CHAMPUS DRG-based payment system. Sample size shall be determined based upon the volume of claims submitted.

(3) *Outlier review.* Claims which qualify for additional payment as a long-stay outlier or as a cost-outlier shall be subject to review to ensure that the additional days or costs were medically necessary and appropriate and met all other requirements for CHAMPUS coverage. In addition, claims which qualify as short-stay outliers shall be reviewed to ensure that the admission was medically necessary and appropriate and that the discharge was not premature.

(4) *Procedure review.* Claims for procedures identified by OCHAMPUS as subject to a pattern of abuse shall be the subject of intensified quality assurance review.

(5) *Other review.* Any other cases or types of cases identified by OCHAMPUS shall be subject to focused review.

(e) *Actions as a result of review*—(1) *Findings related to individual claims.* If it is determined, based upon information obtained during reviews, that a hospital has misrepresented admission, discharge, or billing information, or is found to have quality of care defects, or has taken an action that results in the unnecessary admissions of an individual entitled to benefits, unnecessary multiple admission of an individual, or other inappropriate medical or other practices with respect to beneficiaries or billing for services furnished to beneficiaries, the PRO, in conjunction with the fiscal intermediary, shall, as appropriate:

(i) Deny payment for or recoup (in whole or in part) any amount claimed or paid for the inpatient hospital and professional services related to such determination.

(ii) Require the hospital to take other corrective action necessary to prevent or correct the inappropriate practice.

(iii) Advise the provider and beneficiary of appeal rights, as required by §199.10 of this part.

(iv) Notify OCHAMPUS of all such actions.

(2) *Findings related to a pattern of inappropriate practices.* In all cases where a pattern of inappropriate admissions and billing practices that have the effect of circumventing the CHAMPUS DRG-based payment system is identified, OCHAMPUS shall be notified of the hospital and practice involved.

(3) *Revision of coding relating to DRG validation.* The following provisions apply in connection with the DRG validation process set forth in paragraph (d)(2) of this section.

(i) If the diagnostic and procedural information in the patient's medical record is found to be inconsistent with the hospital's coding or DRG assignment, the hospital's coding on the CHAMPUS claim will be appropriately changed and payments recalculated on the basis of the appropriate DRG assignment.

(ii) If the information stipulated under paragraph (d)(2) of this section is found not to be correct, the PRO will change the coding and assign the appropriate DRG on the basis of the changed coding.

(f) *Special procedures in connection with certain types of health care services or certain types of review activities*—(1) *In general.* Many provisions of this section are directed to the context of services covered by the CHAMPUS DRG-based payment system. This section, however, is also applicable to other services. In addition, many provisions of this section relate to the context of peer review activities performed by Peer Review Organizations whose sole functions for CHAMPUS relate to the Quality and Utilization Review Peer Review Organization program. However, it also applies to review activities conducted by contractors who have responsibilities broader than those related to the quality and utilization review program. Paragraph (f) of this section authorizes certain special procedures that will apply in connection with such services and such review activities.

(2) *Services not covered by the DRG-based payment system.* In implementing the quality and utilization review program in the context of services not covered by the DRG-based payment system, the Director, OCHAMPUS may establish procedures, appropriate to the types of services being reviewed, substantively comparable to services covered by the DRG-based payment system regarding obligations of providers to cooperate in the quality and utilization review program, authority to require appropriate corrective actions and other procedures. The Director, OCHAMPUS may also establish such special, substantively comparable procedures in connection with review of health care services which, although covered by the DRG-based payment method, are also affected by some other special circumstances concerning payment method, nature of care, or other potential utilization or quality issue.

(3) *Peer review activities by contractors also performing other administration or management functions*—(i) *Sole-function PRO versus multi-function PRO.* In all cases, peer review activities under the Quality and Utilization Review Peer Review Organization program are carried out by physicians and other qualified health care professionals, usually under contract with OCHAMPUS. In some cases, the Peer Review Organization contractor's only functions are pursuant to the quality and utilization review program. In paragraph (f)(3) of this section, this type of contractor is referred to as a ''sole function PRO.'' In other cases, the Peer Review Organization contractor is also performing other functions in connection with the administration and management of CHAMPUS. In paragraph (f)(3) of this section, this type of contractor is referred to as a ''multi-function PRO.'' As an example of the latter type, managed care contractors may perform a wide range of functions regarding management of the delivery and financing of health care services under CHAMPUS, including but not limited to functions under the Quality and Utilization Review Peer Review Organization program.

(ii) *Special rules and procedures.* With respect to multi-function PROs, the Director, OCHAMPUS may establish special procedures to assure the independence of the Quality and Utilization Review Peer Review Organization program and otherwise advance the objectives of the program. These special rules and procedures include, but are not limited to, the following:

(A) A reconsidered determination that would be final in cases involving sole-function PROs under paragraph (i)(2) of this section will not be final in connection with multi-function PROs. Rather, in such cases (other than any case which is appealable under paragraph (i)(3) of this section), an opportunity for a second reconsideration shall be provided. The second reconsideration will be provided by OCHAMPUS or another contractor independent of the multi-function PRO that performed the review. The second reconsideration may not be further appealed by the provider.

(B) Procedures established by paragraphs (g) through (m) of this section shall not apply to any action of a multi-function PRO (or employee or other person or entity affiliated with the PRO) carried out in performance of functions other than functions under this section.

(g) *Procedures regarding initial determinations.* The CHAMPUS PROs shall establish and follow procedures for initial determinations that are substantively the same or comparable to the procedures applicable to Medicare under 42 CFR 466.83 to 466.104. In addition, these procedures shall provide that a PRO's determination that an admission is medically necessary is not a guarantee of payment by CHAMPUS; normal CHAMPUS benefit and procedural coverage requirements must also be applied.

(h) *Procedures regarding reconsiderations.* The CHAMPUS PROs shall establish and follow procedures for reconsiderations that are substantively the same or comparable to the procedures applicable to reconsiderations under Medicare pursuant to 42 CFR 473.15 to 473.34, except that the time limit for requesting reconsideration (see 42 CFR 473.20(a)(1)) shall be 90 days. A PRO reconsidered determination is final and binding upon all parties to the reconsideration except to the extent of any further appeal pursuant to paragraph (i) of this section.

(i) *Appeals and hearings.* (1) Beneficiaries may appeal a PRO reconsideration determination of OCHAMPUS and obtain a hearing on such appeal to the extent allowed and under the procedures set forth in §199.10(d).

(2) Except as provided in paragraph (i)(3), a PRO reconsidered determination may not be further appealed by a provider.

(3) A provider may appeal a PRO reconsideration determination to OCHAMPUS and obtain a hearing on such appeal to the extent allowed under the procedures set forth in §199.10(d) if it is a determination pursuant to §199.4(h) that the provider knew or could reasonably have been expected to know that the services were excludable.

(4) For purposes of the hearing process, a PRO reconsidered determination shall be considered as the procedural equivalent of a formal review determination under §199.10, unless revised at the initiative of the Director, OCHAMPUS prior to a hearing on the appeal, in which case the revised determination shall be considered as the procedural equivalent of a formal review determination under §199.10.

(5) The provisions of §199.10(e) concerning final action shall apply to hearings cases.

(j) *Acquisition, protection and disclosure of peer review information.* The provisions of 42 CFR part 476, except §476.108, shall be applicable to the CHAMPUS PRO program as they are to the Medicare PRO program.

(k) *Limited immunity from liability for participants in PRO program.* The provisions of section 1157 of the Social Security Act (42 U.S.C. 1320c–6) are applicable to the CHAMPUS PRO program in the same manner as they apply to the Medicare PRO program. Section 1102(g) of title 10, United States Code also applies to the CHAMPUS PRO program.

(l) *Additional provision regarding confidentiality of records*—(1) *General rule.* The provisions of 10 U.S.C. 1102 regarding the confidentiality of medical quality assurance records shall apply to the

activities of the CHAMPUS PRO program as they do to the activities of the external civilian PRO program that reviews medical care provided in military hospitals.

(2) *Specific applications.* (i) Records concerning PRO deliberations are generally nondisclosable quality assurance records under 10 U.S.C. 1102.

(ii) Initial denial determinations by PROs pursuant to paragraph (g) of this section (concerning medical necessity determinations, DRG validation actions, etc.) and subsequent decisions regarding those determinations are not nondisclosable quality assurance records under 10 U.S.C. 1102.

(iii) Information the subject of mandatory PRO disclosure under 42 CFR part 476 is not a nondisclosable quality assurance record under 10 U.S.C. 1102.

(m) *Obligations, sanctions and procedures.* (1) The provisions of 42 CFR 1004.1–1004.80 shall apply to the CHAMPUS PRO program as they do the Medicare PRO program, except that the functions specified in those sections for the Office of Inspector General of the Department of Health and Human Services shall be the responsibility of OCHAMPUS.

(2) The provisions of 42 U.S.C. section 1395ww(f)(2) concerning circumvention by any hospital of the applicable payment methods for inpatient services shall apply to CHAMPUS payment methods as they do to Medicare payment methods.

(3) The Director, or a designee, of CHAMPUS shall determine whether to impose a sanction pursuant to paragraphs (m)(1) and (m)(2) of this section. Providers may appeal adverse sanctions decisions under the procedures set forth in §199.10(d).

(n) *Authority to integrate CHAMPUS PRO and military medical treatment facility utilization review activities.* (1) In the case of a military medical treatment facility (MTF) that has established utilization review requirements similar to those under the CHAMPUS PRO program, the contractor carrying out this function may, at the request of the MTF, utilize procedures comparable to the CHAMPUS PRO program procedures to render determinations or recommendations with respect to utilization review requirements.

(2) In any case in which such a contractor has comparable responsibility and authority regarding utilization review in both an MTF (or MTFs) and CHAMPUS, determinations as to medical necessity in connection with services from an MTF or CHAMPUS-authorized provider may be consolidated.

(3) In any case in which an MTF reserves authority to separate an MTF determination on medical necessity from a CHAMPUS PRO program determination on medical necessity, the MTF determination is not binding on CHAMPUS.

[55 FR 625, Jan. 8, 1990, as amended at 58 FR 58961, Nov. 5, 1993; 60 FR 52095, Oct. 5, 1995; 63 FR 48447, Sept. 10, 1998; 66 FR 40608, Aug. 3, 2001; 67 FR 42721, June 25, 2002; 68 FR 23033, Apr. 30, 2003; 68 FR 32363, May 30, 2003; 68 FR 44881, July 31, 2003; 70 FR 19266, Apr. 13, 2005; 81 FR 61098, Sept. 2, 2016]

§199.16 Supplemental Health Care Program for active duty members.

(a) *Purpose and applicability.* (1) The purpose of this section is to implement, with respect to health care services provided under the supplemental health care program for active duty members of the uniformed services, the provision of 10 U.S.C. 1074(c). This section of law authorizes DoD to establish for the supplemental care program the same payment rules, subject to appropriate modifications, as apply under CHAMPUS.

(2) This section applies to the program, known as the supplemental care program, which provides for the payment by the uniformed services to private sector health care providers for health care services provided to active duty members of the uniformed services. Although not part of CHAMPUS, the supplemental care program is similar to CHAMPUS in that it is a program for the uniformed services to purchase civilian health care services for active duty members. For this reason, the Director, OCHAMPUS assists the uniformed services in the administration of the supplemental care program.

(3) This section applies to all health care services covered by the CHAMPUS. For purposes of this section, health care services ordered by a military treatment facility (MTF) provider for an MTF patient (who is not

an active duty member) for whom the MTF provider maintains responsibility are also covered by the supplemental care program and subject to the requirements of this section.

(b) *Obligation of providers concerning payment for supplemental health care for active duty members*—(1) *Hospitals covered by DRG-based payment system.* For a hospital covered by the CHAMPUS DRG-based payment system to maintain its status as an authorized provider for CHAMPUS pursuant to §199.6, that hospital must also be a participating provider for purposes of the supplemental care program. As a participating provider, each hospital must accept the DRG-based payment system amount determined pursuant to §199.14 as payment in full for the hospital services covered by the system. The failure of any hospital to comply with this obligation subjects that hospital to exclusion as a CHAMPUS-authorized provider.

(2) *Other participating providers.* For any institutional or individual provider, other than those described in paragraph (b)(1) of this section that is a participating provider, the provider must also be a participating provider for purposes of the supplemental care program. The provider must accept the CHAMPUS allowable amount determined pursuant to §199.14 as payment in full for the hospital services covered by the system. The failure of any provider to comply with this obligation subjects the provider to exclusion as a participating provider.

(c) *General rule for payment and administration.* Subject to the special rules and procedures in paragraph (d) of this section and the waiver authority in paragraph (e) of this section, as a general rule the provisions of §199.14 shall govern payment and administration of claims under the supplemental care program as they do claims under CHAMPUS. To the extent necessary to interpret or implement the provisions of §199.14, related provisions of this part shall also be applicable.

(d) *Special rules and procedure.* As exceptions to the general rule in paragraph (c) of this section, the special rules and procedures in this section shall govern payment and administration of claims under the supplemental care program. These special rules and procedures are subject to the TRICARE Prime Remote program for active duty service members set forth in paragraph (e) of this section and the waiver authority of paragraph (f) of this section.

(1) There is no patient cost sharing under the supplemental care program. All amounts due to be paid to the provider shall be paid by the program.

(2) Preauthorization by the Uniformed Services of each service is required for the supplemental care program except for services in cases of medical emergency (for which the definition in Sec. 199.2 shall apply) or in cases governed by the TRICARE Prime Remote program for active duty service members set forth in paragraph (e) of this section. It is the responsibility of the active duty members to obtain preauthorization for each service. With respect to each emergency inpatient admission, after such time as the emergency condition is addressed, authorization for any proposed continued stay must be obtained within two working days of admission.

(3) With respect to the filing of claims and similar administrative matters for which this part refers to activities of the CHAMPUS fiscal intermediaries, for purposes of the supplemental care program, responsibilities for claims processing, payment and some other administrative matters may be assigned by the Director, OCHAMPUS to the same fiscal intermediaries, other contractor, or to the nearest military medical treatment facility or medical claims office.

(4) The annual cost pass-throughs for capital and direct medical education costs that are available under the CHAMPUS DRG-based payment system are also available, upon request, under the supplemental care program. To obtain payment include the number of active duty bed days as a separate line item on the annual request to the CHAMPUS fiscal intermediaries.

(5) For providers other than participating providers, the Director, OCHAMPUS may authorize payment in excess of CHAMPUS allowable amounts. No provider may bill an active duty member any amount in excess of the CHAMPUS allowable amount.

(e) *TRICARE Prime Remote for Active Duty Members*—(1) *General.* The TRICARE Prime Remote (TPR) program is available for certain active duty members of the Uniformed Services assigned to remote locations in the United States and the District of Columbia who are entitled to coverage of medical care, and the standards for timely access to such care, outside a military treatment facility that are comparable to coverage for medical care and standards for timely access to such care as exist under TRICARE Prime under §199.17. Those active duty members who are eligible under the provisions of 10 U.S.C. 1074(c)(3) and who enroll in the TRICARE Prime Remote program, may not be required to receive routine primary medical care at a military medical treatment facility.

(2) *Eligibility.* To receive health care services under the TRICARE Prime Remote program, an individual must be an active duty member of the Uniformed Services on orders for more than thirty consecutive days who meet the following requirements:

(i) Has a permanent duty assignment that is greater than fifty miles or approximately one hour drive from a military treatment facility or military clinic designated as adequate to provide the needed primary care services to the active duty service member; and

(ii) Pursuant to the assignment of such duty, resides at a location that is greater than fifty miles or approximately one hour from a military medical treatment facility or military clinic designated as adequate to provide the needed primary care services to the active duty service member.

(3) *Enrollment.* An active duty service member eligible for the TRICARE Prime Remote program must enroll in the program. If an eligible active duty member does not enroll in the TRICARE Prime Remote program, the member shall receive health care services provide under the supplemental health program subject to all requirements of this section without application of the provisions of paragraph (e) of this section.

(4) *Preauthorization.* If a TRICARE Prime network under §199.17 exists in the remote location, the TRICARE Prime Remote enrolled active duty member will select or be assigned a primary care manager. In the absence of a TRICARE primary care manager in the remote location and if the active duty member is not assigned to a military primary care manager based on fitness for duty requirements, the TRICARE Prime Remote enrolled active duty member may use a local TRICARE authorized provider for primary health care services without preauthorization. Any referral for specialty care will require the TRICARE Prime Remote enrolled active duty member to obtain preauthorization for such services.

(f) *Waiver authority.* With the exception of statutory requirements, any restrictions or limitations pursuant to the general rule in paragraph (c) of this section, and special rules and procedures in paragraph (d) of this section, may be waived by the Director, OCHAMPUS, at the request of an authorized official of the uniformed service concerned, based on a determination that such waiver is necessary to assure adequate availability of health care services to active duty members.

(g) *Authorities.* (1) The Uniformed Services may establish additional procedures, consistent with this part, for the effective administration of the supplemental care program in their respective services.

(2) The Assistant Secretary of Defense for Health Affairs is responsible for the overall policy direction of the supplemental care program and the administration of this part.

(3) The Director, OCHAMPUS shall issue procedural requirements for the implementation of this section, including requirement for claims submission similar to those established by §199.7.

[56 FR 23801, May 24, 1991, as amended at 58 FR 58963, Nov. 5, 1993; 67 FR 5479, Feb. 6, 2002; 71 FR 50348, Aug. 25, 2006]

§199.17 TRICARE program.

(a) *Establishment.* The TRICARE program is established for the purpose of implementing a comprehensive managed health care program for the delivery and financing of health care services in the Military Health System.

(1) *Purpose.* The TRICARE program implements a number of improvements

primarily through modernized managed care support contracts that include special arrangements with civilian sector health care providers and better coordination between military medical treatment facilities (MTFs) and these civilian providers to deliver an integrated, health care delivery system that provides beneficiaries with access to high quality healthcare. Implementation of these improvements, to include enhanced access, improved health outcomes, increased efficiencies and elimination of waste, in addition to improving and maintaining operational medical force readiness, includes adoption of special rules and procedures not ordinarily followed under CHAMPUS or MTF requirements. This section establishes those special rules and procedures.

(2) *Statutory authority.* Many of the provisions of this section are authorized by statutory authorities other than those which authorize the usual operation of the CHAMPUS program, especially 10 U.S.C. 1079 and 1086. The TRICARE program also relies upon other available statutory authorities, including 10 U.S.C. 1075 (TRICARE Select), 10 U.S.C. 1075a (TRICARE Prime cost sharing), 10 U.S.C. 1095f (referrals and pre-authorizations under TRICARE Prime), 10 U.S.C. 1099 (health care enrollment system), 10 U.S.C. 1097 (contracts for medical care for retirees, dependents and survivors: Alternative delivery of health care), and 10 U.S.C. 1096 (resource sharing agreements).

(3) *Scope of the program.* The TRICARE program is applicable to all the uniformed services. TRICARE Select and TRICARE-for-Life shall be available in all areas, including overseas as authorized in paragraph (u) of this section. The geographic availability of TRICARE Prime is generally limited as provided in this section. The Assistant Secretary of Defense (Health Affairs) may also authorize modifications to TRICARE program rules and procedures as may be appropriate to the area involved.

(4) *Rules and procedures affected.* Much of this section relates to rules and procedures applicable to the delivery and financing of health care services provided by civilian providers outside military treatment facilities. This section provides that certain rules, procedures, rights and obligations set forth elsewhere in this part (and usually applicable to CHAMPUS) are different under the TRICARE program. To the extent that TRICARE program rules, procedures, rights and obligations set forth in this section are not different from or otherwise in conflict with those set forth elsewhere in this part as applicable to CHAMPUS, the CHAMPUS provisions are incorporated into the TRICARE program. In addition, some rules, procedures, rights and obligations relating to health care services in military treatment facilities are also different under the TRICARE program. In such cases, provisions of this section take precedence and are binding.

(5) *Implementation based on local action.* The TRICARE program is not automatically implemented in all respects in all areas where it is potentially applicable. Therefore, not all provisions of this section are automatically implemented. Rather, implementation of the TRICARE program and this section requires an official action by the Director, Defense Health Agency. Public notice of the initiation of portions of the TRICARE program will be achieved through appropriate communication and media methods and by way of an official announcement by the Director identifying the military medical treatment facility catchment area or other geographical area covered.

(6) *Major features of the TRICARE program.* The major features of the TRICARE program, described in this section, include the following:

(i) *Beneficiary categories.* Under the TRICARE program, health care beneficiaries are generally classified into one of several categories:

(A) Active duty members, who are covered by 10 U.S.C. 1074(a).

(B) Active duty family members, who are beneficiaries covered by 10 U.S.C. 1079 (also referred to in this section as ''active duty family category'').

(C) Retirees and their family members (also referred to in this section as ''retired category''), who are beneficiaries covered by 10 U.S.C. 1086(c) other than those beneficiaries eligible for Medicare Part A.

(D) Medicare eligible retirees and Medicare eligible retiree family members who are beneficiaries covered by 10 U.S.C. 1086(d) as each become individually eligible for Medicare Part A and enroll in Medicare Part B.

(E) Military treatment facility (MTF) only beneficiaries are beneficiaries eligible for health care services in military treatment facilities, but not eligible for a TRICARE plan covering non-MTF care.

(ii) *Health plans available.* The major TRICARE health plans are as follows:

(A) *TRICARE Prime.* ''TRICARE Prime'' is a health maintenance organization (HMO)-like program. It generally features use of military treatment facilities and substantially reduced out-of-pocket costs for care provided outside MTFs. Beneficiaries generally agree to use military treatment facilities and designated civilian provider networks and to follow certain managed care rules and procedures. The primary purpose of TRICARE Prime is to support the effective operation of an MTF, which exists to support the medical readiness of the armed forces and the readiness of medical personnel. TRICARE Prime will be offered in areas where the Director determines that it is appropriate to support the effective operation of one or more MTFs.

(B) *TRICARE Select.* ''TRICARE Select'' is a self-managed, preferred provider organization (PPO) program. It allows beneficiaries to use the TRICARE provider civilian network, with reduced out-of-pocket costs compared to care from non-network providers, as well as military treatment facilities (where they exist and when space is available). TRICARE Select enrollees will not have restrictions on their freedom of choice with respect to authorized health care providers. However, when a TRICARE Select beneficiary receives services covered under the basic program from an authorized health care provider who is not part of the TRICARE provider network that care is covered by TRICARE but is subject to higher cost sharing amounts for ''out-of-network'' care. Those amounts are the same as under the basic program under §199.4.

(C) *TRICARE for Life.* ''TRICARE for Life'' is the Medicare wraparound coverage plan under 10 U.S.C. 1086(d). Rules applicable to this plan are unaffected by this section; they are generally set forth in §§199.3 (Eligibility), 199.4 (Basic Program Benefits), and 199.8 (Double Coverage).

(D) *TRICARE Standard.* ''TRICARE Standard'' generally referred to the basic CHAMPUS program of benefits under §199.4. While the law required termination of TRICARE Standard as a distinct TRICARE plan December 31, 2017, the CHAMPUS basic program benefits under §199.4 continues as the baseline of benefits common to the TRICARE Prime and TRICARE Select plans.

(iii) *Comprehensive enrollment system.* The TRICARE program includes a comprehensive enrollment system for all categories of beneficiaries except TRICARE-for-Life beneficiaries. When eligibility for enrollment for TRICARE Prime and/or TRICARE Select exists, a beneficiary must enroll in one of the plans. Refer to paragraph (o) of this section for TRICARE program enrollment procedures.

(7) *Preemption of State laws.* (i) Pursuant to 10 U.S.C. 1103 the Department of Defense has determined that in the administration of 10 U.S.C. chapter 55, preemption of State and local laws relating to health insurance, prepaid health plans, or other health care delivery or financing methods is necessary to achieve important Federal interests, including but not limited to the assurance of uniform national health programs for military families and the operation of such programs at the lowest possible cost to the Department of Defense, that have a direct and substantial effect on the conduct of military affairs and national security policy of the United States.

(ii) Based on the determination set forth in paragraph (a)(7)(i) of this section, any State or local law relating to health insurance, prepaid health plans, or other health care delivery or financing methods is preempted and does not apply in connection with TRICARE regional contracts. Any such law, or regulation pursuant to such law, is without any force or effect, and State or

local governments have no legal authority to enforce them in relation to the TRICARE regional contracts. (However, the Department of Defense may by contract establish legal obligations of the part of TRICARE contractors to conform with requirements similar or identical to requirements of State or local laws or regulations).

(iii) The preemption of State and local laws set forth in paragraph (a)(7)(ii) of this section includes State and local laws imposing premium taxes on health or dental insurance carriers or underwriters or other plan managers, or similar taxes on such entities. Such laws are laws relating to health insurance, prepaid health plans, or other health care delivery or financing methods, within the meaning of the statutes identified in paragraph (a)(7)(i) of this section. Preemption, however, does not apply to taxes, fees, or other payments on net income or profit realized by such entities in the conduct of business relating to DoD health services contracts, if those taxes, fees or other payments are applicable to a broad range of business activity. For purposes of assessing the effect of Federal preemption of State and local taxes and fees in connection with DoD health and dental services contracts, interpretations shall be consistent with those applicable to the Federal Employees Health Benefits Program under 5 U.S.C. 8909(f).

(b) *TRICARE Prime and TRICARE Select health plans in general.* The two primary plans for beneficiaries in the active duty family category and the retired category (which does not include most Medicare-eligible retirees/dependents) are TRICARE Prime and TRICARE Select. This paragraph (b) further describes the TRICARE Prime and TRICARE Select health plans.

(1) *TRICARE Prime.* TRICARE Prime is a managed care option that provides enhanced medical services to beneficiaries at reduced cost-sharing amounts for beneficiaries whose care is managed by a designated primary care manager and provided by an MTF or network provider. TRICARE Prime is offered in a location in which an MTF is located (other than a facility limited to members of the armed forces) that has been designated by the Director as a Prime Service Area. In addition, where TRICARE Prime is offered it may be limited to active duty family members if the Director determines it is not practicable to offer TRICARE Prime to retired category beneficiaries. TRICARE Prime is not offered in areas where the Director determines it is impracticable. If TRICARE Prime is not offered in a geographical area, certain active duty family members residing in the area may be eligible to enroll in TRICARE Prime Remote program under paragraph (g) of this section.

(2) *TRICARE Select.* TRICARE Select is the self-managed option under which beneficiaries may receive authorized basic program benefits from any TRICARE authorized provider. The TRICARE Select health care plan also provides enhanced program benefits to beneficiaries with access to a preferred-provider network with broad geographic availability within the United States at reduced out-of-pocket expenses. However, when a beneficiary receives services from an authorized health care provider who is not part of the TRICARE provider network, only basic program benefits (not enhanced Select care) are covered by TRICARE and the beneficiary is subject to higher cost sharing amounts for ''out-of-network'' care. Those amounts are the same as under the basic program under § 199.4.

(c) *Eligibility for enrollment in TRICARE Prime and TRICARE Select.* Beneficiaries in the active duty family category and the retired category are eligible to enroll in TRICARE Prime and/or TRICARE Select as outlined in this paragraph (c). A retiree or retiree family member who becomes eligible for Medicare Part A is not eligible to enroll in TRICARE Select; however, as provided in this paragraph (c), some Medicare eligible retirees/family members may be allowed to enroll in TRICARE Prime where available. In general, when a retiree or retiree family member becomes individually eligible for Medicare Part A and enrolls in Medicare Part B, he/she is automatically eligible for TRICARE-for-Life and is required to enroll in the Defense Enrollment Eligibility Reporting System (DEERS) to verify eligibility. Further,

some rules and procedures are different for dependents of active duty members and retirees, dependents, and survivors.

(1) *Active duty members.* Active duty members are required to enroll in Prime where it is offered. Active duty members shall have first priority for enrollment in Prime.

(2) *Dependents of active duty members.* Beneficiaries in the active duty family member category are eligible to enroll in Prime (where offered) or Select.

(3) *Survivors of deceased members.* (i) The surviving spouse of a member who dies while on active duty for a period of more than 30 days is eligible to enroll in Prime (where offered) or Select for a 3 year period beginning on the date of the member's death under the same rules and provisions as dependents of active duty members.

(ii) A dependent child or unmarried person (as described in §199.3(b)(2)(ii) or (iv)) of a member who dies while on active duty for a period of more than 30 days whose death occurred on or after October 7, 2001, is eligible to enroll in Prime (where offered) or Select and is subject to the same rules and provisions of dependents of active duty members for a period of three years from the date the active duty sponsor dies or until the surviving eligible dependent:

(A) Attains 21 years of age; or

(B) Attains 23 years of age or ceases to pursue a full-time course of study prior to attaining 23 years of age, if, at 21 years of age, the eligible surviving dependent is enrolled in a full-time course of study in a secondary school or in a full-time course of study in an institution of higher education approved by the Secretary of Defense and was, at the time of the sponsor's death, in fact dependent on the member for over one-half of such dependent's support.

(4) *Retirees, dependents of retirees, and survivors (other than survivors of deceased members covered under paragraph (c)(3) of this section).* All retirees, dependents of retirees, and survivors who are not eligible for Medicare Part A are eligible to enroll in Select. Additionally, retirees, dependents of retirees, and survivors who are not eligible for Medicare Part A based on age are also eligible to enroll in TRICARE Prime in locations where it is offered and where an MTF has, in the judgment of the Director, a significant number of health care providers, including specialty care providers, and sufficient capability to support the efficient operation of TRICARE Prime for projected retired beneficiary enrollees in that location.

(d) *Health benefits under TRICARE Prime*—(1) *Military treatment facility (MTF) care*—(i) *In general.* All participants in Prime are eligible to receive care in military treatment facilities. Participants in Prime will be given priority for such care over other beneficiaries. Among the following beneficiary groups, access priority for care in military treatment facilities where TRICARE is implemented as follows:

(A) Active duty service members;

(B) Active duty service members' dependents and survivors of service members who died on active duty, who are enrolled in TRICARE Prime;

(C) Retirees, their dependents and survivors, who are enrolled in TRICARE Prime;

(D) Active duty service members' dependents and survivors of deceased members, who are not enrolled in TRICARE Prime; and

(E) Retirees, their dependents and survivors who are not enrolled in TRICARE Prime. For purposes of this paragraph (d)(1), survivors of members who died while on active duty are considered as among dependents of active duty service members.

(ii) *Special provisions.* Enrollment in Prime does not affect access priority for care in military treatment facilities for several miscellaneous beneficiary groups and special circumstances. Those include Secretarial designees, NATO and other foreign military personnel and dependents authorized care through international agreements, civilian employees under workers' compensation programs or under safety programs, members on the Temporary Disability Retired List (for statutorily required periodic medical examinations), members of the reserve components not on active duty (for covered medical services), military prisoners, active duty dependents unable to enroll in Prime and temporarily

away from place of residence, and others as designated by the Assistant Secretary of Defense (Health Affairs). Additional exceptions to the normal Prime enrollment access priority rules may be granted for other categories of individuals, eligible for treatment in the MTF, whose access to care is necessary to provide an adequate clinical case mix to support graduate medical education programs or readiness-related medical skills sustainment activities, to the extent approved by the ASD(HA).

(2) *Non-MTF care for active duty members.* Under Prime, non-MTF care needed by active duty members continues to be arranged under the supplemental care program and subject to the rules and procedures of that program, including those set forth in §199.16.

(3) *Civilian sector Prime benefits.* Health benefits for Prime enrollees for care received from civilian providers are those under §199.4 and the additional benefits identified in paragraph (f) of this section.

(e) *Health benefits under the TRICARE Select plan*—(1) *Civilian sector care.* The health benefits under TRICARE Select for enrolled beneficiaries received from civilian providers are those under §199.4, and, in addition, those in paragraph (f) of this section when received from a civilian network provider.

(2) *Military treatment facility (MTF) care.* All TRICARE Select enrolled beneficiaries continue to be eligible to receive care in military treatment facilities on a space available basis.

(f) *Benefits under TRICARE Prime and TRICARE Select*—(1) *In general.* Except as specifically provided or authorized by this section, all benefits provided, and benefit limitations established, pursuant to this part, shall apply to TRICARE Prime and TRICARE Select.

(2) *Preventive care services.* Certain preventive care services not normally provided as part of basic program benefits under §199.4 are covered benefits when provided to Prime or Select enrollees by providers in the civilian provider network. Such additional services are authorized under 10 U.S.C. 1097, including preventive care services not part of the entitlement under 10 U.S.C. 1074d and services that would otherwise be excluded under 10 U.S.C. 1079(a)(10). Other authority for such additional services includes section 706 of the National Defense Authorization Act for Fiscal Year 2017. The specific set of such services shall be established by the Director and announced annually before the open season enrollment period. Standards for preventive care services shall be developed based on guidelines from the U.S. Department of Health and Human Services. Such standards shall establish a specific schedule, including frequency or age specifications for services that may include, but are not limited to:

(i) Laboratory and imaging tests, including blood lead, rubella, cholesterol, fecal occult blood testing, and mammography;

(ii) Cancer screenings (including cervical, breast, lung, prostate, and colon cancer screenings);

(iii) Immunizations;

(iv) Periodic health promotion and disease prevention exams;

(v) Blood pressure screening;

(vi) Hearing exams;

(vii) Sigmoidoscopy or colonoscopy;

(viii) Serologic screening; and

(ix) Appropriate education and counseling services. The exact services offered shall be established under uniform standards established by the Director.

(3) *Treatment of obesity.* Under the authority of 10 U.S.C. 1097 and sections 706 and 729 of the National Defense Authorization Act for Fiscal Year 2017, notwithstanding 10 U.S.C. 1079(a)(10), treatment of obesity is covered under TRICARE Prime and TRICARE Select even if it is the sole or major condition treated. Such services must be provided by a TRICARE network provider and be medically necessary and appropriate in the context of the particular patient's treatment.

(4) *High value services.* Under the authority of 10 U.S.C. 1097 and other authority, including sections 706 and 729 of the NDAA–17, for purposes of improving population-based health outcomes and incentivizing medical intervention programs to address chronic diseases and other conditions and healthy lifestyle interventions, the Director may waive or reduce cost sharing requirements for TRICARE Prime and TRICARE Select enrollees for care

received from network providers for certain health care services designated for this purpose. The specific services designated for this purpose will be those the Director determines provide especially high value in terms of better health outcomes. The specific services affected for any plan year will be announced by the Director prior to the open season enrollment period for that plan year. Services affected by actions of the Director under this paragraph (f)(4) may be associated with actions taken for high value medications under §199.21(j)(3) for select pharmaceutical agents to be cost-shared at a reduced or zero dollar rate.

(5) *Other services.* In addition to services provided pursuant to paragraphs (f)(2) through (4) of this section, other benefit enhancements may be added and other benefit restrictions may be waived or relaxed in connection with health care services provided to TRICARE Prime and TRICARE Select enrollees. Any such other enhancements or changes must be approved by the Director based on uniform standards.

(g) *TRICARE Prime Remote for Active Duty Family Members*—(1) *In general.* In geographic areas in which TRICARE Prime is not offered and in which eligible family members reside, there is offered under 10 U.S.C. 1079(p) TRICARE Prime Remote for Active Duty Family Members as an enrollment option. TRICARE Prime Remote for Active Duty Family Members (TPRADFM) will generally follow the rules and procedures of TRICARE Prime, except as provided in this paragraph (g) and otherwise except to the extent the Director determines them to be infeasible because of the remote area.

(2) *Active duty family member.* For purposes of this paragraph (g), the term ''active duty family member'' means one of the following dependents of an active duty member of the Uniformed Services:

(i) Spouse, child, or unmarried person, as defined in §199.3(b)(2)(i), (ii), or (iv);

(ii) For a 3-year period, the surviving spouse of a member who dies while on active duty for a period of more than 30 days whose death occurred on or after October 7, 2001; and

(iii) The surviving dependent child or unmarried person, as defined in §199.3(b)(2)(ii) or (iv), of a member who dies while on active duty for a period of more than 30 days whose death occurred on or after October 7, 2001. Active duty family member status is for a period of 3 years from the date the active duty sponsor dies or until the surviving eligible dependent:

(A) Attains 21 years of age; or

(B) Attains 23 years of age or ceases to pursue a full-time course of study prior to attaining 23 years of age, if, at 21 years of age, the eligible surviving dependent is enrolled in a full-time course of study in a secondary school or in a full-time course of study in an institution of higher education approved by the Secretary of Defense and was, at the time of the sponsor's death, in fact dependent on the member for over one-half of such dependent's support.

(3) *Eligibility.* (i) An active duty family member is eligible for TRICARE Prime Remote for Active Duty Family Members if he or she is eligible for CHAMPUS and, on or after December 2, 2003, meets the criteria of paragraphs (g)(3)(i)(A) and (B) or paragraph (g)(3)(i)(C) of this section or on or after October 7, 2001, meets the criteria of paragraph (g)(3)(i)(D) or (E) of this section:

(A) The family member's active duty sponsor has been assigned permanent duty as a recruiter; as an instructor at an educational institution, an administrator of a program, or to provide administrative services in support of a program of instruction for the Reserve Officers' Training Corps; as a full-time adviser to a unit of a reserve component; or any other permanent duty designated by the Director that the Director determines is more than 50 miles, or approximately one hour driving time, from the nearest military treatment facility that is adequate to provide care.

(B) The family members and active duty sponsor, pursuant to the assignment of duty described in paragraph (g)(3)(i)(A) of this section, reside at a location designated by the Director, that the Director determines is more than 50 miles, or approximately one hour driving time, from the nearest

military medical treatment facility adequate to provide care.

(C) The family member, having resided together with the active duty sponsor while the sponsor served in an assignment described in paragraph (g)(3)(i)(A) of this section, continues to reside at the same location after the sponsor relocates without the family member pursuant to orders for a permanent change of duty station, and the orders do not authorize dependents to accompany the sponsor to the new duty station at the expense of the United States.

(D) For a 3 year period, the surviving spouse of a member who dies while on active duty for a period of more than 30 days whose death occurred on or after October 7, 2001.

(E) The surviving dependent child or unmarried person as defined in §199.3(b)(2)(ii) or (iv), of a member who dies while on active duty for a period of more than 30 days whose death occurred on or after October 7, 2001, for three years from the date the active duty sponsor dies or until the surviving eligible dependent:

(*1*) Attains 21 years of age; or

(*2*) Attains 23 years of age or ceases to pursue a full-time course of study prior to attaining 23 years of age, if, at 21 years of age, the eligible surviving dependent is enrolled in a full-time course of study in a secondary school or in a full-time course of study in an institution of higher education approved by the Secretary of Defense and was, at the time of the sponsor's death, in fact dependent on the member for over one-half of such dependent's support.

(ii) A family member who is a dependent of a reserve component member is eligible for TRICARE Prime Remote for Active Duty Family Members if he or she is eligible for CHAMPUS and meets all of the following additional criteria:

(A) The reserve component member has been ordered to active duty for a period of more than 30 days.

(B) The family member resides with the member.

(C) The Director, determines the residence of the reserve component member is more than 50 miles, or approximately one hour driving time, from the nearest military medical treatment facility that is adequate to provide care.

(D) ''Resides with'' is defined as the TRICARE Prime Remote residence address at which the family resides with the activated reservist upon activation.

(4) *Enrollment.* TRICARE Prime Remote for Active Duty Family Members requires enrollment under procedures set forth in paragraph (o) of this section or as otherwise established by the Director.

(5) *Health care management requirements under TRICARE Prime Remote for Active Duty Family Members.* The additional health care management requirements applicable to Prime enrollees under paragraph (n) of this section are applicable under TRICARE Prime Remote for Active Duty Family Members unless the Director determines they are infeasible because of the particular remote location. Enrollees will be given notice of the applicable management requirements in their remote location.

(6) *Cost sharing.* Beneficiary cost sharing requirements under TRICARE Prime Remote for Active Duty Family Members are the same as those under TRICARE Prime under paragraph (m) of this section, except that the higher point-of-service option cost sharing and deductible shall not apply to routine primary health care services in cases in which, because of the remote location, the beneficiary is not assigned a primary care manager or the Director determines that care from a TRICARE network provider is not available within the TRICARE access standards under paragraph (p)(5) of this section. The higher point-of-service option cost sharing and deductible shall apply to specialty health care services received by any TRICARE Prime Remote for Active Duty Family Members enrollee unless an appropriate referral/preauthorization is obtained as required by paragraph (n) of this section under TRICARE Prime. In the case of pharmacy services under §199.21, where the Director determines that no TRICARE network retail pharmacy has been established within a reasonable distance of the residence of the TRICARE Prime Remote for Active Duty Family Members enrollee, cost

sharing applicable to TRICARE network retail pharmacies will be applicable to all CHAMPUS eligible pharmacies in the remote area.

(h) *Resource sharing agreements.* Under the TRICARE program, any military medical treatment facility (MTF) commander may establish resource sharing agreements with the applicable managed care support contractor for the purpose of providing for the sharing of resources between the two parties. Internal resource sharing and external resource sharing agreements are authorized. The provisions of this paragraph (h) shall apply to resource sharing agreements under the TRICARE program.

(1) In connection with internal resource sharing agreements, beneficiary cost sharing requirements shall be the same as those applicable to health care services provided in facilities of the uniformed services.

(2) Under internal resource sharing agreements, the double coverage requirements of §199.8 shall be replaced by the Third Party Collection procedures of 32 CFR part 220, to the extent permissible under such part. In such a case, payments made to a resource sharing agreement provider through the TRICARE managed care support contractor shall be deemed to be payments by the MTF concerned.

(3) Under internal or external resource sharing agreements, the commander of the MTF concerned may authorize the provision of services, pursuant to the agreement, to Medicare-eligible beneficiaries, if such services are not reimbursable by Medicare, and if the commander determines that this will promote the most cost-effective provision of services under the TRICARE program.

(4) Under external resource sharing agreements, there is no cost sharing applicable to services provided by military facility personnel. Cost sharing for non-MTF institutional and related ancillary charges shall be as applicable to services provided under TRICARE Prime or TRICARE Select, as appropriate.

(i) *General quality assurance, utilization review, and preauthorization requirements under the TRICARE program.* All quality assurance, utilization review, and preauthorization requirements for the basic CHAMPUS program, as set forth in this part (see especially applicable provisions in §§199.4 and 199.15), are applicable to Prime and Select except as provided in this chapter. Pursuant to an agreement between a military medical treatment facility and TRICARE managed care support contractor, quality assurance, utilization review, and preauthorization requirements and procedures applicable to health care services outside the military medical treatment facility may be made applicable, in whole or in part, to health care services inside the military medical treatment facility.

(j) *Pharmacy services.* Pharmacy services under Prime and Select are as provided in the Pharmacy Benefits Program (see §199.21).

(k) *Design of cost sharing structures under TRICARE Prime and TRICARE Select*—(1) *In general.* The design of the cost sharing structures under TRICARE Prime and TRICARE Select includes several major factors: beneficiary category (*e.g.*, active duty family member category or retired category, and there are some special rules for survivors of active duty deceased sponsors and medically retired members and their dependents); date of initial military affiliation (*i.e.*, before or on or after January 1, 2018), category of health care service received, and network or non-network status of the provider.

(2) *Categories of health care services.* This paragraph (k)(2) describes the categories of health care services relevant to determining copayment amounts.

(i) Preventive care visits. These are outpatient visits and related services described in paragraph (f)(2) of this section. There are no cost sharing requirements for preventive care listed under §§199.4(e)(28)(i) through (iv) and 199.17(f)(2). Beneficiaries shall not be required to pay any portion of the cost of these preventive services even if the beneficiary has not satisfied any applicable deductible for that year.

(ii) Primary care outpatient visits. These are outpatient visits, not occurring in an ER or urgent care center, with the following provider specialties:

(A) General Practice.

(B) Family Practice.

(C) Internal Medicine.

(D) OB/GYN.

(E) Pediatrics.

(F) Physician's Assistant.

(G) Nurse Practitioner.

(H) Nurse Midwife.

(iii) Specialty care outpatient visits. This category applies to outpatient care provided by provider specialties other than those listed under primary care outpatient visits under paragraph (k)(2)(ii) of this section and not specifically included in one of the other categories of care (*e.g.*, emergency room visits etc.) under paragraph (k)(2) of this section. This category also includes partial hospitalization services, intensive outpatient treatment, and opioid treatment program services. The per visit fee shall be applied on a per day basis on days services are received, with the exception of opioid treatment program services reimbursed in accordance with §199.14(a)(2)(ix)(A)(*3*)(*i*) which per visit fee will apply on a weekly basis.

(iv) Emergency room visits.

(v) Urgent care center visits.

(vi) Ambulance services. This is for ground ambulance services.

(vii) Ambulatory surgery. This is for facility-based outpatient ambulatory surgery services.

(viii) Inpatient hospital admissions.

(ix) Skilled nursing facility or rehabilitation facility admissions. This category includes a residential treatment center, or substance use disorder rehabilitation facility residential treatment program.

(x) Durable medical equipment, prosthetic devices, and other authorized supplies.

(xi) Outpatient prescription pharmaceuticals. These are addressed in §199.21.

(3) *Beneficiary categories further subdivided.* For purposes of both TRICARE Prime and TRICARE Select, enrollment fees and cost sharing by beneficiary category (*e.g.*, active duty family member category or retired category) are further differentiated between two groups:

(i) Group A consists of Prime or Select enrollees whose sponsor originally enlisted or was appointed in a uniformed service before January 1, 2018.

(ii) Group B consists of Prime or Select enrollees whose sponsor originally enlisted or was appointed in a uniformed service on or after January 1, 2018.

(l) *Enrollment fees and cost sharing (including deductibles and catastrophic cap) amounts.* This paragraph (l) provides enrollment fees and cost sharing requirements applicable to TRICARE Prime and TRICARE Select enrollees.

(1) *Enrollment fee and cost sharing under TRICARE Prime.* (i) For Group A enrollees:

(A) There is no enrollment fee for the active duty family member category.

(B) The retired category enrollment fee in calendar year 2018 is equal to the Prime enrollment fee for fiscal year 2017, indexed to calendar year 2018 and thereafter in accordance with 10 U.S.C. 1097. The Assistant Secretary of Defense (Health Affairs) may exempt survivors of active duty deceased sponsors and medically retired Uniformed Services members and their dependents from future increases in enrollment fees. The Assistant Secretary of Defense (Health Affairs) may also waive the enrollment fee requirements for Medicare-eligible beneficiaries.

(C) The cost sharing amounts are established annually in connection with the open season enrollment period. An amount is established for each category of care identified in paragraph (k)(2) of this section, taking into account all applicable statutory provisions, including 10 U.S.C. chapter 55. The amount for each category of care may not exceed the amount for Group B as set forth in 10 U.S.C. 1075a.

(D) The catastrophic cap is $1,000 for active duty families and $3,000 for retired category families.

(ii) For Group B TRICARE Prime enrollees, the enrollment fee, catastrophic cap, and cost sharing amounts are as set forth in 10 U.S.C. 1075a. The cost sharing requirements applicable to services not specifically addressed in the table set forth in 10 U.S.C. 1075a(b)(1) shall be determined by the Director, DHA.

(iii) For both Group A and Group B, for health care services obtained by a Prime enrollee but not obtained in accordance with the rules and procedures

of Prime (*e.g.* failure to obtain a primary care manager referral when such a referral is required or seeing a non-network provider when Prime rules require use of a network provider and one is available) will not be paid under Prime rules but may be covered by the point-of-service option. For services obtained under the point-of-service option, 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. Point-of-service charges do not count against the annual catastrophic cap.

(2) *Enrollment fee and cost sharing under TRICARE Select.* (i) For Group A enrollees:

(A) The enrollment fee in calendar years 2018 through 2020 is zero and the catastrophic cap is as provided in 10 U.S.C. 1079 or 1086. The enrollment fee and catastrophic cap in 2021 and thereafter for certain beneficiaries in the retired category is as provided in 10 U.S.C. 1075(e), except the enrollment fee and catastrophic cap adjustment shall not apply to survivors of active duty deceased sponsors and medically retired Uniformed Services members and their dependents. Payment of TRICARE premiums and enrollment fees will be withheld from the retired, retainer or equivalent pay of these beneficiaries in the retired category to the maximum extent practicable upon complete implementation of this rule and thereafter. Appropriate processes to require and manage these allotments, to include frequency and method, as well as alternatives when allotments are not practicable, shall be determined by the Director, DHA. An exception may be made for certain survivors of active duty deceased sponsors and medically retired Uniformed Services members and their dependents, for which the enrollment fee and catastrophic cap adjustments shall not apply.

(B) The cost sharing amounts for network care for Group A enrollees are calculated for each category of care described in paragraph (k)(2) of this section by taking into account all applicable statutory provisions, including 10 U.S.C. chapter 55, as if TRICARE Extra and Standard programs were still being implemented. When determined practicable, including efficiency and effectiveness in administration, the amounts established are converted to fixed dollar amounts for each category of care for which a fixed dollar amount is established by 10 U.S.C. 1075. When determined not to be practicable, as in the categories of care including ambulatory surgery, inpatient admissions, and inpatient skilled nursing/rehabilitation admissions, the calculated cost-sharing amounts are not converted to fixed dollar amounts. The fixed dollar amount for each category is set prospectively for each calendar year as the amount (rounded down to the nearest dollar amount) equal to 15% for enrollees in the active duty family beneficiary category or 20% for enrollees in the retired beneficiary category of the projected average allowable payment amount for each category of care during the year, as estimated by the Director. The projected average allowable payment amount for primary care (including urgent care) and specialty care outpatient appointments include payments for ancillary services (*e.g.*, laboratory and radiology services) that are provided in connection with the respective outpatient visit. As such, there is no separate cost sharing for these ancillary services.

(C) The cost share for care received from non-network providers is as provided in § 199.4.

(D) The annual deductible amount is as provided in 10 U.S.C. 1079 or 1086.

(ii) For Group B TRICARE Select enrollees, the enrollment fee, annual deductible for services received while in an outpatient status, catastrophic cap., and cost sharing amounts are as provided in 10 U.S.C. 1075 and as consistent with this section. The cost sharing requirements applicable to services not specifically addressed in 10 U.S.C. 1075 shall be determined by the Director, DHA.

(3) *Special cost-sharing rules.* (i) There is no separate cost-sharing applicable to ancillary health care services obtained in conjunction with an outpatient primary or specialty care visit under TRICARE Prime or from network providers under TRICARE Select.

(ii) Cost-sharing for maternity care services shall be determined in accordance with §199.4(e)(16).

(iii) Cost-sharing and copayments (including deductibles) shall be waived for in-network telehealth services during the national emergency for the global coronavirus 2019 (COVID–19) pandemic. This temporary waiver provision terminates July 1, 2022 or the date of termination of the President's declared national emergency for COVID–19, whichever is earlier.

(4) *Special transition rule for the last quarter of calendar year 2017.* In order to transition enrollment fees, deductibles, and catastrophic caps from a fiscal year basis to a calendar year basis, the following special rules apply for the last quarter of calendar year 2017:

(A) A Prime enrollee's enrollment fee for the quarter is one-fourth of the enrollment fee for fiscal year 2017.

(B) The deductible amount and the catastrophic cap amount for fiscal year 2017 will be applicable to the 15-month period of October 1, 2016 through December 31, 2017.

(m) *Limit on out-of-pocket costs under TRICARE Prime and TRICARE Select.* For the purpose of this paragraph (m), out-of-pocket costs means all payments required of beneficiaries under paragraph (l) of this section, including enrollment fees, deductibles, and cost-sharing amounts, with the exception of point-of-service charges. In any case in which a family reaches their applicable catastrophic cap, all remaining payments that would have been required of the beneficiary under paragraph (l) of this section for authorized care, with the exception of applicable point-of-service charges pursuant to paragraph (l)(1)(iii) of this section, will be paid by the program for the remainder of that calendar year.

(n) *Additional health care management requirements under TRICARE Prime.* Prime has additional, special health care management requirements not applicable under TRICARE Select.

(1) *Primary care manager.* (i) All active duty members and Prime enrollees will be assigned a primary care manager pursuant to a system established by the Director, 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 Director. This preference will be entered on a TRICARE Prime enrollment form or similar document. Preference requests will be considered, but primary care manager assignments will be subject to availability under the MTF beneficiary category priority system under paragraph (d) of this section and subject to other operational requirements. (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) *Referral and preauthorization requirements.* (i) Under TRICARE Prime there are certain procedures for referral and preauthorization.

(A) For the purpose of this paragraph (n)(2), referral addresses the issue of who will provide authorized health care services. In many cases, Prime beneficiaries will be referred by a primary care manager to a medical department of an MTF if the type of care needed is available at the MTF. In such a case, failure to adhere to that referral will result in the care being subject to point-of-service charges. In other cases, a referral may be to the civilian provider network, and again, point-of-service charges would apply to a failure to follow the referral.

(B) In contrast to referral, preauthorization addresses the issue of whether particular services may be covered by TRICARE, including whether they appear necessary and appropriate in the context of the patient's diagnosis and circumstances. A major purpose of preauthorization is to prevent surprises about coverage determinations, which are sometimes dependent on particular details regarding the patient's condition and circumstances. While TRICARE Prime has referral requirements that do not exist for TRICARE Select, TRICARE

Select has some preauthorization requirements that do not exist for TRICARE Prime.

(ii) Except as otherwise provided in this paragraph (n)(2), a beneficiary enrolled in TRICARE Prime is required to obtain a referral for care through a designated primary care manager (or other authorized care coordinator) prior to obtaining care under the TRICARE program.

(iii) There is no referral requirement under paragraph (n)(2)(i) of this section in the following circumstances:

(A) In emergencies;

(B) For urgent care services for a certain number of visits per year (zero to unlimited), with the number specified by the Director and notice provided in connection with the open season enrollment period preceding the plan year; and

(C) In any other special circumstances identified by the Director, generally with notice provided in connection with the open season enrollment period for the plan year.

(iv) A primary care manager who believes a referral to a specialty care provider is medically necessary and appropriate need not obtain pre-authorization from the managed care support contractor before referring a patient to a network specialty care provider. Such preauthorization is only required with respect to a primary care manager's referral for:

(A) Inpatient hospitalization;

(B) Inpatient care at a skilled nursing facility;

(C) Inpatient care at a rehabilitation facility; and

(D) Inpatient care at a residential treatment facility.

(v) The restrictions in paragraph (n)(2)(iv) of this section on preauthorization requirements do not apply to any preauthorization requirements that are generally applicable under TRICARE, independent of TRICARE Prime referrals, such as:

(A) Under the Pharmacy Benefits Program under 10 U.S.C. 1074g and §199.21.

(B) For laboratory and other ancillary services.

(C) Durable medical equipment.

(vi) The cost-sharing requirement for a beneficiary enrolled in TRICARE Prime who does not obtain a referral for care when it is required, including care from a non-network provider, is as provided in paragraph (l)(1)(iii) of this section concerning point of service care.

(vii) In the case of care for which preauthorization is not required under paragraph (n)(2)(iv) of this section, the Director may authorize a managed care support contractor to offer a voluntary pre-authorization program to enable beneficiaries and providers to confirm covered benefit status and/or medical necessity or to understand the criteria that will be used by the managed care support contractor to adjudicate the claim associated with the proposed care. A network provider may not be required to use such a program with respect to a referral.

(3) *Restrictions on the use of providers.* The requirements of this paragraph (n)(3) shall be applicable to health care utilization under TRICARE Prime, except in cases of emergency care and under point-of-service option (see paragraph (n)(4) 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 otherwise authorized.

(ii) For any necessary specialty care and non-emergent inpatient care, the primary care manager or other authorized individual will assist in making an appropriate referral.

(iii) 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.

(iv) The following procedures will apply to health care referrals 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)(3)(iv)(A) through (D) of this section, the enrollee will receive authorization to obtain services from a TRICARE-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)(3)(iv)(B) through (E) of this section shall apply.

(4) *Point-of-service option.* TRICARE Prime enrollees retain the freedom to obtain services from civilian providers on a point-of service basis. Any health care services obtained by a Prime enrollee, but not obtained in accordance with the rules and procedures of Prime, will be covered by the point-of-service option. In such cases, all requirements applicable to health benefits under §199.4 shall apply, except that there shall be higher deductible and cost sharing requirements (as set forth in paragraph (l)(1)(iii)) 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.

(5) *Prime travel benefit.* In accordance with guidelines issues by the Assistant Secretary of Defense (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. Such guidelines shall be consistent with appropriate provisions of generally applicable Department of Defense rules and procedures governing travel expenses.

(o) *TRICARE program enrollment procedures.* There are certain requirements pertaining to procedures for enrollment in TRICARE Prime, TRICARE Select, and TRICARE Prime Remote for Active Duty Family Members. (These procedures do not apply to active duty members, whose enrollment is mandatory and automatic.)

(1) *Annual open season enrollment.* (i) As a general rule, enrollment (or a modification to a previous enrollment) must occur during the open season period prior to the plan year, which is on a calendar year basis. The open season enrollment period will be of at least 30 calendar days duration. An enrollment choice will be applicable for the plan year.

(ii) Open season enrollment procedures may include automatic re-enrollment in the same plan for the next plan year for enrollees or sponsors that will occur in the event the enrollee does not take other action during the open season period.

(2) *Exceptions to the calendar year enrollment process.* The Director will identify certain qualifying events that may be the basis for a change in enrollment status during a plan year, such as a change in eligibility status, marriage, divorce, birth of a new family member,

relocation, loss of other health insurance, or other events. In the case of such an event, a beneficiary eligible to enroll in a plan may newly enroll, disenroll, or modify a previous enrollment during the plan year. Initial payment of the applicable enrollment fee shall be collected for new enrollments in accordance with established procedures. Any applicable enrollment fee will be pro-rated. A beneficiary who dis-enrolls without enrolling at the same time in another plan is not eligible to enroll in a plan later in the same plan year unless there is another qualifying event. A beneficiary who is dis-enrolled for failure to pay a required enrollment fee installment is not eligible to re-enroll in a plan later in the same plan year unless there is another qualifying event. Generally, the effective date of coverage will coincide with the date of the qualifying event.

(3) *Installment payments of enrollment fee.* The Director will establish procedures for installment payments of enrollment fees.(4) *Effect of failure to enroll.* Beneficiaries eligible to enroll in Prime or Select and who do not enroll will no longer have coverage under the TRICARE program until the next annual open season enrollment or they have a qualifying event, except that they do not lose any statutory eligibility for space-available care in military medical treatment facilities. There is a limited grace period exception to this enrollment requirement for calendar year 2018, as provided in section 701(d)(3) of the National Defense Authorization Act for Fiscal Year 2017.

(5) *Automatic enrollment for certain dependents.* Under 10 U.S.C. 1097a, in the case of dependents of active duty members in the grade of E–1 to E–4, such dependents who reside in a catchment area of a military treatment facility shall be enrolled in TRICARE Prime. The Director may provide for the automatic enrollment in TRICARE Prime for such dependents of active duty members in the grade of E–5 and higher. In any case of automatic enrollment under this paragraph (o)(5), the member will be provided written notice and the automatic enrollment may be cancelled at the election of the member.

(6) *Grace periods.* The Director may make provisions for grace periods for enrollment-related actions to facilitate effective operation of the enrollment program.

(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. 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.

(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 and provider agreement.

(4) *Provider qualifications.* All preferred providers must meet the following qualifications:

(i) They must be TRICARE-authorized providers and TRICARE- participating providers. In addition, a network provider may not require payment from the beneficiary for any excluded or excludable services that the beneficiary received from the network provider (*i.e.*, the beneficiary will be held harmless) except as follows:

(A) If the beneficiary did not inform the provider that he or she was a TRICARE beneficiary, the provider may bill the beneficiary for services provided.

(B) If the beneficiary was informed in writing that the specific services were excluded or excludable from TRICARE coverage and the beneficiary agreed in writing, in advance of the services being provided, to pay for the services, the provider may bill the beneficiary.

(ii) All physicians in the preferred provider network must have staff privileges in a hospital accredited by The Joint Commission (TJC) or other accrediting body determined by the Director. 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 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 Director.

(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 who not eligible to be participating providers under Medicare.

(v) The network provider must be available to all TRICARE beneficiaries.

(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, Select 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.

(viii) In locations where TRICARE Prime is not available, a TRICARE provider network will, to the extent practicable, be available for TRICARE Select enrollees. In these locations, the minimal requirements for network participation are those set forth in paragraph (p)(4)(i) of this section. Other requirements of this paragraph (p) will apply unless waived by the Director.

(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 (when applicable), can adequately address the health care needs of the enrollees. In the event that a Prime enrollee seeks to obtain from the managed care support contractor an appointment for care but is not offered an appointment within the access time standards from a network provider, the enrollee will be authorized to receive care from a non-network provider without incurring the additional fees associated with point-of-service care. The following are the access standards:

(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 non-emergency 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, may establish, for preferred provider networks, reimbursement rates and methods different from those established pursuant to §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.

(q) *Preferred provider network establishment.* (1) The any qualified provider method may be used to establish a civilian preferred provider network. Under this method, any TRICARE-authorized provider that meets the qualification standards established by the Director, or designee, 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:

(i) The provider must meet all applicable requirements in paragraph (p)(4) of this section.

(ii) The provider must agree to follow all quality assurance and utilization management procedures established pursuant to this section.

(iii) The provider must be a participating provider under TRICARE for all claims.

(iv) The provider must meet all other qualification requirements, and agree to all other rules and procedures, that are established, publicly announced, and uniformly applies by the Director (or other authorized official).

(v) 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 Director (or other authorized official) upon appropriate notice to the other party. The Director shall establish an agreement model or other guidelines to promote uniformity in the agreements.

(2) In addition to the above requirements, the Director, or designee, may establish additional categories of preferred providers of high quality/high value that require additional qualifications.

(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 (see especially applicable provisions of §199.9) are applicable to the TRICARE program.

(s) [Reserved]

(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, or designated TRICARE contractor.

(u) *Care provided outside the United States.* The TRICARE program is not automatically implemented in all respects outside the United States. This paragraph (u) sets forth the provisions of this section applicable to care received outside the United States under the following TRICARE health plans.

(1) *TRICARE Prime.* The Director may, in conjunction with implementation of the TRICARE program, authorize a special Prime program for command sponsored dependents of active duty members who accompany the members in their assignments in foreign countries. Under this special program, a preferred provider network may be established through contracts or agreements with selected health care providers. Under the network,

Prime covered services will be provided to the enrolled covered dependents subject to applicable Prime deductibles, copayments, and point-of-service charges. To the extent practicable, rules and procedures applicable to TRICARE Prime under this section shall apply unless specific exemptions are granted in writing by the Director. The use of this authority by the Director for any particular geographical area will be published on the primary publicly available Internet Web site of the Department and on the publicly available Internet Web site of the managed care support contractor that has established the provider network under the TRICARE program. Published information will include a description of the preferred provider network program and other pertinent information. The Director shall also issue policies, instructions, and guidelines necessary to implement this special program.

(2) *TRICARE Select.* The TRICARE Select option shall be available outside the United States except that a preferred provider network of providers shall only be established in areas where the Director determines that it is economically in the best interest of the Department of Defense. In such a case, the Director shall establish a preferred provider network through contracts or agreements with selected health care providers for eligible beneficiaries to receive covered benefits subject to the enrollment and cost-sharing amounts applicable to the specific category of beneficiary. When an eligible beneficiary, other than a TRICARE for Life beneficiary, receives covered services from an authorized TRICARE non-network provider, including in areas where a preferred provider network has not been established by the Director, the beneficiary shall be subject to cost-sharing amounts applicable to out-of-network care. To the extent practicable, rules and procedures applicable to TRICARE Select under this section shall apply unless specific exemptions are granted in writing by the Director. The use of this authority by the Director to establish a TRICARE preferred provider network for any particular geographical area will be published on the primary publicly available Internet Web site of the Department and on the publicly available Internet Web site of the managed care support contractor that has established the provider network under the TRICARE program. Published information will include a description of the preferred provider network program and other pertinent information. The Director shall also issue policies, instructions, and guidelines necessary to implement this special program.

(3) *TRICARE for Life.* The TRICARE for Life (TFL) option shall be available outside the United States. Eligible TFL beneficiaries may receive covered services and supplies authorized under §199.4, subject to the applicable catastrophic cap, deductibles and cost-shares under §199.4, whether received from a network provider or any authorized TRICARE provider not in a preferred provider network. However, if a TFL beneficiary receives covered services from a PPN provider, the beneficiary's out-of-pocket costs will generally be lower.

(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, 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.

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§ 199.18 [Reserved]

§ 199.20 Continued Health Care Benefit Program (CHCBP).

(a) *Purpose.* The CHCBP is a premium-based temporary health care coverage program, authorized by 10 U.S.C. 1078a, and available to individuals who meet the eligibility and enrollment criteria as set forth in paragraph (d)(1) of this section. The CHCBP is not part of the TRICARE program. However, as set forth in this section, it functions under similar rules and procedures to the TRICARE Select program. Because the purpose of the CHCBP is to provide a continuation health care benefit for Department of Defense and the other uniformed services beneficiaries losing eligibility, it will be administered so that it appears, to the maximum extent practicable, to be part of the TRICARE Select program. Medical coverage under this program will be the same as the benefits payable under the TRICARE Select program. There is a cost for enrollment to the CHCBP and these premium costs must be paid by CHCBP enrollees before any care may be cost shared.

(b) *General provisions.* Except for any provisions the Director of the TRICARE Management Activity may exclude, the general provisions of §199.1 shall apply to the CHCBP as they do to TRICARE.

(c) *Definitions.* Except as may be specifically provided in this section, to the extent terms defined in §199.2 are relevant to the administration of the CHCBP, the definitions contained in that section shall apply to the CHCBP as they do to the TRICARE Select program.

(d) *Eligibility and enrollment.* (1) *Eligibility*, Enrollment in the CHCBP is open to any individual, except as noted in this section, who:

(i) Ceases to meet the requirements for eligibility under 10 U.S.C. chapter 55 or 10 U.S.C. 1145, and

(ii) Who on the day before they cease to meet the eligibility requirements for such care they were covered under a health benefit plan under 10 U.S.C. chapter 55 or transitional healthcare under 10 U.S.C. 1145, and

(iii) Who would otherwise not be eligible for any benefits under 10 U.S.C. chapter 55 or 10 U.S.C. 1145 except for CHCBP.

(2) *Exceptions.* The following individuals are not eligible to enroll in CHCBP:

(i) Members of uniformed services, who are discharged or released from active duty either voluntarily or involuntarily under conditions that are adverse.

(ii) Individuals who lost their eligibility or entitlement to care under 10 U.S.C. chapter 55 or 10 U.S.C. 1145 before October 1, 1994.

(iii) Individuals who are locked out of other TRICARE programs per that program's requirements.

(3) *Effective date.* Eligibility in the CHCBP is limited to individuals who lost their entitlement to benefits under the MHS on or after October 1, 1994. The effective date of their coverage under CHCBP shall begin on the day after they cease to be eligible for care under 10 U.S.C. chapter 55 or 10 U.S.C. 1145.

(4) *Notification of eligibility.*

(i) The Department of Defense and the other uniformed services (National Oceanic and Atmospheric Administration (NOAA), Public Health Service (PHS), and Coast Guard) will notify persons in the uniformed services eligible to receive health benefits under the CHCBP. In the case of a member who becomes (or will become) eligible for continued coverage, the Department of Defense shall notify the member of their rights for coverage as part of preseparation counseling conducted under 10 U.S.C. 1142.

(ii) In the case of a dependent of a member or former member who become eligible for continued coverage under paragraph (d)(1)(ii) of this section:

(A) The member or former member may submit to the CHCBP contractor a notice with supporting documentation of the dependent's change in status (including the dependent's name, address, and such other information needed); and

(B) The CHCBP contractor, within fourteen (14) days after receiving such information, will inform the dependent of the dependent's rights under 10 U.S.C. 1142.

(iii) In the case of a former spouse of a member or former member who becomes eligible for continued coverage, the member, former member or former spouse may submit to the CHCBP contractor a notice of the former spouse's change in status. The CHCBP contractor within fourteen (14) days after receiving such information will notify the individual of their potential eligibility for CHCBP.

(5) *Election of coverage.* In order to obtain coverage under the CHCBP, a written election by the eligible beneficiary must be made within a prescribed time period.

(i) In the case of a member discharged or released from active duty or full-time National Guard duty (whether voluntarily or involuntarily), or a RC member formerly eligible for care under 10 U.S.C. chapter 55, the written election shall be submitted to the CHCBP contractor before the end of the 60-day period beginning on the later of:

(A) The date of the discharge or release of the member; or

(B) The date that the period of transitional health care applicable to the member under 10 U.S.C. 1145(a) ends; or

(C) The date the member receives the notification required in paragraph (d)(3) of this section.

(ii) In the case of a child who ceases to meet the requirements for being an unremarried dependent child of a member or former member under 10 U.S.C. 1072(2)(D) or an unmarried dependent of a member or former member of the uniformed services under 10 U.S.C. 1072(2)(I), the written election shall be submitted to the CHCBP contractor before the end of the 60-day period beginning on the later of:

(A) The date that the dependent ceases to meet the definition of a dependent under 10 U.S.C. 1072(2)(D) or 10 U.S.C. 1072(2)(I); or

(B) The date that the dependent receives the notification required in paragraph (d)(3) of this section,

(iii) In the case of former spouse of a member or former member, the written election shall be submitted to the CHCBP contractor before the end of the 60-day period beginning on the date as of which the former spouse first ceases to meet the requirements for being considered a dependent under 10 U.S.C. 1072(2).

(iv) In the case of an unmarried surviving spouse of a member or former member of the uniformed services who on the day before the death of the member or former member was covered under 10 U.S.C. chapter 55 or 10 U.S.C. 1145(a), the written election shall be submitted to the CHCBP contractor within 60 days of the date of the member or former member's death.

(v) A member of the uniformed services who is eligible for enrollment under paragraph (d)(1) of this section may elect self-only or family coverage. Family members who may be included in such family coverage are the spouse and children of the member.

(vi) All other categories eligible for enrollment under paragraph (d)(1) of this section must elect self-only coverage.

(6) *Enrollment.* To enroll in the CHCBP, an eligible individual must submit the completed enrollment form designated by the Director, TRICARE as well as any documentation as requested on the enrollment form to verify the applicant's eligibility for enrolling in CHCBP, and payment to cover the quarter's premium. The CHCBP contractor may request additional information and documentation to confirm the applicant's eligibility for CHCBP.

(7) *Period of coverage.* Except as noted below CHCBP coverage may not extend beyond 18 months from the date the individual becomes eligible for CHCBP. Although beneficiaries have sixty (60) days to elect coverage under the CHCBP, upon enrolling, the period of coverage must begin the day after entitlement or eligibility to a military health care plan ends as though no break in coverage had occurred notwithstanding the date the enrollment form with any applicable premium is submitted.

(i) Exceptions:

(A) In the case of a child of a member or former member, the date which is 36 months after the date on which the person first ceases to meet the requirements for being considered an unmarried dependent child under 10 U.S.C. 1072(2)(D) or 10 U.S.C. 1072(2)(I).

(B) In the case of an unremarried former spouse (as this term is defined in 10 U.S.C. 1072(2)(G) or (H)) of a member or former member, the date which is 36 months after the later of:

(*1*) The date on which the final decree of divorce, dissolution, or annulment occurs; or

(*2*) If applicable, the date the one-year extension of dependency under 10 U.S.C. 1072(2)(H) expires.

(C) In the case of an unremarried surviving spouse (widow or widower) (under 10 U.S.C. 1072(2)(B) or (C)) of a member or former member of the uniformed services who is not otherwise eligible for care under 10 U.S.C. chapter 55, the date which is 36 months after the date the surviving spouse becomes ineligible under 10 U.S.C chapter 55 or 10 U.S.C. 1145(a).

(D) In the case of a former spouse of a member or former member (other than the former spouse whose marriage was dissolved after the separation of the member from the service unless such separation was by retirement), the period of coverage under the CHCBP is unlimited, if former spouse:

(*1*) Has not remarried before age of 55 after the marriage to the member or former member was dissolved; and

(*2*) Was eligible for TRICARE as a dependent or enrolled in CHCBP at any time during the 18 month period before the date of the divorce, dissolution, or annulment; and

(*3*) Is receiving a portion of the retired or retainer pay of a member or former member or an annuity based on the retainer pay of the member; or

(*4*) Has a court order for payment of any portion of the retired or retainer pay or has a written agreement (whether voluntary or pursuant to a court order) which provides for an election by the member or former member to provide an annuity to the former spouse.

(E) For the beneficiary who becomes eligible for the CHCBP by ceasing to meet the requirements for being considered an unmarried dependent child of a member or former member, health care coverage may not extend beyond the date which is 36 months after the date the member becomes ineligible for medical and dental care under 10 U.S.C. 1074(a) and any transitional health care under 10 U.S.C. 1145(a).

(e) *CHCBP benefits*—(1) *In general*. Except as provided in paragraph (e)(2) of this section, the provisions of §199.4 shall apply to the CHCBP as they do to TRICARE Select under §199.17.

(2) *Exceptions*. The following provisions of §199.4 are not applicable to the CHCBP:

(i) Section 199.4(a)(2) concerning eligibility.

(ii) All provisions regarding requirements to use facilities of the uniformed services because CHCBP enrollees are not eligible to use those facilities.

(3) *Beneficiary liability*. For purposes of CHCBP coverage, the beneficiary deductible, catastrophic cap and cost share provisions of the TRICARE Select plan applicable to Group B beneficiaries under §199.17(l)(2)(ii) shall apply based on the category of beneficiary (*e.g.*, Active Duty Family Member or Retiree Family) to which the CHCBP enrollee last belonged, except that for separating active duty members, amounts applicable to TRICARE Select Active Duty Family Members shall apply. The premium under paragraph (q) of this section applies instead of any TRICARE Select plan enrollment fee under §199.17.

(f) *Authorized providers*. The provisions of §199.6 shall apply to the CHCBP as they do to TRICARE Select program.

(g) *Claims submission, review, and payment*. The provisions of §199.7 shall apply to the CHCBP as they do to TRICARE Select program except no provisions regarding nonavailability statements shall apply.

(h) *Double coverage*. The provisions of §199.8 shall apply to the CHCBP as they do to TRICARE Select program.

(i) *Administrative remedies for fraud, abuse, and conflict of interest*. The provisions of §199.9 shall apply to the CHCBP as they do to TRICARE Select program.

(j) *Appeal and hearing procedures*. The provisions of §199.10 shall apply to the CHCBP as they do to TRICARE Select program.

(k) *Overpayments recovery*. The provisions of §199.11 shall apply to the CHCBP as they do to TRICARE Select program.

(l) *Third party recoveries.* The provisions of §199.12 shall apply to the CHCBP as they do to TRICARE Select program.

(m) *Provider reimbursement methods.* The provisions of §199.14 shall apply to the CHCBP as they do to TRICARE Select program.

(n) *Quality and Utilization Review Peer Review Organization Program.* The provisions of §199.15 shall apply to the CHCBP as they do to TRICARE Select program.

(o) [Reserved]

(p) *Special programs not applicable*—(1) *In general.* Special programs established under this part that are not part of the TRICARE Select program are not, unless specifically provided in this section, available to participants in the CHCBP.

(2) *Examples.* The special programs referred to in paragraph (p)(1) of this section include but are not limited to:

(i) The Extended Care Health Option under §199.5;

(ii) The TRICARE Dental Program or Retiree Dental Program under §199.13 and 199.22 respectively;

(iii) The Supplemental Health Care Program under §199.16; and

(iv) The TRICARE Prime Program under §199.17.

(q) *Premiums*—(1) *Rates.* Premium rates will be established by the Assistant Secretary of Defense (Health Affairs) for two rate groups—individual and family. Eligible beneficiaries will select the level of coverage they require at the time of initial enrollment (either individual or family) and pay the appropriate premium payment. The rates are based on Federal Employees Health Benefits Program employee and agency contributions required for a comparable health benefits plan, plus an administrative fee. The administrative fee, not to exceed ten percent of the basic premium amount, shall be determined based on actual expected administrative costs for administration of the program. Premiums may be revised annually and shall be published when the premium amount is changed. Premiums will be paid by enrollees quarterly.

(2) *Effects of failure to make premium payments.* Failure by enrollees to submit timely and proper premium payments will result in denial of continued enrollment and denial of payment of medical claims. Premium payments that are late thirty (30) days or more past the start of the quarter for which payment is due will result in the termination of beneficiary enrollment. Beneficiaries denied continued enrollment due to lack of premium payments will not be allowed to reenroll. In such a case, benefit coverage will cease at the end of the ninety (90) day period for which a premium payment was received. Enrollees will be held liable for medical costs incurred after losing eligibility.

(r) *Procedures.* The Director, TRICARE Management Activity, may establish other rules and procedures for the administration of the CHCBP.

[76 FR 57639, Sept. 16, 2011, as amended at 82 FR 45457, Sept. 29, 2017]

§199.21 TRICARE Pharmacy Benefits Program.

(a) General—(1) *Statutory authority.* Title 10, U.S. Code, Section 1074g requires that the Department of Defense establish an effective, efficient, integrated pharmacy benefits program for the Military Health System. This law is independent of a number of sections of Title 10 and other laws that affect the benefits, rules, and procedures of TRICARE, resulting in changes to the rules otherwise applicable to TRICARE Prime, Standard, and Extra.

(2) *Pharmacy benefits program.* (i) *Applicability.* The pharmacy benefits program, which includes the uniform formulary and its associated tiered copayment structure, is applicable to all of the uniformed services. Geographically, except as specifically provided in paragraph (a)(2)(ii) of this section, this program is applicable to all 50 states and the District of Columbia, Guam, Puerto Rico, and the Virgin Islands. In addition, if authorized by the Assistant Secretary of Defense (Health Affairs) (ASD(HA)), the TRICARE pharmacy benefits program may be implemented in areas outside the 50 states and the District of Columbia, Guam, Puerto Rico, and the Virgin Islands. In such case, the ASD (HA) may also authorize modifications to the pharmacy benefits program rules and procedures as may be appropriate to the area involved.

(ii) *Applicability exception*. The pharmaceutical benefit under the TRICARE smoking cessation program under §199.4(e)(30) is available to TRICARE beneficiaries who are not entitled to Medicare benefits authorized under Title XVIII of the Social Security Act. Except as noted in §199.4(e)(30), the smoking cessation program, including the pharmaceutical benefit, is not applicable or available to beneficiaries who reside overseas, including the U. S. territories of Guam, Puerto Rico, and the Virgin Islands, except that under the authority of §199.17 active duty service members and active duty dependents enrolled in TRICARE Prime residing overseas, including the U. S. territories of Guam, Puerto Rico, and the Virgin Islands, shall have access to smoking cessation pharmaceuticals through either an MTF or the TMOP program where available.

(3) *Uniform formulary*. The pharmacy benefits program features a uniform formulary of pharmaceutical agents as defined in §199.2.

(i) The uniform formulary will assure the availability of pharmaceutical agents in the complete range of therapeutic classes authorized as basic program benefits.

(ii) As required by 10 U.S.C. 1074g(a)(2) and implemented under the procedures established by paragraphs (e) and (f) of this section, pharmaceutical agents in each therapeutic class are selected for inclusion on the uniform formulary based upon the relative clinical effectiveness and cost effectiveness of the agents in such class. If a pharmaceutical agent in a therapeutic class is determined by the Department of Defense Pharmacy and Therapeutics Committee not to have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome over other pharmaceutical agents included on the uniform formulary, the Committee may recommend it be classified as a non-formulary agent. In addition, if the evaluation by the Pharmacy and Therapeutics Committee concludes that a pharmaceutical agent in a therapeutic class is not cost effective relative to other pharmaceutical agents in that therapeutic class, considering costs, safety, effectiveness, and clinical outcomes, the Committee may recommend it be classified as a non-formulary agent.

(iii) Pharmaceutical agents which are used exclusively in medical treatments or procedures that are expressly excluded from the TRICARE benefit by statute or regulation will not be considered for inclusion on the uniform formulary. Excluded pharmaceutical agents shall not be available as non-formulary agents, nor will they be cost-shared under the TRICARE pharmacy benefits program.

(b) *Definitions*. For most definitions applicable to the provisions of this section, refer to §199.2. The following definitions apply only to this section:

(1) *Clinically necessary*. Also referred to as clinical necessity. Sufficient evidence submitted by a beneficiary or provider on behalf of the beneficiary that establishes that one or more of the following conditions exist: The use of formulary pharmaceutical agents is contraindicated; the patient experiences significant adverse effects from formulary pharmaceutical agents in the therapeutic class, or is likely to experience significant adverse effects from formulary pharmaceutical agents in the therapeutic class; formulary pharmaceutical agents result in therapeutic failure, or the formulary pharmaceutical agent is likely to result in therapeutic failure; the patient previously responded to a non-formulary pharmaceutical agent and changing to a formulary pharmaceutical agent would incur an unacceptable clinical risk; or there is no alternative pharmaceutical agent on the formulary.

(2) *Therapeutic class*. A group of pharmaceutical agents that are similar in chemical structure, pharmacological effect, and/or clinical use.

(3) *Over-the-counter drug*. A drug that is not subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)).

(c) *Department of Defense Pharmacy and Therapeutics Committee*—(1) *Purpose*. The Department of Defense Pharmacy and Therapeutics Committee is established by 10 U.S.C. 1074g to assure that the selection of pharmaceutical agents for the uniform formulary is based on broadly representative professional expertise concerning relative clinical and

cost effectiveness of pharmaceutical agents and accomplishes an effective, efficient, integrated pharmacy benefits program.

(2) *Composition.* As required by 10 U.S.C. 1074g(b), the committee includes representatives of pharmacies of the uniformed services facilities and representatives of providers in facilities of the uniformed services. Committee members will have expertise in treating the medical needs of the populations served through such entities and in the range of pharmaceutical and biological medicines available for treating such populations.

(3) *Executive Council.* The Pharmacy and Therapeutics Committee may have an Executive Council, composed of those voting and non-voting members of the Committee who are military or civilian employees of the Department of Defense. The function of the Executive Council is to review and analyze issues relating to the operation of the uniform formulary, including issues of an inherently governmental nature, procurement sensitive information, and matters affecting military readiness. The Executive Council presents information to the Pharmacy and Therapeutics Committee, but is not authorized to act for the Committee.

(d) *Uniform Formulary Beneficiary Advisory Panel.* As required by 10 U.S.C. 1074g(c), a Uniform Formulary Beneficiary Advisory Panel reviews and comments on the development of the uniform formulary. The Panel includes members that represent non-governmental organizations and associations that represent the views and interests of a large number of eligible covered beneficiaries, contractors responsible for the TRICARE retail pharmacy program, contractors responsible for the TRICARE mail-order pharmacy program, and TRICARE network providers. The panel will meet after each Pharmacy and Therapeutics Committee quarterly meeting. The Panel's comments will be submitted to the Director, TRICARE Management Activity. The Director will consider the comments before implementing the uniform formulary or any recommendations for change made by the Pharmacy and Therapeutics Committee. The Panel will function in accordance with the Federated Advisory Committee Act (5 U.S.C. App. 2).

(e) *Determinations regarding relative clinical and cost effectiveness for the selection of pharmaceutical agents for the uniform formulary*—(1) *Clinical effectiveness.* (i) It is presumed that pharmaceutical agents in a therapeutic class are clinically effective and should be included on the uniform formulary unless the Pharmacy and Therapeutics Committee finds by a majority vote that a pharmaceutical agent does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome over the other pharmaceutical agents included on the uniform formulary in that therapeutic class. This determination is based on the collective professional judgment of the DoD Pharmacy and Therapeutics Committee and consideration of pertinent information from a variety of sources determined by the Committee to be relevant and reliable. The DoD Pharmacy and Therapeutics Committee has discretion based on its collective professional judgment in determining what sources should be reviewed or relied upon in evaluating the clinical effectiveness of a pharmaceutical agent in a therapeutic class.

(ii) Sources of information may include but are not limited to:

(A) Medical and pharmaceutical textbooks and reference books;

(B) Clinical literature;

(C) U.S. Food and Drug Administration determinations and information;

(D) Information from pharmaceutical companies;

(E) Clinical practice guidelines, and

(F) Expert opinion.

(iii) The DoD Pharmacy and Therapeutics Committee will evaluate the relative clinical effectiveness of pharmaceutical agents within a therapeutic class by considering information about their safety, effectiveness, and clinical outcome.

(iv) Information considered by the Committee may include but is not limited to:

(A) U.S. Food and Drug Administration approved and other studied indications;

(B) Pharmacology;

(C) Pharmacokinetics;

(D) Contraindications;
(E) Warnings/precautions;
(F) Incidence and severity of adverse effects;
(G) Drug to drug, drug to food, and drug to disease interactions;
(H) Availability, dosing, and method of administration;
(I) Epidemiology and relevant risk factors for diseases/conditions in which the pharmaceutical agents are used;
(J) Concomitant therapies;
(K) Results of safety and efficacy studies;
(L) Results of effectiveness/clinical outcomes studies, and
(M) Results of meta-analyses.

(2) Cost effectiveness. (i) In considering the relative cost effectiveness of pharmaceutical agents in a therapeutic class, the DoD Pharmacy and Therapeutics Committee shall evaluate the costs of the agents in relation to the safety, effectiveness, and clinical outcomes of the other agents in the class.

(ii) Information considered by the Committee concerning the relative cost effectiveness of pharmaceutical agents may include but is not limited to:

(A) Cost of the pharmaceutical agent to the Government;
(B) Impact on overall medical resource utilization and costs;
(C) Cost-efficacy studies;
(D) Cost-effectiveness studies;
(E) Cross-sectional or retrospective economic evaluations;
(F) Pharmacoeconomic models;
(G) Patent expiration dates;
(H) Clinical practice guideline recommendations, and
(I) Existence of existing or proposed blanket purchase agreements, incentive price agreements, or contracts.

(3) *Special rules for best clinical effectiveness.* (i) Under the authority of 10 U.S.C. 1074g(a)(10), the Pharmacy and Therapeutics Committee may recommend and the Director may, after considering the comments and recommendations of the Beneficiary Advisory Panel, approve special uniform formulary actions to encourage use of pharmaceutical agents that provide the best clinical effectiveness to covered beneficiaries and DoD, including consideration of better care, healthier people, and smarter spending. Such special actions may operate as exceptions to the normal rules and procedures under 10 U.S.C. 1074g(a)(2), (5) and (6) and the related provisions of this section.

(ii) Actions under paragraph (e)(3)(i) of this section may include a complete or partial exclusion from the pharmacy benefits program of any pharmaceutical agent the Director determines provides very little or no clinical effectiveness relative to similar agents to covered beneficiaries and DoD. A partial exclusion under this paragraph may take the form (as one example) of a limitation on the clinical conditions, diagnoses, or indications for which the pharmaceutical agent may be prescribed. A partial exclusion may be implemented through any means recommended by the Pharmacy and Therapeutics Committee, including but not limited to preauthorization under paragraph (k) of this section. In the case of a partial exclusion, a pharmaceutical agent may be available on the non-formulary tier of the uniform formulary for limited purposes and for other purposes be excluded.

(iii) Actions under paragraph (e)(3)(i) of this section may also include giving preferential status to any non-generic pharmaceutical agent of the uniform formulary by treating it for purposes of cost-sharing as a generic product.

(f) *Evaluation of pharmaceutical agents for determinations regarding inclusion on the uniform formulary.* The DoD Pharmacy and Therapeutics Committee will periodically evaluate or re-evaluate individual pharmaceutical agents and therapeutic classes of pharmaceutical agents for determinations regarding inclusion or continuation on the uniform formulary. Such evaluation or re-evaluation may be prompted by a variety of circumstances including, but not limited to:

(1) Approval of a new pharmaceutical agent by the U.S. Food and Drug Administration;
(2) Approval of a new indication for an existing pharmaceutical agent;
(3) Changes in the clinical use of existing pharmaceutical agents;
(4) New information concerning the safety, effectiveness or clinical outcomes of existing pharmaceutical agents;
(5) Price changes;

(6) Shifts in market share;

(7) Scheduled review of a therapeutic class; and

(8) Requests from Pharmacy and Therapeutics Committee members, military treatment facilities, or other Military Health System officials.

(g) *Administrative procedures for establishing and maintaining the uniform formulary*—(1) *Pharmacy and Therapeutics Committee determinations.* Determinations of the Pharmacy and Therapeutics Committee are by majority vote and recorded in minutes of Committee meetings. The minutes set forth the determinations of the committee regarding the pharmaceutical agents selected for inclusion in the uniform formulary and summarize the reasons for those determinations. For any pharmaceutical agent (including maintenance medications) for which a recommendation is made that the status of the agent be changed from the formulary tier to the non-formulary tier of the uniform formulary, or that the agent requires a pre-authorization, the Committee shall also make a recommendation as to effective date of such change that will not be longer than 180 days from the final decision date but may be less. The minutes will include a record of the number of members voting for and against the Committee's action.

(2) *Beneficiary Advisory Panel.* Comments and recommendations of the Beneficiary Advisory Panel are recorded in minutes of Panel meetings. The minutes set forth the comments and recommendations of the Panel and summarize the reasons for those comments and recommendations. The minutes will include a record of the number of members voting for or against the Panel's comments and recommendations.

(3) *Uniform formulary final decisions.* The Director of the TRICARE Management Activity makes the final DoD decisions regarding the uniform formulary. Those decisions are based on the Director's review of the final determinations of the Pharmacy and Therapeutics Committee and the comments and recommendations of the Beneficiary Advisory Panel. No pharmaceutical agent may be designated as non-formulary on the uniform formulary unless it is preceded by such recommendation by the Pharmacy and Therapeutics Committee. The decisions of the Director of the TRICARE Management Activity are in writing and establish the effective date(s) of the uniform formulary actions.

(4) *Transition to the Uniform Formulary.* Beginning in Fiscal Year 2005, under an updated charter for the DoD P&T Committee, the committee shall meet at least quarterly to review therapeutic classes of pharmaceutical agents and make recommendations concerning which pharmaceutical agents should be on the Uniform Formulary, the Basic Care Formulary (BCF), and Extended Core Formulary (ECF). The P&T Committee will review the classes in a methodical, but expeditious manner. During the transition period from the previous methodology of formulary management involving only the MTFs and the TMOP Program, previous decisions by the predecessor DoD P&T Committee concerning MTF and Mail Order Pharmacy Program formularies shall continue in effect. As therapeutic classes are reviewed under the new formulary management process, the processes established by this section shall apply.

(5) *Administrative procedure for newly approved drugs.* In the case of a newly approved innovator drug, other than a generic drug, the innovator drug will, not later than 120 days after the date of approval by the Food and Drug Administration, be added to the uniform formulary unless prior to that date the P&T Committee has recommended that the agent be listed as a non-formulary drug. If the Director, DHA subsequently approves that recommendation, the drug will be so listed. If the Director, DHA disapproves the recommendation to list the drug as non-formulary Third Tier, the drug will be then classified per the Director's decision. If, prior to the expiration of 120 days, the P&T Committee recommends that the agent be added to the uniform formulary and the recommendation is approved by the Director, DHA, that will be done as soon as feasible. Pending action under this paragraph (g)(5), the newly approved pharmaceutical agent will be considered to be in a classification pending status and will be

available to beneficiaries under Third Tier terms applicable to all other non-formulary agents.

(h) *Obtaining pharmacy services under the retail network pharmacy benefits program.* —(1) *Points of service.* There are four outpatient pharmacy points of service:

(i) Military Treatment Facilities (MTFs);

(ii) Retail network pharmacies: Those are non-MTF pharmacies that are a part of the network established for TRICARE retail pharmacy services;

(iii) Retail non-network pharmacies: Those are non-MTF pharmacies that are not part of the network established for TRICARE retail pharmacy services, and

(iv) the TRICARE Mail Order Pharmacy (TMOP).

(2) *Availability of formulary pharmaceutical agents*—(i) *General.* Subject to paragraphs (h)(2)(ii) and (h)(2)(iii) of this section, formulary pharmaceutical agents are available under the Pharmacy Benefits Program from all points of service identified in paragraph (h)(1) of this section.

(ii) *Availability of formulary pharmaceutical agents at military treatment facilities (MTF).* Pharmaceutical agents included on the uniform formulary are available through facilities of uniformed services, consistent with the scope of health care services offered in such facilities and additional determinations by the P&T Committee of the relative clinical effectiveness and cost effectiveness, based on costs to the Program associated with providing the agents to beneficiaries. The BCF is a subset of the uniform formulary and is a mandatory component of formularies at all full-service MTF pharmacies. The BCF contains the minimum set of pharmaceutical agents that each full-service MTF pharmacy must have on its formulary to support the primary care scope of practice for Primary Care Manager enrollment sites. Limited-service MTF pharmacies (e.g., specialty pharmacies within an MTF or pharmacies servicing only active duty military members) are not required to include the entire BCF on their formularies, but may limit their formularies to those BCF agents appropriate to the needs of the patients they serve. An ECF may list preferred agents in drug classes other than those covered by the BCF. Among BCF and ECF agents, individual MTF formularies are determined by local P&T Committees based on the scope of health care services provided at the respective MTFs. All pharmaceutical agents on the local formulary of full-service MTF pharmacies must be available to all categories of beneficiaries.

(iii) Pharmaceutical agents prescribed for smoking cessation are not available for coverage when obtained through a retail pharmacy. This includes network and non-network retail pharmacies.

(3) *Availability of non-formulary pharmaceutical agents*—(i) *General.* Non-formulary pharmaceutical agents are generally not available in military treatment facilities or in the retail point of service. They are available in the mail order program.

(ii) *Availability of non-formulary pharmaceutical agents at military treatment facilities.* Even when particular non-formulary agents are not generally available at military treatment facilities, they will be made available to eligible covered beneficiaries through the non-formulary special approval process as noted in this paragraph (h)(3)(ii) when there is a valid medical necessity for use of the non-formulary pharmaceutical agent.

(iii) *Availability of clinically appropriate non-formulary pharmaceutical agents to members of the Uniformed Services.* The pharmacy benefits program is required to assure the availability of clinically appropriate pharmaceutical agents to members of the uniformed services, including, where appropriate, agents not included on the uniform formulary. Clinically appropriate pharmaceutical agents will be made available to members of the Uniformed Services, including, where medical necessity has been validated, agents not included on the uniform formulary. MTFs shall establish procedures to evaluate the clinical necessity of prescriptions written for members of the uniformed services for pharmaceutical agents not included on the uniform formulary. If it is determined that the prescription is clinically necessary, the MTF will provide

the pharmaceutical agent to the member.

(iv) *Availability of clinically appropriate pharmaceutical agents to other eligible beneficiaries at retail pharmacies or the TMOP.* Eligible beneficiaries will receive non-formulary pharmaceutical agents at the formulary cost-share when medical necessity has been established by the beneficiary and/or his/her provider. The peer review provisions of § 199.15 shall apply to the clinical necessity pre-authorization determinations. TRICARE may require that the time for review be expedited under the pharmacy benefits program.

(4) *Availability of vaccines/immunizations.* This paragraph (h)(4) applies to the following three immunizations: H1N1 vaccine, seasonal influenza vaccine, and pneumococcal vaccine. A retail network pharmacy may be an authorized provider under the Pharmacy Benefits Program when functioning within the scope of its state laws to provide authorized vaccines/immunizations to an eligible beneficiary. The Pharmacy Benefits Program will cover the vaccine and its administration by the retail network pharmacy, including administration by pharmacists who meet the applicable requirements of state law to administer the vaccine. A TRICARE authorized vaccine/immunization includes vaccines/immunizations authorized as preventive care under the basic program benefits of § 199.4 of this Part, as well as such care authorized for Prime enrollees under the uniform HMO benefit of section 199.18. For Prime enrollees under the uniform HMO benefit, a referral is not required under paragraph (n)(2) of § 199.18 for preventive care vaccines/immunizations received from a retail network pharmacy that is a TRICARE authorized provider. Any additional policies, instructions, procedures, and guidelines appropriate for implementation of this benefit may be issued by the TMA Director, or designee.

(5) *Availability of selected over-the-counter (OTC) drugs under the pharmacy benefits program.* Although the pharmacy benefits program generally covers only prescription drugs, in some cases over-the-counter drugs may be covered and may be placed on the uniform formulary.

(i) An OTC drug may be included on the uniform formulary upon the recommendation of the Pharmacy and Therapeutics Committee and approval of the Director, DHA, based on a finding that it is cost-effective and clinically effective, as compared with other drugs in the same therapeutic class of pharmaceutical agents. Clinical need is judged by the criteria found in paragraph (e)(1)(i) and (ii) of this section. Cost effectiveness is determined based on criteria found in paragraph (e)(2) of this section.

(ii) OTC drugs placed on the uniform formulary, in general, will be treated the same as generic drugs on the uniform formulary for purposes of availability in MTF pharmacies, retail pharmacies, and the mail order pharmacy program and other requirements. However, upon the recommendation of the Pharmacy and Therapeutics Committee and approval of the Director, DHA, the requirement for a prescription may be waived for a particular OTC drug for certain emergency care treatment situations. In addition, a special copayment may be established under paragraph (i)(2)(xii) of this section for OTC drugs specifically used in certain emergency care treatment situations.

(i) *Cost-sharing requirements under the pharmacy benefits program*—(1) *General.* Under 10 U.S.C. 1074g(a)(6), cost-sharing requirements are established in this section for the pharmacy benefits program independent of those established under other provisions of this Part. Cost-shares under this section partially defray government costs of administering the pharmacy benefits program when collected by the government for prescriptions dispensed through the retail network pharmacies or the TRICARE Mail Order Pharmacy. The higher cost-share paid for prescriptions dispensed by a non-network retail pharmacy is established to encourage the use of the most economical venue to the government. Cost-sharing requirements are based on the classification of a pharmaceutical agent as generic, formulary, or non-formulary, in conjunction with the point of service from which the agent is acquired.

(2) *Cost-sharing amounts.* Active duty members of the uniformed services do

not pay cost-shares or annual deductibles. For other categories of beneficiaries, after applicable annual deductibles are met, cost-sharing amounts prior to October 1, 2016, are set forth in this paragraph (i)(2).

(i) For pharmaceutical agents obtained from a military treatment facility, there is no cost-sharing or annual deductible.

(ii) For pharmaceutical agents obtained from a retail network pharmacy, the cost share will be as provided in 10 U.S.C. 1074g(a)(6), except that there is a $0 cost-share for vaccines/immunizations authorized as preventive care for eligible beneficiaries.

(iii) For formulary and generic pharmaceutical agents obtained from a retail non-network pharmacy, except as provided in paragraph (i)(2)(vi) of this section, there is a 20 percent or $20.00 cost-share (whichever is greater) per prescription for up to a 30-day supply of the pharmaceutical agent.

(iv) For pharmaceutical agents obtained under the TRICARE mail order program, the cost share will be as provided in 10 U.S.C. 1074g(a)(6), except that there is a $0 cost-share for smoking cessation pharmaceutical agents covered under the smoking cessation program.

(v) [Reserved]

(vi) For TRICARE Prime beneficiaries there is no annual deductible applicable for pharmaceutical agents obtained from retail network pharmacies or the TRICARE mail-order program. However, for TRICARE Prime beneficiaries who obtain formulary or generic pharmaceutical agents from retail non-network pharmacies, an enrollment year deductible of $300 per person and $600 per family must be met after which there is a beneficiary cost-share of 50 percent per prescription for up to a 30-day supply of the pharmaceutical agent.

(vii) For TRICARE Select beneficiaries the annual deductible which must be met before the cost-sharing amounts for pharmaceutical agents in paragraph (i)(2) of this section are applicable is as provided for each category of TRICARE Select enrollee in §199.17(l)(2).

(viii) For TRICARE beneficiaries not otherwise qualified to enroll in TRICARE Prime or Select, the annual deductible which must be met before the cost-sharing amounts for pharmaceutical agents in paragraph (i)(2) of this section are applicable is as provided in §199.4(f).

(ix) The TRICARE catastrophic cap limits apply to pharmacy benefits program cost-sharing.

(x) For any year after 2027, the cost-sharing amounts under this paragraph shall be equal to the cost-sharing amounts for the previous year adjusted by an amount, if any, determined by the Director to reflect changes in the costs of pharmaceutical agents and prescription dispensing, rounded to the nearest dollar. These cost changes, if any, will consider costs under the TRICARE pharmacy benefits program calculated separately for each of the following categories based on prescriptions filled in the most recent period for which TRICARE cost data are available, updated to the current year, if necessary, by appropriate industry data:

(A) Generic drugs in the retail point of service;

(B) Formulary drugs in the retail point of service;

(C) Generic drugs in the mail order point of service;

(D) Formulary drugs in the mail order point of service;

(E) Non-formulary drugs.

(xi) For a Medicare-eligible beneficiary, the cost-sharing requirements may not be in excess of the cost-sharing requirements applicable to all other beneficiaries covered by 10 U.S.C. 1086.

(xii) *Special copayment rule for OTC drugs in the retail pharmacy network.* As a general rule, OTC drugs placed on the uniform formulary under paragraph (h)(5) of this section will have copayments equal to those for generic drugs on the uniform formulary. However, upon the recommendation of the Pharmacy and Therapeutics Committee and approval of the Director, DHA, the copayment may be established at $0.00 for any particular OTC drug in the retail pharmacy network.

(3) *Special cost-sharing rule when there is a clinical necessity for use of a non-formulary pharmaceutical agent.* (i) When there is a clinical necessity for the use

of a non-formulary pharmaceutical agent that is not otherwise excluded as a covered benefit, the pharmaceutical agent will be provided at the same co-payment as a formulary pharmaceutical agent can be obtained.

(ii) A clinical necessity for use of a non-formulary pharmaceutical agent is established when the beneficiary or their provider submits sufficient information to show that one or more of the following conditions exist:

(A) The use of formualry pharmaceutical agents is contraindicated;

(B) The patient experiences significant adverse effects from formulary pharmaceutical agents, or the provider shows that the patient is likely to experience significant adverse effects from formulary pharmaceutical agents;

(C) Formulary pharmaceutical agents result in therapeutic failure, or the provider shows that the formulary pharmaceutical agent is likely to result in therapeutic failure;

(D) The patient previously responded to a non-formulary pharmaceutical agent and changing to a formulary pharmaceutical agent would incur unacceptable clinical risk; or

(E) There is no alternative pharmaceutical agent on the formulary.

(iii) Information to establish clinical necessity for use of a non-formulary pharmaceutical agent should be provided to TRICARE for prescriptions submitted to a retail network pharmacy.

(iv) Information to establish clinical necessity for use of a non-formulary pharmaceutical agent should be provided as part of the claims processes for non-formulary pharmaceutical agents obtained through non-network points of service, claims as a result of other health insurance, or any other situations requiring the submission of a manual claim.

(v) Information to establish clinical necessity for use of a non-formulary pharmaceutical agent may be provided with the prescription submitted to the TMOP contractor.

(vi) Information to establish clinical necessity for use of a non-formulary pharmaceutical agent may also be provided at a later date, but no later than sixty days from the dispensing date, as an appeal to reduce the non-formulary co-payment to the same co-payment as a formulary drug.

(vii) The process of establishing clinical necessity will not unnecessarily delay the dispensing of a prescription. In situations where clinical necessity cannot be determined in a timely manner, the non-formulary pharmaceutical agent will be dispensed at the non-formulary co-payment and a refund provided to the beneficiary should clinical necessity be established.

(viii) Peer review and appeal and hearing procedures. All levels of peer review, appeals, and grievances established by the Contractor for internal review shall be exhausted prior to forwarding to TRICARE Management Activity for a formal review. Procedures comparable to those established under §§199.15 and 199.10 of this part shall apply. If it is determined that the prescription is clinically necessary, the pharmaceutical agent will be provided to the beneficiary at the formulary cost-share. TRICARE may require that the time periods for peer review or for appeal and hearing be expedited under the pharmacy benefits program. For purposes of meeting the amount in dispute requirement of §199.10(a)(7), the relevant amount is the difference between the cost shares of a formulary versus non-formulary drug. The amount for each of multiple prescriptions involving the same drug to treat the same medical condition and filled within a 12-month period may be combined to meet the required amount in dispute.

(j) *Use of generic drugs under the pharmacy benefits program.* (1) The designation of a drug as a generic, for the purpose of applying cost-shares at the generic rate, will be determined through the use of standard pharmaceutical references as part of commercial best business practices. Pharmaceutical agents will be designated as generics when listed with an ''A'' rating in the current Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) published by the Food and Drug Administration, or any successor to such reference. Generics are multisource products that must contain the same active ingredients, are of

the same dosage form, route of administration and are identical in strength or concentration.

(2) The pharmacy benefits program generally requires mandatory substitution of generic drugs listed with an ''A'' rating in the current Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) published by the FDA and generic equivalents of grandfather or Drug Efficacy Study Implementation (DESI) category drugs for brand name drugs. In cases in which there is a clinical justification for a brand name drug in lieu of a generic equivalent, under the standards and procedures of paragraph (h)(3) of this section, the generic substitution policy is waived.

(3) When a blanket purchase agreement, incentive price agreement, Government contract, or other circumstances results in a brand pharmaceutical agent being the most cost effective agent for purchase by the Government, the Pharmacy and Therapeutics Committee may also designate that the drug be cost-shared at the generic rate.

(4) Upon the recommendation of the Pharmacy and Therapeutics Committee, a generic drug may be classified as non-formulary if it is less cost effective than non-generic formulary drugs in the same drug class.

(5) The beneficiary copayment amount for any generic drug prescription may not exceed the total charge for that prescription.

(k) *Preauthorization of certain pharmaceutical agents.* (1) Selected pharmaceutical agents may be subject to prior authorization or utilization review requirements to assure medical necessity, clinical appropriateness and/or cost effectiveness.

(2) The Pharmacy and Therapeutics Committee will assess the need to prior authorize a given agent by considering the relative clinical and cost effectiveness of pharmaceutical agents within a therapeutic class. Pharmaceutical agents that require prior authorization will be identified by a majority vote of the Pharmacy and Therapeutics Committee. The Pharmacy and Therapeutics Committee will establish the prior authorization criteria for the pharamaceutical agent.

(3) Prescriptions for pharmaceutical agents for which prior authorization criteria are not met will not be cost-shared under the TRICARE pharmacy benefits program.

(4) The Director, TRICARE Management Activity, may issue policies, procedures, instructions, guidelines, standards or criteria to implement this paragraph (k).

(l) *TRICARE Senior Pharmacy Program.* Section 711 of the Floyd D. Spence National Defense Authorization Act for Fiscal Year 2001 (Public Law 106–398, 114 Stat. 1654A–175) established the TRICARE Senior Pharmacy Program for Medicare eligible beneficiaries effective April 1, 2001. These beneficiaries are required to meet the eligibility criteria as prescribed in §199.3 of this part. The benefit under the TRICARE Senior Pharmacy Program applies to prescription drugs and medicines provided on or after April 1, 2001.

(m) *Effect of other health insurance.* The double coverage rules of section 199.8 of this part are applicable to services provided under the pharmacy benefits program. For this purpose, the Medicare prescription drug benefit under Medicare Part D, prescription drug benefits provided under Medicare Part D plans are double coverage plans and such plans will be the primary payer, to the extent described in section 199.8 of this part. Beneficiaries who elect to use these pharmacy benefits shall provide DoD with other health insurance information.

(n) *Procedures.* The Director, TRICARE Management Activity shall establish procedures for the effective operation of the pharmacy benefits program. Such procedures may include restrictions of the quantity of pharmaceuticals to be included under the benefit, encouragement of the use of generic drugs, implementation of quality assurance and utilization management activities, and other appropriate matters.

(o) *Preemption of State laws.* (1) Pursuant to 10 U.S.C. 1103, the Department of Defense has determined that in the administration of 10 U.S.C. chapter 55, preemption of State and local laws relating to health insurance, prepaid

health plans, or other health care delivery or financing methods is necessary to achieve important Federal interests, including but not limited to the assurance of uniform national health programs for military families and the operation of such programs at the lowest possible cost to the Department of Defense, that have a direct and substantial effect on the conduct of military affairs and national security policy of the United States.

(2) Based on the determination set forth in paragraph (o)(1) of this section, any State or local law relating to health insurance, prepaid health plans, or other health care delivery or financing methods is preempted and does not apply in connection with TRICARE pharmacy contracts. Any such law, or regulation pursuant to such law, is without any force or effect, and State or local governments have no legal authority to enforce them in relation to the TRICARE pharmacy contracts. However, the Department of Defense may by contract establish legal obligations on the part of TRICARE contractors to conform with requirements similar or identical to requirements of State or local laws or regulations.

(3) The preemption of State and local laws set forth in paragraph (o)(1) of this section includes State and local laws imposing premium taxes on health or dental insurance carriers or underwriters or other plan managers, or similar taxes on such entities. Such laws are laws relating to health insurance, prepaid health plans, or other health care delivery or financing methods, within the meaning of the statutes identified in paragraph (o)(1) of this section. Preemption, however, does not apply to taxes, fees, or other payments on net income or profit realized by such entities in the conduct of business relating to DoD pharmacy services contracts, if those taxes, fees or other payments are applicable to a broad range of business activity. For purposes of assessing the effect of Federal preemption of State and local taxes and fees in connection with DoD pharmacy services contracts, interpretations shall be consistent with those applicable to the Federal Employees Health Benefits Program under 5 U.S.C. 8909(f).

(p) *General fraud, abuse, and conflict of interest requirements under TRICARE pharmacy benefits program.* All fraud, abuse, and conflict of interest requirements for the basic CHAMPUS program, as set forth in this part 199 (see applicable provisions of §199.9 of this part) are applicable to the TRICARE pharmacy benefits program. Some methods and procedures for implementing and enforcing these requirements may differ from the methods and procedures followed under the basic CHAMPUS program.

(q) *Pricing standards for retail pharmacy program*—(1) *Statutory requirement.* (i) As required by 10 U.S.C. 1074g(f), with respect to any prescription filled on or after the date of the enactment of the National Defense Authorization Act for Fiscal Year 2008, the TRICARE retail pharmacy program shall be treated as an element of the DoD for purposes of the procurement of drugs by Federal agencies under 38 U.S.C. 8126 to the extent necessary to ensure pharmaceuticals paid for by the DoD that are provided by pharmacies under the program to eligible covered beneficiaries under this section are subject to the pricing standards in such section 8126.

(ii) Under paragraph (q)(1)(i) of this section, all covered drug TRICARE retail pharmacy network prescriptions are subject to Federal Ceiling Prices under 38 U.S.C. 8126.

(2) *Manufacturer written agreement.* (i) A written agreement by a manufacturer to honor the pricing standards required by 10 U.S.C. 1074g(f) and referred to in paragraph (q)(1) of this section for pharmaceuticals provided through retail network pharmacies shall with respect to a particular covered drug be a condition for:

(A) Inclusion of that drug on the uniform formulary under this section; and

(B) Availability of that drug through retail network pharmacies without preauthorization under paragraph (k) of this section.

(ii) A covered drug not under an agreement under paragraph (q)(2)(i) of this section requires preauthorization under paragraph (k) of this section to be provided through a retail network

pharmacy under the Pharmacy Benefits Program. This preauthorization requirement does not apply to other points of service under the Pharmacy Benefits Program.

(iii) For purposes of this paragraph (q)(2), a covered drug is a drug that is a covered drug under 38 U.S.C. 8126, but does not include:

(A) A drug that is not a covered drug under 38 U.S.C. 8126;

(B) A drug provided under a prescription that is not covered by 10 U.S.C. 1074g(f);

(C) A drug that is not provided through a retail network pharmacy under this section;

(D) A drug provided under a prescription which the TRICARE Pharmacy Benefits Program is the second payer under paragraph (m) of this section;

(E) A drug provided under a prescription and dispensed by a pharmacy under section 340B of the Public Health Service Act; or

(F) Any other exception for a drug, consistent with law, established by the Director, TMA.

(iv) The requirement of this paragraph (q)(2) may, upon the recommendation of the Pharmacy and Therapeutics Committee, be waived by the Director, TMA if necessary to ensure that at least one drug in the drug class is included on the Uniform Formulary. Any such waiver, however, does not waive the statutory requirement referred to in paragraph (q)(1) that all covered TRICARE retail network pharmacy prescriptions are subject to Federal Ceiling Prices under 38 U.S.C. 8126; it only waives the exclusion from the Uniform Formulary of drugs not covered by agreements under this paragraph (q)(2).

(3) *Refund procedures.* (i) Refund procedures to ensure that pharmaceuticals paid for by the DoD that are provided by retail network pharmacies under the pharmacy benefits program are subject to the pricing standards referred to in paragraph (q)(1) of this section shall be established. Such procedures may be established as part of the agreement referred to in paragraph (q)(2), or in a separate agreement, or pursuant to §199.11.

(ii) The refund procedures referred to in paragraph (q)(3)(i) of this section shall, to the extent practicable, incorporate common industry practices for implementing pricing agreements between manufacturers and large pharmacy benefit plan sponsors. Such procedures shall provide the manufacturer at least 70 days from the date of the submission of the TRICARE pharmaceutical utilization data needed to calculate the refund before the refund payment is due. The basis of the refund will be the difference between the average non-federal price of the drug sold by the manufacturer to wholesalers, as represented by the most recent annual non-Federal average manufacturing prices (non-FAMP) (reported to the Department of Veterans Affairs (VA)) and the corresponding FCP or, in the discretion of the manufacturer, the difference between the FCP and direct commercial contract sales prices specifically attributable to the reported TRICARE paid pharmaceuticals, determined for each applicable NDC listing. The current annual FCP and the annual non-FAMP from which it was derived will be applicable to all prescriptions filled during the calendar year.

(iii) A refund due under this paragraph (q) is subject to §199.11 of this part and will be treated as an erroneous payment under that section.

(A) A manufacturer may under section 199.11 of this part request waiver or compromise of a refund amount due under 10 U.S.C. 1074g(f) and this paragraph (q).

(B) During the pendency of any request for waiver or compromise under paragraph (q)(3)(iii)(A) of this section, a manufacturer's written agreement under paragraph (q)(2) shall be deemed to exclude the matter that is the subject of the request for waiver or compromise. In such cases the agreement, if otherwise sufficient for the purpose of the condition referred to in paragraph (q)(2), will continue to be sufficient for that purpose. Further, during the pendency of any such request, the matter that is the subject of the request shall not be considered a failure of a manufacturer to honor a requirement or an agreement for purposes of paragraph (q)(4).

(C) In addition to the criteria established in §199.11, a request for waiver may also be premised on the voluntary

removal by the manufacturer in writing of a drug from coverage in the TRICARE Pharmacy Benefit Program.

(iv) In the case of disputes by the manufacturer of the accuracy of TMA's utilization data, a refund obligation as to the amount in dispute will be deferred pending good faith efforts to resolve the dispute in accordance with procedures established by the Director, TMA. If the dispute is not resolved within 60 days, the Director, TMA will issue an initial administrative decision and provide the manufacturer with opportunity to request reconsideration or appeal consistent with procedures under section 199.10 of this part. When the dispute is ultimately resolved, any refund owed relating to the amount in dispute will be subject to an interest charge from the date payment of the amount was initially due, consistent with section 199.11 of this part.

(4) *Remedies*. In the case of the failure of a manufacturer of a covered drug to honor a requirement of this paragraph (q) or to honor an agreement under this paragraph (q), the Director, TMA, in addition to other actions referred to in this paragraph (q), may take any other action authorized by law.

(5) *Beneficiary transition provisions*. In cases in which a pharmaceutical is removed from the uniform formulary or designated for preauthorization under paragraph (q)(2) of this section, the Director, TMA may for transitional time periods determined appropriate by the Director or for particular circumstances authorize the continued availability of the pharmaceutical in the retail pharmacy network or in MTF pharmacies for some or all beneficiaries as if the pharmaceutical were still on the uniform formulary.

(r) *Refills of maintenance medications for eligible covered beneficiaries through the mail order pharmacy program*—(1) *In general*. Consistent with section 702 of the National Defense Authorization Act for Fiscal Year 2015, this paragraph requires that for non-generic covered maintenance medications, beneficiaries are generally required to obtain their prescription through the national mail-order pharmacy program or through military treatment facility pharmacies. For purposes of this paragraph, eligible covered beneficiaries are those defined under sections 1072 and 1086 of title 10, United States Code.

(2) *Medications covered*. The Director, DHA, will establish, maintain, and periodically revise and update a list of non-generic covered maintenance medications subject to the requirement of paragraph (r)(1) of this section. The current list will be accessible through the TRICARE Pharmacy Program Internet Web site and by telephone through the TRICARE Pharmacy Program Service Center. Each medication included on the list will meet the following requirements:

(i) It will be a medication prescribed for a chronic, long-term condition that is taken on a regular, recurring basis.

(ii) It will be clinically appropriate to dispense the medication from the mail order pharmacy.

(iii) It will be cost effective to dispense the medication from the mail order pharmacy.

(iv) It will be available for an initial filling of a 30-day or less supply through retail pharmacies.

(v) It will be generally available at military treatment facility pharmacies for initial fill and refills.

(vi) It will be available for refill through the national mail-order pharmacy program.

(3) *Refills covered*. For purposes of the program under paragraph (r)(1) of this section, a refill is:

(i) A subsequent filling of an original prescription under the same prescription number or other authorization as the original prescription; or

(ii) A new original prescription issued at or near the end date of an earlier prescription for the same medication for the same patient.

(4) *Waiver of requirement*. A waiver of the general requirement to obtain maintenance medication prescription refills from the mail order pharmacy or military treatment facility pharmacy will be granted in the following circumstances:

(i) There is a blanket waiver for prescription medications that are for acute care needs.

(ii) There is a blanket waiver for prescriptions covered by other health insurance.

(iii) There is a case-by-case waiver to permit prescription maintenance medication refills at a retail pharmacy when necessary due to personal need or hardship, emergency, or other special circumstance. This waiver is obtained through an administrative override request to the TRICARE pharmacy benefits manager under procedures established by the Director, DHA.

(5) *Procedures.* Under the program established by paragraph (r)(1) of this section, the Director, DHA will establish procedures for the effective operation of the program. Among these procedures are the following:

(i) The Department will implement the program by utilizing best commercial practices to the extent practicable.

(ii) An effective communication plan that includes efforts to educate beneficiaries in order to optimize participation and satisfaction will be implemented.

(iii) Beneficiaries with active retail prescriptions for a medication on the maintenance medication list will be notified that their medication is included under the program. Beneficiaries will be advised that they may receive two 30 day fill at retail while they transition their prescription to the mail order program.

(iv) Requests for a third fill at retail will result in 100% patient cost shares and will be blocked from any TRICARE payments and the beneficiary advised to call the pharmacy benefits manager (PBM) for assistance.

(v) The PBM will provide a toll free number to assist beneficiaries in transferring their prescriptions from retail to the mail order program. With the beneficiary's permission, the PBM will contact the physician or other health care provider who prescribed the medication to assist in transferring the prescription to the mail order program.

(vi) In any case in which a beneficiary required under paragraph (r) of this section to obtain a maintenance medication prescription refill from national mail order pharmacy program and attempts instead to refill such medications at a retail pharmacy, the PBM will also maintain the toll free number to assist the beneficiary. This assistance may include information on how to request a waiver, consistent with paragraph (r)(4)(iii) of this section, or in taking any other appropriate action to meet the beneficiary's needs and to implement the program.

(vii) The PBM will ensure that a pharmacist is available at all times through the toll-free telephone number to answer beneficiary questions or provide other appropriate assistance.

(6) This program will remain in effect indefinitely with any adjustments or modifications required by law.

[69 FR 17048, Apr. 1, 2004, as amended at 74 FR 11292, Mar. 17, 2009; 74 FR 55776, Oct. 29, 2009; 74 FR 65438, Dec. 10, 2009; 75 FR 63397, Oct. 15, 2010; 76 FR 41065, July 13, 2011; 78 FR 13241, Feb. 27, 2013; 78 FR 75247, Dec. 11, 2013; 80 FR 46798, Aug. 6, 2015; 80 FR 44272, July 27, 2015; 81 FR 76310, Nov. 2, 2016; 82 FR 45458, Sept. 29, 2017; 83 FR 63577, Dec. 11, 2018]

§ 199.22 TRICARE Retiree Dental Program (TRDP).

(a) *Establishment.* The TRDP is a premium based indemnity dental insurance coverage program that will be available to certain retirees and their surviving spouses, their dependents, and certain other beneficiaries, as specified in paragraph (d) of this section. The TRDP is authorized by 10 U.S.C. 1076c.

(1) The Director will, except as authorized in paragraph (a)(2) of this section, make available a premium based indemnity dental insurance plan for eligible TRDP beneficiaries specified in paragraph (d) of this section consistent with the provisions of this section.

(2) The TRDP premium based indemnity dental insurance program under paragraph (a) of this section may be provided by allowing eligible beneficiaries specified in paragraph (d) of this section to enroll in an insurance plan under chapter 89A of title 5, United States Code that provides benefits similar to those benefits provided under paragraph (f) of this section. Such enrollment shall be authorized pursuant to an agreement entered into between the Department of Defense and the Office of Personnel Management which agreement, in the event of any inconsistency, shall take precedence over provisions in this section.

(b) *General provisions.* (1) At a minimum, benefits are the diagnostic services, preventive services, basic restorative services (including endodontics),

oral surgery services, and emergency services specified in paragraph (f)(1) of this section. Additional services comparable to those contained in paragraph (e)(2) of §199.13 may be covered pursuant to benefit policy decisions made by the Director, TRICARE Management Activity, or designee.

(2) Premium costs for this coverage will be paid by the enrollee.

(3) *Geographic scope*. (i) The TRDP is applicable to authorized providers in the 50 United States and the District of Columbia, Canada, Puerto Rico, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, and the U.S. Virgin Islands.

(ii) The Assistant Secretary of Defense (Health Affairs) (ASD (HA)) may extend the TRDP to geographic areas other than those specified in paragraph (b)(3)(i) of this section. In extending the TRDP overseas, the ASD (HA) is authorized to establish program elements, methods of administration, and payment rates and procedures that are different from those in effect for the areas specified in paragraph (b)(3)(i) of this section to the extent the ASD (HA), or designee, determines necessary for the effective and efficient operation of the TRDP. These differences may include, but are not limited to, specific provisions for preauthorization of care, varying licensure and certification requirements for foreign providers, and other differences based on limitations in the availability and capabilities of the Uniformed Services overseas dental treatment facilities and a particular nation's civilian sector providers in certain areas. The Director, TRICARE Management Activity shall issue guidance, as necessary, to implement the provisions of this paragraph. TRDP enrollees residing in overseas locations will be eligible for the same benefits as enrollees residing in the continental United States, although dental services may not be available or accessible in all locations.

(4) Except as otherwise provided in this section or by the Assistant Secretary of Defense (Health Affairs) or designee, the TRDP is administered in a manner similar to the TRICARE Dental Program under §199.13 of this part.

(5) The TRDP shall be administered through a contract.

(c) Except as may be specifically provided in this section, to the extent terms defined in §199.2 and §199.13(b) are relevant to the administration of the TRICARE Retiree Dental Program, the definitions contained in §199.2 and §199.13(b) shall apply to the TRDP as they do to TRICARE/CHAMPUS and the TRICARE Dental Program.

(d) *Eligibility and enrollment*—(1) *Eligibility*. Enrollment in the TRICARE Retiree Dental Program is open to:

(i) Members of the Uniformed Services who are entitled to retired pay, or former members of the armed forces who are Medal of Honor recipients and who are not otherwise entitled to dental benefits;

(ii) Members of the Retired Reserve under the age of 60;

(iii) Eligible dependents of a member described in paragraph (d)(1)(i) or paragraph (d)(1)(ii) of this section who are covered by the enrollment of the member;

(iv) Eligible dependents of a member described in paragraph (d)(1)(i) or paragraph (d)(1)(ii) of this section when the member is not enrolled in the program and the member meets at least one of the conditions in paragraphs (d)(1)(iv)(A) through (C) of this section. Already enrolled members must satisfy any remaining enrollment commitment prior to enrollment of dependents becoming effective under this paragraph, at which time the dependent-only enrollment will continue on a voluntary basis as specified in paragraph (d)(4) of this section. Members must provide documentation to the TRDP contractor giving evidence of compliance with paragraphs (d)(1)(iv)(A), (B), or (C) of this section at the time of application for enrollment of their dependents under this paragraph.

(A) The member is enrolled under Section 1705 of Title 38, United States Code, to receive ongoing, comprehensive dental care from the Department of Veterans Affairs pursuant to Section 1712 of Title 38, United States Code, and 38 CFR 17.93, 17.161, or 17.166. Authorization of such dental care must be confirmed in writing by the Department of Veterans Affairs.

(B) The member is enrolled in a dental plan that is available to the member as a result of employment of the member that is separate from the Uniformed Service of the member, and the dental plan is not available to dependents of the member as a result of such separate employment by the member. Enrollment in this dental plan and the exclusion of dependents from enrollment in the plan must be confirmed by documentation from the member's employer or the dental plan's administrator.

(C) The member is prevented by a current and enduring medical or dental condition from being able to obtain benefits under the TRDP. The specific medical or dental condition and reason for the inability to use the program's benefits over time, if not apparent based on the condition, must be documented by the member's physician or dentist.

(v) The unremarried surviving spouse and eligible child dependents of a deceased member who died while in status described in paragraph (d)(1)(i) or paragraph (d)(1)(ii) of this section; the unremarried surviving spouse and eligible child dependents who receive a surviving spouse annuity; or the unremarried surviving spouse and eligible child dependents of a deceased member who died while on active duty for a period of more than 30 days and whose eligible dependents are not eligible or no longer for the TRICARE Dental Program.

NOTE TO PARAGRAPHS (d)(1)(iii), (d)(1)(iv), AND (d)(1)(v): Eligible dependents of Medal of Honor recipients are described in §199.3(b)(2)(i) (except for former spouses) and §199.3(b)(2)(ii) (except for a child placed in legal custody of a Medal of Honor recipient under §199.3(b)(2)(ii)(H)(*4*)).

(2) *Notification of eligibility*. The contractor will notify persons eligible to receive dental benefits under the TRICARE Retiree Dental Program.

(3) *Election of coverage*. In order to initiate dental coverage, election to enroll must be made by the member or eligible dependent. Enrollment in the TRICARE Retiree Dental Program is voluntary and will be accomplished by submission of an application to the TRDP contractor.

(4) *Enrollment periods*—(i) *Enrollment period for basic benefits*. The initial enrollment for the basic dental benefits described in paragraph (f)(1) of this section shall be for a period of 24 months followed by month-to-month enrollment as long as the enrollee remains eligible and chooses to continue enrollment. An enrollee's disenrollment from the TRDP at any time for any reason, including termination for failure to pay premiums, is subject to a lockout period of 12 months. After any lockout period, eligible individuals may elect to reenroll and are subject to a new initial enrollment period. The enrollment periods and conditions stipulated in this paragraph apply only to the basic benefit coverage described in paragraph (f)(1) of this section. Effective with the implementation of an enhanced benefit program, new enrollments for basic coverage will cease. Enrollees in the basic program at that time may continue their enrollment for basic coverage, subject to the applicable provisions of this section, as long as the contract administering that coverage is in effect.

(ii) *Enrollment period for enhanced benefits*. The initial enrollment period for enhanced benefit coverage described in paragraph (f)(2) of this section shall be established by the Director, TMA, or designee, to be a period of not less than 12 months and not more than 24 months. The initial enrollment period shall be followed by renewal enrollment periods of up to 12 months as long as the enrollee chooses to continue enrollment and remains eligible. An enrollee who chooses not to continue enrollment upon completion of an enrollment period may re-enroll at any time. However, an enrollee who is disenrolled from the TRDP before completion of an initial or subsequent enrollment period for reasons other than those in paragraphs in (d)(5)(ii)(A) and (B) of this section shall incur a lockout period of 12 months before re-enrollment can occur. Former enrollees who re-enroll following a lockout period or following a period of disenrollment after completion of an enrollment period must comply with all provisions that apply to new enrollees, including a new enrollment commitment.

(5) *Termination of coverage*—(i) *Involuntary termination.* TRDP coverage is terminated when the member's entitlement to retired pay is terminated, the member's status as a member of the Retired Reserve is terminated, a dependent child loses eligible child dependent status, or a surviving spouse remarries.

(ii) *Voluntary termination.* All enrollee requests for termination of TRDP coverage before the completion of an enrollment period shall be submitted to the TRDP contractor for determination of whether the enrollee qualifies to be disenrolled under paragraphs (d)(5)(ii)(A) or (B) of this section.

(A) *Enrollment grace period.* Regardless of the reason, TRDP coverage shall be cancelled, or otherwise terminated, upon request from an enrollee if the request is received by the TRDP contractor within 30 calendar days following the enrollment effective date and there has been no use of TRDP benefits under the enrollment during that period. If such is the case, the enrollment is voided and all premium payments are refunded. However, use of benefits during this 30-day enrollment grace period constitutes acceptance by the enrollee of the enrollment and the enrollment period commitment. In this case, a request for termination of enrollment under paragraph (d)(5)(ii)(A) of this section will not be honored, and premiums will not be refunded.

(B) *Extenuating circumstances.* Under limited circumstances, TRDP enrollees shall be disenrolled by the contractor before the completion of an enrollment period commitment upon request by an enrollee if the enrollee submits written, factual documentation that independently verifies that one of the following extenuating circumstances occurred during the enrollment period. In general, the circumstances must be unforeseen and long-term and must have originated after the effective date of TRDP coverage.

(*1*) The enrollee is prevented by a serious medical condition from being able to utilize TRDP benefits,

(*2*) The enrollee would suffer severe financial hardship by continuing TRDP enrollment; or

(*3*) Any other circumstances which the Secretary considers appropriate.

(C) *Effective date of voluntary termination.* For cases determined to qualify for disenrollment under the grace period provisions in paragraph (d)(5)(ii)(A) of this section, enrollment is completely nullified effective from the beginning date of coverage. For cases determined to qualify for disenrollment under the extenuating circumstances provisions in paragraph (d)(5)(ii)(B) of this section, the effective date of disenrollment is the first of the month following the contractor's initial determination on the disenrollment request or the first of the month following the last use of TRDP benefits under the enrollment, whichever is later.

(D) *Appeal process for denied voluntary enrollment termination.* An enrollee has the right to appeal the contractor's determination that a disenrollment request does not qualify under paragraphs (d)(5)(ii)(A) or (B) of this section. The enrollee may appeal that determination by submitting a written appeal to the TMA, Office of Appeals and Hearings, with a copy of the contractor's determination notice and relevant documentation supporting the disenrollment request. This appeal must be received by TMA within 60 days of the date on the contractor's determination notice. The burden of proof is on the enrollee to establish affirmatively by substantial evidence that the enrollee qualifies to be disenrolled under paragraphs (d)(5)(ii)(A) or (B) of this section. TMA will issue written notification to the enrollee and the contractor of its appeal determination within 60 days from the date of receipt of the appeal request. That determination is final.

(6) *Continuation of dependents' enrollment upon death of enrollee.* Coverage of a dependent in the TRDP under an enrollment of a member or surviving spouse who dies during the period of enrollment shall continue until the end of that period and may be renewed by (or for) the dependent, so long as the premium paid is sufficient to cover continuation of the dependent's enrollment. Coverage may be terminated when the premiums paid are no longer sufficient to cover continuation of the enrollment.

(e) *Premium payments.* Persons enrolled in the dental plan will be responsible for paying the full cost of the premiums in order to obtain the dental insurance.

(1) *Premium payment method.* The premium payment may be collected pursuant to procedures established by the Assistant Secretary of Defense (Health Affairs) or designee.

(2) *Effects of failure to make premium payments.* Failure to make premium payments will result in the enrollee's disenrollment from the TRDP and a lockout period of 12 months. Following this period of time, eligible individuals will be able to re-enroll.

(3) *Member's payment of premiums.* The cost of the TRDP monthly premium will be paid by the enrollee. Interested beneficiaries may contact the dental contractor-insurer to obtain the enrollee premium cost.

(f) *Plan benefits.* The Director, TRICARE Management Activity, or designee, may modify the services covered by the TRDP to the extent determined appropriate based on developments in common dental care practices and standard dental programs. In addition, the Director, TRICARE Management Activity, or designee, may establish such exclusions and limitations as are consistent with those established by dental insurance and prepayment plans to control utilization and quality of care for the services and items covered by the TRDP.

(1) The minimum TRDP benefit is basic dental care to include diagnostic services, preventive services, restorative services, endodontic services, periodontic services, oral surgery services, and other general services. The following is the minimum TRDP covered dental benefit:

(i) *Diagnostic services.*

(A) Clinical oral examinations.

(B) Radiographs and diagnostic imaging.

(C) Tests and laboratory examinations.

(ii) *Preventive services.*

(A) Dental prophylaxis.

(B) Topical fluoride treatment (office procedure).

(C) Sealants.

(D) Other preventive services.

(E) Space maintenance.

(iii) *Restorative services.*

(A) Amalgam restorations.

(B) Resin-based composite restorations.

(C) Other restorative services.

(iv) *Endodontic services.*

(A) Pulp capping.

(B) Pulpotomy and pulpectomy.

(C) Root canal therapy.

(D) Apexification and recalcification procedures.

(E) Apicoectomy and periradicular services.

(F) Other endodontic procedures.

(v) *Periodontic Services.*

(A) Surgical services.

(B) Periodontal services.

(vi) *Oral surgery.*

(A) Extractions.

(B) Surgical extractions.

(C) Alveoloplasty.

(D) Biopsy.

(E) Other surgical procedures.

(vii) *Other general services.*

(A) Palliative (emergenery) treatment of dental pain.

(B) Therapeutic drug injection.

(C) Other drugs and/or medicaments.

(D) Treatment of postsurgical complications.

(2) *Enhanced benefits.* In addition to the minimum TRDP services in paragraph (f)(1) of this section, other services that are comparable to those contained in paragraph (e)(2) of §199.13 may be covered pursuant to TRDP benefit policy decisions made by the Director, OCHAMPUS, or designee. In general, these include additional diagnostic and preventive services, major restorative services, prosthodontics (removable and fixed), additional oral surgery services, orthodontics, and additional adjunctive general services (including general anesthesia and intravenous sedation). Enrollees in the basis plan will be given an enrollment option at the time the enhanced plan is implemented.

(3) *Alternative course of treatment policy.* The Director, TRICARE Management Activity, or designee, may establish, in accordance with generally accepted dental benefit practices, an alternative course of treatment policy which provides reimbursement in instances where the dentist and TRDP enrollee select a more expensive service, procedure, or course of treatement

than in customarily provided. The alternative course of treatment policy must meet the following conditions:

(i) The service, procedure, or course of treatment must be consistent with sound professional standards of generally accepted dental practice for the dental condition concerned.

(ii) The service, procedure, or course of treatment must be a generally accepted alternative for a service or procedure covered by the TRDP for the dental condition.

(iii) Payment for the alternative service or procedure may not exceed the lower of the prevailing limits for the alternative procedure, the prevailing limits or dental plan contractor's scheduled allowance for the otherwise authorized benefit procedure for which the alternative is substituted, or the actual charge for the alternative procedure.

(g) *Maximum coverage amounts.* Each enrollee is subject to an annual maximum coverage amount for non-orthodontic dental benefits and, if an orthodontic benefit is offered, a lifetime maximum coverage amount for orthodontics as established by the Director, TRICARE Management Activity, or designee.

(h) *Annual notification of rates.* TRDP premiums will be determined as part of the competitive contracting process. Information on the premium rates will be widely distributed.

(i) *Authorized providers.* The TRDP enrollee may seek covered services from any provider who is fully licensed and approved to provide dental care in the state where the provider is located.

(j) *Benefit payment.* Enrollees are not required to utilize the special network of dental providers established by the TRDP contractor. For enrollees who do use these network providers, however, providers shall not balance bill any amount in excess of the maximum payment allowable by the TRDP. Enrollees using non-network providers may balance billed amounts in excess of allowable charges. The maximum payment allowable by the TRDP (minus the appropriate cost-share) will be the lesser of:

(1) Billed charges; or

(2) Usual, Customary and Reasonable rates, in which the customary rate is calculated at the 50th percentile of billed charges in that geographic area, as measured in an undiscounted charge profile in 1995 or later for that geographic area (as defined by three-digit zip code).

(k) *Appeal procedures.* All levels of appeal established by the contractor shall be exhausted prior to an appeal being filed with the TMA. Procedures comparable to those established for appeal of benefit determinations under §199.10 of this part shall apply together with the procedures for appeal of voluntary disenrollment determinations described in paragraph (d)(5)(ii)(D) of this section.

(l) *Preemption of State laws.* (1) Pursuant to 10 U.S.C. 1103, the Department of Defense has determined that in the administration of chapter 55 of title 10, U.S. Code, preemption of State and local laws relating to health insurance, prepaid health plans, or other health care delivery or financing methods is necessary to achieve important Federal interests, including but not limited to the assurance of uniform national health programs for military families and the operation of such programs at the lowest possible cost to the Department of Defense, that have a direct and substantial effect on the conduct of military affairs and national security policy of the United States. This determination is applicable to the dental services contracts that implement this section.

(2) Based on the determination set forth in paragraph (l)(1) of this section, any State or local law or regulation pertaining to health or dental insurance, prepaid health or dental plans, or other health or dental care delivery, administration, and financing methods is preempted and does not apply in connection with the TRICARE Retiree Dental Program contract. Any such law, or regulation pursuant to such law, is without any force or effect, and State or local governments have no legal authority to enforce them in relation to the TRICARE Retiree Dental Program contract. (However, the Department of Defense may, by contract, establish legal obligations on the part of the TRICARE Retiree Dental Program contractor to conform with requirements similar to or identical to

requirements of State or local laws or regulations).

(3) The preemption of State and local laws set forth in paragraph (l)(2) of this section includes State and local laws imposing premium taxes on health or dental insurance carriers or underwriters or other plan managers, or similar taxes on such entities. Such laws are laws relating to health insurance, prepaid health plans, or other health care delivery or financing methods, within the meaning of section 1103. Preemption, however, does not apply to taxes, fees, or other payments on net income or profit realized by such entities in the conduct of business relating to DoD health services contracts, if those taxes, fees or other payments are applicable to a broad range of business activity. For the purposes of assessing the effect of Federal preemption of State and local taxes and fees in connection with DoD health and dental services contracts, interpretations shall be consistent with those applicable to the Federal Employees Health Benefits Program under 5 U.S.C. 8909(f).

(m) *Administration.* The Assistant Secretary of Defense (Health Affairs) or designee may establish other rules and procedures for the administration of the TRICARE Retiree Dental Program.

[62 FR 66993, Dec. 23, 1997, as amended at 65 FR 48913, Aug. 10, 2000; 65 FR 49492, Aug. 14, 2000; 66 FR 9658, Feb. 9, 2001; 67 FR 4354, Jan. 30, 2002; 67 FR 15725, Apr. 3, 2002; 72 FR 54213, Sept. 24, 2007; 72 FR 64537, Nov. 16, 2007; 73 FR 59504, Oct. 9, 2008; 82 FR 45458, Sept. 29, 2017]

§ 199.23 Special Supplemental Food Program.

(a) *General provisions.* This section prescribes guidelines and policies for the delivery and administration of the Special Supplemental Food Program for Women, Infants, and Children Overseas (WIC Overseas Program). The purpose of the WIC Overseas Program is to provide supplemental foods and nutrition education, at no cost, to eligible persons and to serve as an adjunct to good health care during critical times of growth and development, in order to prevent the occurrence of health problems, including drug and other substance abuse, and to improve the health status of program participants. The benefit is similar to the benefit provided under the U.S. Department of Agriculture (USDA) administered Women, Infants, and Children (WIC) Program.

(b) *Definitions.* For most definitions applicable to the provisions of this section, refer to sec. 199.2. The following definitions apply only to this section:

(1) *Applicant.* Pregnant women, breastfeeding women, postpartum women, infants, and children who are applying to receive WIC Overseas benefits, and the breastfed infants of applicant breastfeeding women. This term also includes individuals who are currently participating in the Program but are re-applying because their certification is about to expire.

(2) *Breastfeeding women.* Women up to 1-year postpartum who are breastfeeding their infants. Their eligibility will end on the last day of the month of their infant's first birthday.

(3) *Certification.* The implementation of criteria and procedures to assess and document each applicant's eligibility for the Program.

(4) *Children.* Persons who have had their first birthday but have not yet attained their fifth birthday. Their eligibility will end on the last day of the month of their fifth birthday.

(5) *Competent Professional Authority (CPA).* An individual on the staff of the WIC Overseas office authorized to determine nutritional risk, prescribe supplemental foods, and design nutrition education programs. The following are authorized to serve as a competent professional authority: physicians, nutritionists, registered nurses, and dieticians may serve as a competent professional authority. Additionally, a CPA may be other persons designated by the regional program manager who meet the definition of CPA prescribed by the USDA as being professionally competent to evaluate nutritional risk. The definition also applies to an individual who is not on the staff of the WIC Overseas office but who is qualified to provide data upon which nutritional risk determinations are made by a competent professional authority on the staff of the local WIC Overseas office.

(6) *Contract brand.* The brand of a particular food item that has been competitively selected by the DoD to be the exclusive supplier of that type of food item to the program.

(7) *Date-to-use.* The date by which the drafts must be used to purchase food items.

(8) *Department.* The Department of Defense (DoD), unless otherwise noted.

(9) *Dependent.* (i) A spouse, or (ii) An unmarried child who is:

(A) Under 21 years of age; or

(B) Incapable of self-support because of mental or physical incapacity and is in fact dependent on the member for more than ½ of the child's support; or

(C) Is under 23 years of age, is enrolled in a full-time course of study in an institution of higher education and is in fact dependent on the member for more than one-half of the child's support.

(10) *Drafts.* Paper food instruments, similar to vouchers, issued in the WIC Overseas offices to program participants. Participants may redeem their drafts at participating commissaries and NEXMARTs for the types and quantities of foods specified on the face of the draft.

(11) *Economic unit.* All individuals contributing to or subsidizing the income of a household, whether they physically reside in that household or not.

(12) *Eligible civilian.* An eligible civilian is a person who is not a member of the armed forces and who is:

(i) A dependent of a member of the armed forces residing with the member outside the United States, whether or not that dependent is command sponsored, or

(ii) An employee of a military department who is a national of the United States and is residing outside the United States in connection with such individual's employment or a dependent of such individual residing with the employee outside the United States; or

(iii) An employee of a Department of Defense contractor who is a national of the United States and is residing outside the United States in connection with such individual's employment or a dependent of such individual residing with the employee outside the United States.

(13) *Family.* A group of related or nonrelated individuals who are one economic unit.

(14) *Hematological test.* A test of an applicant's or participant's blood as described in 7 CFR part 246.7(e).

(15) *Income guidelines.* Income poverty guidelines published by the U.S. DHHS. These guidelines are adjusted annually by the Department of Health and Human Services (DHHS), with each annual adjustment effective July 1 of each year. For purposes of WIC Overseas Program income eligibility determinations, income guidelines shall mean the income guidelines published by the DHHS pertaining to the State of Alaska.

(16) *Infants.* Persons under 1 year of age.

(17) *National of the U.S.* A person who:

(i) Is a citizen of the U.S.; or

(ii) Is not a citizen of the United States, but who owes permanent allegiance to the United States, as determined in accordance with the Immigration and Nationality Act.

(18) *NEXMART.* Navy Exchange Market.

(19) *Nutrition education.* Individual or group sessions and the provision of materials designed to improve health status, achieve positive change in dietary habits, and emphasize relationships between nutrition and health, all in keeping with the individual's personal, cultural, and socioeconomic preferences.

(20) *Nutritional risk.* (i) The presence of detrimental or abnormal nutritional conditions detectable by biochemical, physical, developmental or anthropometric data, or

(ii) Other documented nutritionally related medical conditions, or

(iii) Documented evidence of dietary deficiencies that impair or endanger health, or

(iv) Conditions that directly affect the nutritional health of a person, such as alcoholism or drug abuse, or

(v) Conditions that predispose persons to inadequate nutritional patterns, habits of poor nutritional choices or nutritionally related medical conditions.

(21) *Participants.* Pregnant women, breastfeeding women, postpartum women, infants, and children who are receiving supplemental foods or food

instruments under the WIC Overseas Program, and the breastfed infants of participant breastfeeding women.

(22) *Postpartum Women*. Women up to 6 months after the end of their pregnancy. Their eligibility will end on the last day of the sixth month after their delivery.

(23) *Pregnant Women*. Women determined to have one or more embryos or fetuses in utero. Pregnant women are eligible to receive WIC benefits through 6 weeks postpartum, at which time they reapply for the program as postpartum or breastfeeding women.

(24) *Rebate*. The amount of money refunded under cost containment procedures to the Department from the manufacturer of a contract brand food item.

(25) *Regional Lead Agent*. The designated major military medical center that acts as the regional lead agent, having tri-service responsibility for the development and execution of a single, integrated health care network.

(26) *Supplemental foods*. Foods containing nutrients determined by nutritional research to be lacking in the diets of certain pregnant, breastfeeding, and postpartum women, infants, and children. WIC Overseas may substitute different foods providing the nutritional equivalent of foods prescribed by Domestic WIC programs, as required by 10 U.S.C. 1060a(c)(1)(B).

(27) *Verification*. Verification of drafts is a review before payment out of Defense Health Program funds to determine whether the commissary or NEXMART complied with applicable date-to-use, food specification, and other redemption criteria.

(c) *Certification of eligibility*. (1) to the extent practicable, participants shall be certified as eligible to receive Program benefits according to income and nutritional risk certification guidelines contained in regulations published by the USDA pertaining to the Women, Infants, and Children program required under 7 CFR 246.7(d)(2)(iv)(B). Applicants must meet the following eligibility criteria:

(i) Meet one of the participant type requirements: be a member of the armed forces on duty overseas; a family member/dependent of a member of the armed forces on duty overseas; a U.S. national employee of a military department serving overseas; a family member of a U.S. national employee of a DoD contractor serving overseas; a family member of a U.S. national employee of a DoD contractor serving overseas;

(ii) Reside in the geographic area served by the WIC Overseas office;

(iii) Meet the income criteria specified in this section; and

(iv) Meet the nutrition risk criteria specified in this section.

(2) In terms of income eligibility, the following apply:

(i) The Department of Defense shall use the Alaska income poverty guidelines published by the DHHS for making determinations regarding income eligibility for the Program.

(ii) Program income eligibility guidelines shall be adjusted annually to conform to annual adjustments made by the DHHS.

(iii) For income eligibility, the Program may consider the income of the family during the past 12 months and the family's current rate of income to determine which indicator accurately reflects the family's status.

(iv) A pregnant woman who is ineligible for participation in the Program because she does not meet income criteria shall be deemed eligible if the criteria would be met by increasing the number of individuals in her family (economic unit) by the number of children in utero.

(v) The Program shall define income according to USDA regulations with regard to the USDA-administered WIC Program. In particular—

(A) A basic allowance for housing is excluded from income as required by section 674 of the National Defense Authorization Act for Fiscal Year 2000.

(B) The value of in-kind housing benefits is excluded from income as required under USDA regulations.

(C) Cost of living allowances for duty outside the continental U.S. (OCONUS) is excluded from income as required under 7 CFR 246.7(d)(2)(iv)(A)(*2*).

(D) Public assistance and welfare payments are included in income.

(3) Participants must be found to be at nutritional risk to be eligible for program benefits.

(i) A Competent Professional Authority (CPA) shall determine if an applicant is at nutritional risk.

(ii) At the request of the program, applicants shall provide, according to schedules set by the USDA in 7 CFR 246.7(e) (unless deemed impracticable), nutritional risk data as a condition of certification in the Program. Such data includes:

(A) Anthropometric measurements,

(B) The results of hematological tests,

(C) Physical examination,

(D) Dietary information, or

(E) Developmental testing

(iii) A pregnant woman who meets all other eligibility criteria and for whom a nutritional risk assessment cannot immediately be completed will be considered presumptively eligible to participate in the Program for a period up to 60 days.

(iv) Infants under 6 months of age may be deemed to be at nutritional risk if the infant's mother was a Program participant during pregnancy or if medical records document that the mother was at nutritional risk during pregnancy.

(v) Unless otherwise specified herein or in 7 CFR 246.7(e), required nutritional risk data shall be provided to, or obtained by, the WIC Overseas Program office within 90 days of enrollment.

(4) In the event that it is impracticable for the WIC Overseas Program to adhere to the income and nutritional risk eligibility guidelines contained in USDA regulations, the Director, TRICARE Management Activity (TMA) may waive the Department's use of USDA WIC Program eligibility criteria by determining that it is impracticable to use these standards to certify participants in the WIC Overseas Program.

(i) Such determination shall consider relevant practical, administrative, national security, financial factors and existing Department policies and their application to the population served by the WIC Overseas Program.

(ii) Absent a written finding of impracticability described in section 199.23(c)(4), the eligibility criteria for the WIC program, contained in USDA regulations shall apply.

(5) An applicant for the WIC Overseas Program who presents a valid WIC Program Verification of Certification card, which is issued to participants in the domestic WIC Program when they intend to move, shall be considered eligible for participation in the WIC Overseas Program for the duration of the individual's current domestic WIC certification period, as long as he/she is an eligible service/family member or eligible civilian/family member.

(d) *Program benefits.* (1) Drafts. WIC participants shall be issued drafts that may be redeemed for supplemental food prescribed under the program.

(i) Drafts shall at a minimum list the food items to be redeemed and the date-to-use.

(ii) Food items listed on the draft must be approved for use under the Program.

(iii) Drafts generally shall allow for a three-month supply of food items for each participant, unless the participant's nutritional status necessitates more frequent contacts with the WIC Overseas office.

(iv) Participating commissaries and NEXMARTS shall accept the drafts in exchange for approved food items.

(v) Commissary and NEXMART personnel shall be trained on verification and processing of drafts.

(vi) Program guidelines shall provide for training of new participants in how to redeem drafts.

(2) *Supplemental Food.* Participants shall redeem drafts for appropriate food packages at intervals determined in accordance with the USDA regulations.

(i) The Director, TMA shall identify to the Defense Commissary Agency (DeCA) and NEXCOM a list of food items approved for the WIC Overseas Program. This list shall be developed in consultation with the USDA and shall include information regarding the appropriate package and/or container sizes and quantities available for participants, as well as the frequency with which food items can be acquired. Additions and/or deletions of food items from this list shall be communicated to the commissaries and NEXMARTS on an ongoing basis.

(ii) A CPA shall prescribe appropriate foods from among the approved list to be included in food packages.

(iii) A CPA shall coordinate documentation of medical need when such documentation is a prerequisite for prescribing certain food items.

(iv) The Director, TMA may authorize changes regarding the supplemental foods to be made available in the WIC Overseas Program when local conditions preclude strict compliance or when such compliance is impracticable.

(3) *Nutrition Education*. Nutrition education shall be provided to all participants at intervals prescribed in USDA regulations at 7 CFR Part 246.11.

(i) The WIC Overseas nutrition education program shall be locally overseen by a CPA based on guidance and materials provided by TMA.

(ii) Nutrition education and its means of delivery be tailored to the greatest extent practicable to the specific nutritional, cultural, practical, and other needs of the participant. Participant profiles created during certification may be used in designing appropriate nutrition education. A CPA may develop individual care plans, as necessary, consistent with USDA regulations.

(iii) Nutrition education shall consist of sessions wherein individual participants or groups of participants meet with a CPA in an interactive setting such that participants can ask, and the CPA can answer, questions related to nutrition practices. In addition, nutrition education shall utilize prepared educational materials and/or Internet sites. Both the sessions and the information materials shall be designed to improve health status, achieve positive change in dietary habits, and emphasize relationships between nutrition and health. Individual and group sessions can be accomplished through, among other things, face-to-face meetings, remote tele-videoconferencing, real-time computer-based distance learning, or other means.

(iv) Nutrition education services shall generally be provided to participants twice during each 6-month certification period, unless a different schedule is specified in USDA regulations.

(v) The nutrition education program shall promote breastfeeding as the optimal method of infant nutrition, encourage pregnant participants to breastfeed unless contraindicated for health reasons, and educate all participating women about the harmful effects of substance abuse.

(vi) Individual participants shall not be denied supplemental food due to the failure to attend scheduled nutrition education sessions.

(e) *Financial management*. The Department shall establish procedures to provide for the verification of drafts prior to payment.

(i) Verification may utilize sampling techniques.

(ii) Payment of drafts shall be made out of Defense Health Program funds.

(f) *Rebate agreements*. (1) DoD is authorized to enter into an agreement with a manufacturer of a particular brand of a food item that provides for the exclusive supply to the program of the same or similar types of food items by that manufacturer.

(i) The agreement shall identify a contract brand of food item.

(ii) Under the agreement, the manufacturer shall rebate to the Department an agreed portion of the amounts paid by DoD for the procurement of the contract brand.

(2) The DoD shall use competitive procedures under title 10, chapter 137 to select the contract brand.

(3) Amounts rebated shall be credited to the appropriation available for carrying out the program and shall be applied against expenditures for the program in the same period as the other sums in the appropriation.

(g) *Administrative appeals and civil rights*. (1) Applicants who are denied certification or participants that are denied recertification shall be provided with a notice of ineligibility. The notice shall include information on the applicant's right to appeal the determination and instructions on doing so.

(2) Benefits shall not be provided while an appeal is pending when an applicant is denied benefits, a participant's certification has expired or a participant becomes categorically ineligible.

(3) A request for appeal shall be submitted in writing within five working

days. If the decision is an adverse one it shall include notice to the applicant of his further appeal rights as reflected in (iii) below, and that he/she has five working days to effect any such appeal.

(4) Appeal reviews shall be conducted in the first instance by the CPA or team leader in charge of the local WIC Overseas office.

(i) Written notice of a decision shall be provided to the applicant within five working days.

(ii) If the appeal is upheld, retroactive benefits shall not be provided.

(iii) At an applicant's request a denied appeal may be forwarded to the regional program manager for review, who will provide a decision on the appeal within 5 working days.

(iv) If the regional program manager denies the appeal, there shall be no further right of appeal.

(5) Complaints about discriminatory treatment shall be handled in accordance with procedures established at each local WIC Overseas site.

(h) *Operations and Administration.* (1) Information collected about WIC Overseas applicants and participants shall be collected, maintained, and disclosed in accordance with applicable laws and regulations.

(2) Information and personnel security requirements shall be consistent with applicable laws and regulations.

[69 FR 15678, Mar. 26, 2004]

§ 199.24 TRICARE Reserve Select.

(a) *Establishment.* TRICARE Reserve Select offers the TRICARE Select self-managed, preferred-provider network option under § 199.17 to qualified members of the Selected Reserve, their immediate family members, and qualified survivors under this section.

(1) *Purpose.* TRICARE Reserve Select is a premium-based health plan that is available for purchase by members of the Selected Reserve and certain survivors of Selected Reserve members as specified in paragraph (c) of this section.

(2) *Statutory Authority.* TRICARE Reserve Select is authorized by 10 U.S.C. 1076d.

(3) *Scope of the Program.* TRICARE Reserve Select is applicable in the 50 United States, the District of Columbia, Puerto Rico, and, to the extent practicable, other areas where members of the Selected Reserve serve. In locations other than the 50 states of the United States and the District of Columbia, the Assistant Secretary of Defense (Health Affairs) may authorize modifications to the program rules and procedures as may be appropriate to the area involved.

(4) *Major Features of TRICARE Reserve Select.* The major features of the program include the following:

(i) *TRICARE Select rules applicable.* (A) Unless specified in this section or otherwise prescribed by the Director, provisions of TRICARE Select under § 199.17 apply to TRICARE Reserve Select.

(B) Certain special programs established in 32 CFR part 199 are not available to members covered under TRICARE Reserve Select. These include the Extended Care Health Option (§ 199.5), the Special Supplemental Food Program (see § 199.23), and the Supplemental Health Care Program (§ 199.16), except when referred by a Military Treatment Facility (MTF) provider for incidental consults and the MTF provider maintains clinical control over the episode of care. The TRICARE Dental Program (§ 199.13) is independent of this program and is otherwise available to all members of the Selected Reserve and their eligible family members whether or not they purchase TRICARE Reserve Select coverage. The Continued Health Care Benefits Program (§ 199.20) is also independent of this program and is otherwise available to all members who qualify.

(ii) *Premiums.* TRICARE Reserve Select coverage is available for purchase by any Selected Reserve member if the member fulfills all of the statutory qualifications. A member of the Selected Reserve covered under TRICARE Reserve Select shall pay 28 percent of the total amount that the ASD(HA) determines on an appropriate actuarial basis as being appropriate for that coverage. There is one premium rate for member-only coverage and one premium rate for member and family coverage.

(iii) *Procedures.* Under TRICARE Reserve Select, Reserve Component members who fulfilled all of the statutory qualifications may purchase either the

member-only type of coverage or the member-and-family type of coverage by submitting a completed request in the appropriate format along with an initial payment of the applicable premium. Rules and procedures for purchasing coverage and paying applicable premiums are prescribed in this section.

(iv) *Benefits.* When their coverage becomes effective, TRICARE Reserve Select beneficiaries receive the TRICARE Select benefit including access to military treatment facility services and pharmacies, as described in §§199.17 and 199.21. TRICARE Reserve Select coverage features the deductible, catastrophic cap and cost share provisions of the TRICARE Select plan applicable to Group B active duty family members under §199.17(l)(2)(ii) for both the member and the member's covered family members; however, the TRICARE Reserve Select premium under paragraph (c) of this section applies instead of any TRICARE Select plan enrollment fee under §199.17. Both the member and the member's covered family members are provided access priority for care in military treatment facilities on the same basis as active duty service members' dependents who are not enrolled in TRICARE Prime as described in §199.17(d)(1)(i)(D).

(b) *Qualifications for TRICARE Reserve Select coverage*—(1) *Ready Reserve member.* A Ready Reserve member qualifies to purchase TRICARE Reserve Select coverage prior to January 1, 2030, if the Service member meets the criteria listed in both paragraphs (b)(1)(i) and (ii) of this section. Beginning January 1, 2030, only the criteria in paragraph (b)(1)(i) of this section is necessary for qualification.

(i) Is a member of the Selected Reserve of the Ready Reserve of the Armed Forces, or a member of the Individual Ready Reserve of the Armed Forces who has volunteered to be ordered to active duty pursuant to the provisions of 10 U.S.C. 12304 in accordance with section 10 U.S.C. 10144(b); and

(ii) Is not enrolled in, or eligible to enroll in, a health benefits plan under 5 U.S.C. chapter 89. That statute has been implemented under 5 CFR part 890 as the Federal Employees Health Benefits (FEHB) program. For purposes of the FEHB program, the terms ''enrolled,'' ''enroll'' and ''enrollee'' are defined in 5 CFR 890.101. Further, the member (or certain former member involuntarily separated) no longer qualifies for TRICARE Reserve Select when the member (or former member) has been eligible for coverage to be effective in a health benefits plan under the FEHB program for more than 60 days.

(2) *TRICARE Reserve Select survivor.* If a qualified Service member dies while in a period of TRICARE Reserve Select coverage, the immediate family member(s) of such member is qualified to purchase new or continue existing TRICARE Reserve Select coverage for up to six months beyond the date of the member's death as long as they meet the definition of immediate family members as specified in paragraph (g)(2) of this section. This applies regardless of type of coverage in effect on the day of the TRICARE Reserve Select member's death.

(c) *TRICARE Reserve Select premiums.* Members are charge premiums for coverage under TRICARE Reserve Select that represent 28 percent of the total annual premium amount that the Director determines on an appropriate actuarial basis as being appropriate for coverage under the TRICARE Select benefit for the TRICARE Reserve Select eligible population. Premiums are to be paid monthly, except as otherwise provided through administrative implementation, pursuant to procedures established by the Director. The monthly rate for each month of a calendar year is one-twelfth of the annual rate for that calendar year.

(1) *Annual establishment of rates.* TRICARE Reserve Select monthly premium rates shall be established and updated annually on a calendar year basis for each of the two types of coverage, member-only and member- and-family as described in paragraph (d)(1) of this section. Starting with calendar year 2009, the appropriate actuarial basis for purposes of this paragraph (c) shall be determined for each calendar year by utilizing the actual reported cost of providing benefits under this section to members and their dependents during the calendar years preceding such calendar year. Reported actual TRS cost

data from calendar years 2006 and 2007 was used to determine premium rates for calendar year 2009. This established pattern will be followed to determine premium rates for all calendar years subsequent to 2009.

(2) *Premium adjustments.* In addition to the determinations described in paragraph (c)(1) of this section, premium adjustments may be made prospectively for any calendar year to reflect any significant program changes or any actual experience in the costs of administering TRICARE Reserve Select.

(3) *Survivor premiums.* A surviving family member of a Reserve Component service member who qualified for TRICARE Reserve Select coverage as described in paragraph (b)(2) of this section will pay premium rates as follows. The premium amount shall be at the member-only rate if there is only one surviving family member to be covered by TRICARE Reserve Select and at the member and family rate if there are two or more survivors to be covered.

(d) *Procedures.* The Director may establish procedures for the following.

(1) *Purchasing coverage.* Procedures may be established for a qualified member to purchase one of two types of coverage: Member-only coverage or member and family coverage. Immediate family members of a qualified member as specified in paragraph (g)(2) of this section may be included in such family coverage. To purchase either type of TRICARE Reserve Select coverage for effective dates of coverage described below, members and survivors qualified under either paragraph (b)(1) or (2) of this section must submit a request in the appropriate format, along with an initial payment of the applicable premium required by paragraph (c) of this section in accordance with established procedures.

(i) *Continuation coverage.* Procedures may be established for a qualified member or qualified survivor to purchase TRICARE Reserve Select coverage with an effective date immediately following the date of termination of coverage under another TRICARE program.

(ii) *Qualifying event.* Procedures for qualifying events in TRICARE Select plans under §199.17(o) shall apply to TRICARE Reserve Select coverage. Additionally, the Director may identify other events unique to needs of the Reserve Components as qualifying events.

(iii) *Enrollment.* Procedures for enrollment in TRICARE Select plans under §199.17(o) shall apply to TRICARE Reserve Select enrollment. Generally, the effective date of coverage will coincide with the first day of a month unless enrollment is due to a qualifying event and a different date on or after the qualifying event is required to prevent a lapse in health care coverage.

(iv) *Survivor coverage under TRICARE Reserve Select.* Procedures may be established for a surviving family member of a Reserve Component service member who qualified for TRICARE Reserve Select coverage as described in paragraph (b)(2) of this section to purchase new TRICARE Reserve Select coverage or continue existing TRICARE Reserve Select coverage for up to six months beyond the date of the member's death. The effective date of coverage will be the day following the date of the member's death.

(2) *Termination.* Termination of coverage for the TRS member/survivor will result in termination of coverage for the member's/survivor's family members in TRICARE Reserve Select. Procedures may be established for coverage to be terminated as follows.

(i) Coverage shall terminate when members or survivors no longer qualify for TRICARE Reserve Select as specified in paragraph (b) of this section, with one exception. If a member is involuntarily separated from the Selected Reserve under other than adverse conditions, as characterized by the Secretary concerned, and is covered by TRICARE Reserve Select on the last day of his or her membership in the Selected Reserve, then TRICARE Reserve Select coverage may terminate up to 180 days after the date on which the member was separated from the Selected Reserve. This applies regardless of type of coverage. This exception expires December 31, 2018.

(ii) Coverage may terminate for members, former members, and survivors who gain coverage under another TRICARE program.

(iii) In accordance with the provisions of §199.17(o)(2) coverage terminates for members/survivors who fail to make premium payments in accordance with established procedures.

(iv) Coverage may be terminated for members/survivors upon request at any time by submitting a completed request in the appropriate format in accordance with established procedures.

(3) *Re-enrollment following termination.* Absent a new qualifying event, members/survivors (subject to paragraph (d)(1)(iv) of this section) are not eligible to re-enroll in TRICARE Reserve Select until the next annual open season.

(4) *Processing.* Upon receipt of a completed request in the appropriate format, enrollment actions will be processed into DEERS in accordance with established procedures.

(5) *Periodic revision.* Periodically, certain features, rules or procedures of TRICARE Reserve Select may be revised. If such revisions will have a significant effect on members' or survivors' costs or access to care, members or survivors may be given the opportunity to change their type of coverage or terminate coverage coincident with the revisions.

(e) *Preemption of State laws.* (1) Pursuant to 10 U.S.C. 1103, the Department of Defense has determined that in the administration of chapter 55 of title 10, U.S. Code, preemption of State and local laws relating to health insurance, prepaid health plans, or other health care delivery or financing methods is necessary to achieve important Federal interests, including but not limited to the assurance of uniform national health programs for military families and the operation of such programs, at the lowest possible cost to the Department of Defense, that have a direct and substantial effect on the conduct of military affairs and national security policy of the United States. This determination is applicable to contracts that implement this section.

(2) Based on the determination set forth in paragraph (f)(1) of this section, any State or local law or regulation pertaining to health insurance, prepaid health plans, or other health care delivery, administration, and financing methods is preempted and does not apply in connection with TRICARE Reserve Select. Any such law, or regulation pursuant to such law, is without any force or effect, and State or local governments have no legal authority to enforce them in relation to TRICARE Reserve Select. (However, the Department of Defense may, by contract, establish legal obligations on the part of DoD contractors to conform with requirements similar to or identical to requirements of State or local laws or regulations with respect to TRICARE Reserve Select).

(3) The preemption of State and local laws set forth in paragraph (f)(2) of this section includes State and local laws imposing premium taxes on health insurance carriers or underwriters or other plan managers, or similar taxes on such entities. Such laws are laws relating to health insurance, prepaid health plans, or other health care delivery or financing methods, within the meaning of 10 U.S.C. 1103. Preemption, however, does not apply to taxes, fees, or other payments on net income or profit realized by such entities in the conduct of business relating to DoD health services contracts, if those taxes, fees or other payments are applicable to a broad range of business activity. For the purposes of assessing the effect of Federal preemption of State and local taxes and fees in connection with DoD health services contracts, interpretations shall be consistent with those applicable to the Federal Employees Health Benefits Program under 5 U.S.C. 8909(f).

(f) *Administration.* The Director may establish other rules and procedures for the effective administration of TRICARE Reserve Select, and may authorize exceptions to requirements of this section, if permitted by law.

(g) *Terminology.* The following terms are applicable to the TRICARE Reserve Select program.

(1) *Coverage.* This term means the medical benefits covered under the TRICARE Select program as further outlined in §199.17 whether delivered in military treatment facilities or purchased from civilian sources.

(2) *Immediate family member.* This term means spouse (except former

spouses) as defined in §199.3(b)(2)(i), or child as defined in §199.3(b)(2)(ii).

(3) *Qualified member*. This term means a member who has satisfied all the criteria that must be met before the member is authorized for TRS coverage.

(4) *Qualified survivor*. This term means an immediate family member who has satisfied all the criteria that must be met before the survivor is authorized for TRS coverage.

[72 FR 46383, Aug. 20, 2007, as amended at 76 FR 57641, Sept. 16, 2011; 80 FR 55254, Sept. 15, 2015; 82 FR 45458, Sept. 29, 2017; 86 FR 67862, Nov. 30, 2021]

§199.25 TRICARE Retired Reserve.

(a) *Establishment*. TRICARE Retired Reserve offers the TRICARE Select self-managed, preferred-provider network option under §199.17 to qualified members of the Retired Reserve, their immediate family members, and qualified survivors under this section.

(1) *Purpose*. As specified in paragraph (c) of this section, TRICARE Retired Reserve is a premium-based health plan that is available for purchase by any Retired Reserve member who is qualified for non-regular retirement, but is not yet 60 years of age, unless that member is either enrolled in, or eligible to enroll in, a health benefit plan under Chapter 89 of Title 5, United States Code, as well as certain survivors of Retired Reserve members.

(2) *Statutory Authority*. TRICARE Retired Reserve is authorized by 10 U.S.C. 1076e.

(3) *Scope of the Program*. TRICARE Retired Reserve is geographically applicable to the same extent as specified in 32 CFR 199.1(b)(1).

(4) *Major Features of TRICARE Retired Reserve*. The major features of the program include the following:

(i) *TRICARE Select rules applicable*. (A) Unless specified in this section or otherwise prescribed by the ASD (HA), provisions of TRICARE Select under §199.17 apply to TRICARE Retired Reserve.

(B) Certain special programs established in 32 CFR part 199 are not available to members covered under TRICARE Retired Reserve. The Extended Health Care Option (ECHO) program (sec. 199.5) is not included. The Supplemental Health Care Program (sec. 199.16) is not included, except when a TRICARE Retired Reserve covered beneficiary is referred by a Military Treatment Facility (MTF) provider for incidental consults and the MTF provider maintains clinical control over the episode of care. The TRICARE Retiree Dental Program (sec. 199.13) is independent of this program and is otherwise available to all members who qualify for the TRICARE Retiree Dental Program whether or not they purchase TRICARE Retired Reserve coverage. The Continued Health Care Benefits Program (sec. 199.13) is also independent of this program and is otherwise available to all members who qualify for the Continued Health Care Benefits Program.

(ii) *Premiums*. TRICARE Retired Reserve coverage is available for purchase by any Retired Reserve member if the member fulfills all of the statutory qualifications as well as certain survivors. A member of the Retired Reserve or qualified survivor covered under TRICARE Retired Reserve shall pay the amount equal to the total amount that the ASD(HA) determines on an appropriate actuarial basis as being appropriate for that coverage. There is one premium rate for member-only coverage and one premium rate for member and family coverage.

(iii) *Procedures*. Under TRICARE Retired Reserve, Retired Reserve members (or their survivors) who fulfilled all of the statutory qualifications may purchase either the member-only type of coverage or the member and family type of coverage by submitting a completed request in the appropriate format along with an initial payment of the applicable premium. Procedures for purchasing coverage and paying applicable premiums are prescribed in this section.

(iv) *Benefits*. When their coverage becomes effective, TRICARE Retired Reserve beneficiaries receive the TRICARE Select benefit including access to military treatment facilities on a space available basis and pharmacies, as described in §199.17. TRICARE Retired Reserve coverage features the deductible, cost sharing, and catastrophic cap provisions of the TRICARE Select plan applicable to Group B retired

members and dependents of retired members under §199.17(l)(2)(ii); however, the TRICARE Reserve Select premium under paragraph (c) of this section applies instead of any TRICARE Select plan enrollment fee under §199.17. Both the member and the member's covered family members are provided access priority for care in military treatment facilities on the same basis as retired members and their dependents who are not enrolled in TRICARE Prime as described in §199.17(d)(1)(i)(E).

(b) *Qualifications for TRICARE Retired Reserve coverage—(1) Retired Reserve Member*. A Retired Reserve member qualifies to purchase TRICARE Retired Reserve coverage if the member meets both the following criteria:

(i) Is a member of a Reserve component of the armed forces who is qualified for a non-regular retirement at age 60 under chapter 1223 of title 10, U.S.C., but who is not yet age 60 and

(ii) Is not enrolled in, or eligible to enroll in, a health benefits plan under chapter 89 of title 5, U.S.C. That statute has been implemented under part 890 of title 5, CFR as the Federal Employee Health Benefits (FEHB) program. For purposes of the FEHB program, the terms ''enrolled,'' ''enroll'' and ''enrollee'' are defined in §890.101 of title 5, CFR.

(2) *Retired Reserve Survivor*. If a qualified member of the Retired Reserves dies while in a period of TRICARE Retired Reserve coverage, the immediate family member(s) of such member shall remain qualified to purchase new or continue existing TRICARE Retired Reserve coverage until the date on which the deceased member of the Retired Reserve would have attained age 60 as long as they meet the definition of immediate family members specified in paragraph (g)(2) of this section. This applies regardless whether either member-only coverage or member and family coverage was in effect on the day of the TRICARE Retired Reserve member's death.

(c) *TRICARE Retired Reserve premiums*. Members are charged for coverage under TRICARE Retired Reserve that represent the full cost of the program as determined by the Director utilizing an appropriate actuarial basis for the provision of the benefits provided under the TRICARE Select program for the TRICARE Retired Reserve eligible beneficiary population. Premiums are to be paid monthly, except as otherwise provided through administrative implementation, pursuant to procedures established by the Director. The monthly rate for each month of a calendar year is one-twelfth of the annual rate for that calendar year.

(1) *Annual establishment of rates*.—(i) TRICARE Retired Reserve monthly premium rates shall be established and updated annually on a calendar year basis by the ASD(HA) for each of the two types of coverage, member-only coverage and member-and-family coverage as described in paragraph (d)(1) of this section.

(ii) The appropriate actuarial basis used for calculating premium rates shall be one that most closely approximates the actual cost of providing care to the same demographic population as those enrolled in TRICARE Retired Reserve as determined by the ASD(HA). TRICARE Retired Reserve premiums shall be based on the actual costs of providing benefits to TRICARE Retired Reserve members and their dependents during the preceding years if the population of Retired Reserve members enrolled in TRICARE Retired Reserve is large enough during those preceding years to be considered actuarially appropriate. Until such time that actual costs from those preceding years becomes available, TRICARE Retired Reserve premiums shall be based on the actual costs during the preceding calendar years for providing benefits to the population of retired members and their dependents in the same age categories as the retired reserve population in order to make the underlying group actuarially appropriate. An adjustment may be applied to cover overhead costs for administration of the program by the government.

(2) *Premium adjustments*. In addition to the determinations described in paragraph (c)(1) of this section, premium adjustments may be made prospectively for any calendar year to reflect any significant program changes or any actual experience in the costs of administering the TRICARE Retired Reserve Program.

(3) *Survivor Premiums.* A surviving family member of a Retired Reserve member who qualified for TRICARE Retired Reserve coverage as described herein will pay premium rates at the member-only rate if there is only one surviving family member to be covered by TRICARE Retired Reserve and at the member-and-family rate if there are two or more survivors to be covered.

(d) *Procedures.* The Director may establish procedures for the following.

(1) *Purchasing Coverage.* Procedures may be established for a qualified member to purchase one of two types of coverage: Member-only coverage or member and family coverage. Immediate family members of the Retired Reserve member as specified in paragraph (g)(2) of this section may be included in such family coverage. To purchase either type of TRICARE Retired Reserve coverage for effective dates of coverage described below, Retired Reserve members and survivors qualified under either paragraph (b)(1) or (b)(2) of this section must submit a request in the appropriate format, along with an initial payment of the applicable premium required by paragraph (c) of this section in accordance with established procedures.

(i) *Continuation Coverage.* Procedures may be established for a qualified member or qualified survivor to purchase TRICARE Retired Reserve coverage with an effective date immediately following the date of termination of coverage under another TRICARE program.

(ii) *Qualifying event.* Procedures for qualifying events in TRICARE Select plans under §199.17(o) shall apply to TRICARE Retired Reserve coverage.

(iii) *Enrollment.* Procedures for enrollment in TRICARE Select plans under §199.17(o) shall apply to TRICARE Retired Reserve enrollment. Generally, the effective date of coverage will coincide with the first day of a month unless enrollment is due to a qualifying event and a different date on or after the qualifying event is required to prevent a lapse in health care coverage.

(iv) *Survivor coverage under TRICARE Retired Reserve.* Procedures may be established for a surviving family member of a qualified Retired Reserve member who qualified for TRICARE Retired Reserve coverage as described in paragraph (b)(2) of this section to purchase new TRICARE Retired Reserve coverage or continue existing TRICARE Retired Reserve coverage. Procedures similar to those for qualifying life events may be established for a qualified surviving family member to purchase new or continuing coverage with an effective date coinciding with the day of the member's death. Procedures similar to those for open enrollment may be established for a qualified surviving family member to purchase new coverage at any time with an effective date coinciding with the first day of a month.

(2) *Termination.* Termination of coverage for the TRR member/survivor will result in termination of coverage for the member's/survivor's family members in TRICARE Retired Reserve. Procedures may be established for coverage to be terminated as follows.

(i) Coverage shall terminate when members or survivors no longer qualify for TRICARE Retired Reserve as specified in paragraph (c) of this section. For purposes of this section, the member or their survivor no longer qualifies for TRICARE Retired Reserve when the member has been eligible for coverage in a health benefits plan under Chapter 89 of Title 5, U.S.C. for more than 60 days. Further, coverage shall terminate when the Retired Reserve member attains the age of 60 or, if survivor coverage is in effect, when the deceased Retired Reserve member would have attained the age of 60.

(ii) Coverage may terminate for members, former members, and survivors who gain coverage under another TRICARE program.

(iii) In accordance with the provisions of §199.17(o)(2) coverage terminates for members/survivors who fail to make premium payments in accordance with established procedures.

(iv) Coverage may be terminated for members/survivors upon request at any time by submitting a completed request in the appropriate format in accordance with established procedures.

(3) *Re-enrollment following termination.* Absent a new qualifying event, members/survivors are not eligible to re-enroll in TRICARE Retired Reserve until the next annual open season.

(4) *Processing.* Upon receipt of a completed request in the appropriate format, enrollment actions will be processed into DEERS in accordance with established procedures.

(5) *Periodic revision.* Periodically, certain features, rules or procedures of TRICARE Retired Reserve may be revised. If such revisions will have a significant effect on members' or survivors' costs or access to care, members or survivors may be given the opportunity to change their type of coverage or terminate coverage coincident with the revisions.

(e) *Preemption of State laws.*— (1) Pursuant to 10 U.S.C. 1103, the Department of Defense has determined that in the administration of chapter 55 of title 10, U.S. Code, preemption of State and local laws relating to health insurance, prepaid health plans, or other health care delivery or financing methods is necessary to achieve important Federal interests, including but not limited to the assurance of uniform national health programs for military families and the operation of such programs, at the lowest possible cost to the Department of Defense, that have a direct and substantial effect on the conduct of military affairs and national security policy of the United States. This determination is applicable to contracts that implement this section.

(2) Based on the determination set forth in paragraph (f)(1) of this section, any State or local law or regulation pertaining to health insurance, prepaid health plans, or other health care delivery, administration, and financing methods is preempted and does not apply in connection with TRICARE Retired Reserve. Any such law, or regulation pursuant to such law, is without any force or effect, and State or local governments have no legal authority to enforce them in relation to TRICARE Retired Reserve. (However, the Department of Defense may, by contract, establish legal obligations on the part of DoD contractors to conform with requirements similar to or identical to requirements of State or local laws or regulations with respect to TRICARE Retired Reserve).

(3) The preemption of State and local laws set forth in paragraph (f)(2) of this section includes State and local laws imposing premium taxes on health insurance carriers or underwriters or other plan managers, or similar taxes on such entities. Such laws are laws relating to health insurance, prepaid health plans, or other health care delivery or financing methods, within the meaning of 10 U.S.C. 1103. Preemption, however, does not apply to taxes, fees, or other payments on net income or profit realized by such entities in the conduct of business relating to DoD health services contracts, if those taxes, fees or other payments are applicable to a broad range of business activity. For the purposes of assessing the effect of Federal preemption of State and local taxes and fees in connection with DoD health services contracts, interpretations shall be consistent with those of the Federal Employees Health Benefits Program under 5 U.S.C. 8909(f).

(f) *Administration.* The Director may establish other rules and procedures for the effective administration of TRICARE Retired Reserve, and may authorize exceptions to requirements of this section, if permitted by law.

(g) *Terminology.* The following terms are applicable to the TRICARE Retired Reserve program.

(1) *Coverage.* This term means the medical benefits covered under the TRICARE Select program as further outlined in §199.17 whether delivered in military treatment facilities or purchased from civilian sources.

(2) *Immediate family member.* This term means spouse (except former spouses) as defined in paragraph 199.3(b)(2)(i) of this part, or child as defined in paragraph 199.3 (b)(2)(ii).

(3) *Qualified member.* This term means a member who has satisfied all the criteria that must be met before the member is authorized for TRR coverage.

(4) *Qualified survivor.* This term means an immediate family member who has satisfied all the criteria that

must be met before the survivor is authorized for TRR coverage.

[75 FR 47455, Aug. 6, 2010, as amended at 79 FR 78702, Dec. 31, 2014; 82 FR 45459, Sept. 29, 2017]

§ 199.26 TRICARE Young Adult.

(a) *Establishment.* The TRICARE Young Adult (TYA) program offers options of medical benefits provided under the TRICARE program to qualified unmarried adult children of TRICARE-eligible uniformed service sponsors who do not otherwise have eligibility for medical coverage under a TRICARE program at age 21 (23 if enrolled in a full-time course of study at an approved institution of higher learning, and the sponsor provides over 50 percent of the student's financial support), and are under age 26.

(1) *Purpose.* As specified in paragraph (c) of this section, TYA is a premium-based health option that is available for purchase by any qualified adult child as that term is defined in paragraph (b) of this section. The TYA program allows a qualified adult child to purchase TRICARE coverage.

(2) *Statutory authority.* TYA is authorized by 10 U.S.C. 1110b.

(3) *Scope of the program.* TYA is geographically applicable to the same extent as specified in §199.1(b)(1).

(4) *Major features of TYA.* (i) *TRICARE rules applicable.*

(A) Unless specified in this section or otherwise prescribed by the Assistant Secretary of Defense (Health Affairs) (ASD (HA)), provisions of this part apply to TYA.

(B) The TRICARE Dental Program (§199.13) and the TRICARE Retiree Dental Program (§199.22) are not covered under TYA.

(C) TRICARE Select is available to all TYA-eligible young adult dependents.

(D) TRICARE Prime is available to TYA-eligible young adult dependents, provided that TRICARE Prime (including the Uniformed Services Family Health Plan) is available in the geographic location where the TYA enrollee resides. TYA-eligible young adults are:

(*1*) Dependents of sponsors on active duty orders written, or otherwise continuously, for more than 30 days or covered by TAMP (under §199.3(e));

(*2*) Dependents of sponsors who are retired members other than retired members of the Retired Reserve; and

(*3*) Survivors of members who died while on active duty for more than 30 days or while receiving retired or retainer pay.

(ii) *Premiums.* TYA coverage is a premium based program that an eligible young adult dependent may purchase. There is only individual coverage, and a premium shall be charged for each dependent even if there is more than one qualified dependent in the uniformed service sponsor's family that qualifies for TYA coverage. Dependents qualifying for TYA status can purchase individual TRICARE Select or TRICARE Prime coverage (as applicable) according to the rules governing the TRICARE option for which they are qualified on the basis of their uniformed service sponsor's TRICARE-eligible status (active duty, retired, Selected Reserve, or Retired Reserve) and the availability of a desired option in their geographic location. Premiums shall be determined in accordance with paragraph (c) of this section.

(iii) *Procedures.* Under TYA, qualified dependents under paragraph (b) of this section may purchase individual TYA coverage by submitting a completed request in the appropriate format along with an initial payment of the applicable premium. Procedures for purchasing coverage and paying applicable premiums are prescribed in paragraph (d) of this section.

(iv) *Benefits.* When their TYA coverage becomes effective, qualified beneficiaries receive the benefit of the TRICARE option that they selected, including, if applicable, access to military treatment facilities and pharmacies. TYA coverage features the cost share, deductible and catastrophic cap provisions applicable to Group B beneficiaries based on the program selected, *i.e.*, the TRICARE Select program under §199.17(l)(2)(ii) or the TRICARE Prime program under §199.17(l)(ii), as well as the status of their military sponsor. Access to military treatment facilities under the system of access priorities in §199.17(d)(1) is also based on the program selected as well as the

status of the military sponsor. Premiums are not credited to deductibles or catastrophic caps; however, TYA premiums shall apply instead of any applicable TRICARE Prime or Select enrollment fee.

(b) *Eligibility for TRICARE Young Adult coverage*—(1) *Young Adult Dependent.* A young adult dependent qualifies to purchase TYA coverage if the dependent meets the following criteria:

(i) Would be a dependent child under 10 U.S.C. 1072, but for exceeding the age limit under that section (abused dependents and NATO dependents are not eligible for TYA coverage); and

(ii) Is a dependent under the age of 26; and

(iii) Is not enrolled, or eligible to enroll, for medical coverage in an eligible employer-sponsored health plan as defined in section 5000A(f)(2) of the Internal Revenue Code of 1986; and

(iv) Is not otherwise eligible under §199.3; and

(v) Is not a member of the uniformed services.

(2) The dependents' sponsor is responsible for keeping the Defense Enrollment Eligibility Reporting System (DEERS) current with eligibility data through the sponsor's Service personnel office. Using information from the DEERS, the TRICARE regional contractors have the responsibility to validate a dependent's qualifications to purchase TYA coverage.

(c) *TRICARE Young Adult premiums.* Qualified young adult dependents are charged premiums for coverage under TYA that represent the full cost of the program, including reasonable administrative costs, as determined by the Director utilizing an appropriate actuarial basis for the provision of TRICARE benefits for the TYA-eligible beneficiary population. Separate premiums shall be established for TRICARE Select and Prime plans. There may also be separate premiums based on the uniformed services sponsor's status. Premiums are to be paid monthly, except as otherwise provided through administrative implementation, pursuant to procedures established by the Director. The monthly rate for each month of a calendar year is one-twelfth of the annual rate for that calendar year.

(1) *Annual establishment of rates.* (i) Monthly premium rates shall be established and updated annually on a calendar year basis by the ASD(HA) for TYA individual coverage.

(ii) The appropriate actuarial basis used for calculating premium rates shall be one that most closely approximates the actual cost of providing care to a similar demographic population (based on age and health plans) as those enrolled in TYA, as determined by the ASD(HA). TYA premiums shall be based on the actual costs of providing benefits to TYA dependents during the preceding years if the population of TYA enrollees is large enough during those preceding years to be considered actuarially appropriate. Until such time that actual costs from those preceding years become available, TYA premiums shall be based on the actual costs during the preceding calendar years for providing benefits to the population of similarly aged dependents to make the underlying group actuarially appropriate. An adjustment may be applied to cover overhead costs for administration of the program.

(2) *Premium adjustments.* In addition to the determinations described in paragraph (c)(1) of this section, premium adjustments may be made prospectively for any calendar year to reflect any significant program changes mandated by legislative enactment, including but not limited to significant new programs or benefits.

(d) *Procedures.* The Director may establish procedures for the following.

(1) *Purchasing coverage.* Procedures may be established for a qualified dependent to purchase individual coverage. To purchase TYA coverage for effective dates of coverage described below, qualified dependents must submit a request in the appropriate format, along with an initial payment of the applicable premium required by paragraph (c) of this section in accordance with established procedures.

(i) *Continuation coverage.* Procedures may be established for a qualified dependent to purchase TYA coverage with an effective date immediately following the date of termination of coverage under another TRICARE program. Application for continuation coverage must be made within 30 days

of the date of termination of coverage under another TRICARE program.

(ii) *Enrollment.* Procedures for enrollment in TRICARE plans under §199.17(o) shall apply to a qualified dependent purchasing TYA coverage. Generally, the effective date of coverage will coincide with the first day of a month unless enrollment is due to a qualifying event and a different date on or after the qualifying event is required to prevent a lapse in health care coverage.

(2) *Termination.* Procedures may be established for TYA coverage to be terminated as follows.

(i) Loss of eligibility or entitlement for coverage by the sponsor will result in termination of the dependent's TYA coverage unless otherwise specified. The effective date of the sponsor's loss of eligibility for care will also be the effective date of termination of benefits under the TYA program unless specified otherwise.

(A) *Active duty military sponsor.* TYA coverage ends effective the date of military sponsor's separation from military service, unless the dependent would be eligible under section 199.3(e) of this Part but for the dependent's age, for the duration of the Transitional Assistance Management Program (TAMP) eligibility or until reaching age 26, whichever comes first. Upon the death of an active duty sponsor, dependents eligible for Transitional Survivor coverage may purchase TYA coverage if otherwise qualified.

(B) *Selected Reserve (Sel Res) Sponsor.* Sel Res sponsors must be currently enrolled in TRICARE Reserve Select (TRS) before a young adult dependent is eligible to purchase TYA. If TRS coverage is terminated by the sponsor, TYA coverage ends effective the same termination date as the sponsor. If the Sel Res sponsor dies while enrolled in TRS, the young adult dependent is eligible to purchase TYA coverage for six months after the date of death of the Sel Res sponsor, if otherwise qualified.

(C) *Retired Reserve Sponsor.* Retired Reserve members not yet eligible for retired or retainer pay must be enrolled in TRICARE Retired Reserve (TRR) to establish TYA eligibility for their young adult dependents. If TRR coverage is terminated by the sponsor, the TYA coverage for the young adult dependent ends effective the same date as the sponsor's termination of coverage under TRR. If the retired reserve sponsor dies while enrolled in TRR, the young adult dependent may continue to purchase TYA coverage until the date on which the deceased member would have attained age 60, if otherwise qualified. If the Retired Reserve member dies and is not enrolled in TRR, there is no eligibility for TYA coverage until the sponsor would have reached age 60. On the date the Retired Reserve member would have reached 60, a young adult dependent who otherwise qualifies for TYA qualifies as a dependent of a deceased retired sponsor and can purchase TYA coverage.

(ii) Failure of a young adult dependent to maintain the eligibility qualifications in paragraph (b) of this section shall result in the termination of coverage under the TYA program. The effective date of termination shall be the date upon which the adult young dependent failed to meet any of the prerequisite qualifications. If a subsequent change in circumstances re-establishes eligibility (such as losing eligibility for an eligible employer-sponsored plan), the young adult dependent may re-enroll for coverage under the TYA program.

(iii) Coverage may also be terminated due to a change in the sponsor's status, and the young adult dependent must re-qualify and reapply for TYA coverage within 30 days of termination to preclude a gap in coverage.

(iv) Termination of coverage results in denial of claims for services with a date of service after the effective date of termination.

(v) Coverage may be terminated for young adult dependents upon request at any time by submitting a completed request in the appropriate format in accordance with established procedures.

(vi) In accordance with the provisions of §199.17(o)(2), coverage terminates for young adult dependents who fail to make premium payments in accordance with established procedures.

(vii) Absent a new qualifying event, young adults are not eligible to re-enroll in TYA until the next annual open season.

(3) *Eligibility for the Continued Health Care Benefit Program.* Upon termination of eligibility to purchase TYA coverage, dependents may purchase coverage for up to 36 months through the Continued Health Care Benefit Program under §199.20 unless locked out of TYA.

(4) *Changing coverage.* Upon application and payment of appropriate premiums, qualified dependents already enrolled in and who are current in their premium payments may elect to change to another TRICARE program for which the qualified dependent is eligible based on the sponsor's eligibility and the geographic location of the qualified young adult dependent. Upon change in sponsor status (for example, active duty to retired status), TYA coverage may be automatically transferred to the appropriate TRICARE option consistent with the sponsor's new status. Recurring TYA premiums may be adjusted accordingly. Administrative processes may be established for changes in program enrollment; however, no change shall be effective until the applicable premium has been paid.

(e) *Preemption of State laws.*—The preemption provisions of §199.17(a)(7) are applicable to the TYA program.

(f) *Administration.* The Director may establish other processes, policies and procedures for the effective administration of the TYA Program and may authorize exceptions to requirements of this section, if permitted.

[78 FR 32119, May 29, 2013, as amended at 82 FR 45460, Sept. 29, 2017]

APPENDIX A TO PART 199—ACRONYMS

AFR—Air Force Regulation
AR—Army Regulation
ASD (HA)—Assistant Secretary of Defense (Health Affairs)
CCLR—Claims Collection Litigation Report
CEOB—CHAMPUS Explanation of Benefits
CFR—Code of Federal Regulations
CHAMPUS—Civilian Health and Medical Program of the Uniformed Services
CRD—Chronic Renal Disease
CT—Computerized Tomography
DASD (A)—Deputy Assistant Secretary of Defense (Administration)
D.D.S.—Doctor of Dental Surgery
DEERS—Defense Enrollment Eligibility Reporting System
DHHS—Department of Health and Human Services
D.M.D.—Doctor of Dental Medicine
DME—Durable Medical Equipment
D.O.—Doctor of Osteopathy
DoD—Department of Defense
DSM-III—Diagnostic and Statistical Manual of Mental Disorders (Third Edition)
ECHO—Extended Care Health Option
EEG—Electroencephalogram
EST—Electroshock Therapy
FAR—Federal Acquisition Regulation
FEHBP—Federal Employees Health Benefits Program
FMCRA—Federal Medical Care Recovery Act
FR—Federal Register
HBA—Health Benefits Advisor
HL—Hearing Threshold Level
Hz—Hertz
ICD–9–CM—International Classification of Diseases, 9th Revision, Clinical Modification
ICU—Intensive Care Unit
IQ—Intelligence Quotient
JCAH—Joint Commission on Accreditation of Hospitals
L.P.N.—Licensed Practical Nurse
L.V.N.—Licensed Vocational Nurse
MBD—Minimal Brain Dysfunction
MCO—Marine Corps Order
M.D.—Doctor of Medicine
MIA—Missing in Action
NATO—North Atlantic Treaty Organization
NAVMILPERSCOMINST—Navy Military Personnel Command Instruction
NAVPERS—Navy Personnel
NOAA—National Oceanic and Atmospheric Administration
OCHAMPUS—Office of Civilian Health and Medical Program of the Uniformed Services
OCHAMPUSEUR—Office of Civilian Health and Medical Program of the Uniformed Services for Europe
OCHAMPUSPAC—Office of Civilian Health and Medical Program of the Uniformed Services for the Pacific Area
OCHAMPUSSO—Office of Civilian Health and Medical Program of the Uniformed Services for the Southern Hemisphere
OMB—Office of Management and Budget
PKU—Phenylketonuria
R.N.—Registered Nurse
RTC—Residential Treatment Center
SNF—Skilled Nursing Facility
STF—Specialized Treatment Facility
U.S.C.—United States Code
USPHS—U.S. Public Health Service

[51 FR 24008, July 1, 1986, as amended at 62 FR 35097, June 30, 1997; 63 FR 48448, Sept. 10, 1998; 69 FR 44952, July 28, 2004; 69 FR 51569, Aug. 20, 2004]

PART 200—CIVIL MONEY PENALTY AUTHORITIES FOR THE TRICARE PROGRAM

Subpart A—General Provisions

Subpart B—Civil Money Penalties (CMPs) and Assessments for False or Fraudulent Claims and Other Similar Misconduct

Subpart C—CMPs and Assessments for Anti-Kickback Violations

Subparts D–N [Reserved]

Subpart O—Procedures for the Imposition of CMPs and Assessments

Subpart P—Appeals of CMPs and Assessments

AUTHORITY: 5 U.S.C. 301; 10 U.S.C. chapter 55; 42 U.S.C. 1320a–7a.

SOURCE: 85 FR 60705, Sept. 28, 2020, unless otherwise noted.

Subpart A—General Provisions

§ 200.100 Basis and purpose.

(a) *Basis.* This part implements section 1128A of the Social Security Act (42 U.S.C. 1320a–7a) (the Act).

(b) *Purpose.* This part—

(1) Provides for the imposition of civil money penalties and, as applicable, assessments against persons who have committed an act or omission that violates one or more provisions of this part; and

(2) Sets forth the appeal rights of persons subject to a penalty and assessment.

§ 200.110 Definitions.

For purposes of this part, with respect to terms not defined in this section but defined in 32 CFR 199.2, the definition in such § 199.2 shall apply. For purposes of this part, the following definitions apply:

Assessment means the amounts described in this part and includes the plural of that term.

Claim means an application for payment for an item or service under TRICARE/CHAMPUS.

Defense Health Agency or DHA means the Director of the Defense Health Agency or designee.

Items and services or items or services includes without limitation, any item, device, drug, biological, supply, or service (including management or administrative services), including, but not limited to, those that are listed in