

Part 199.6

TRICARE-Authorized Providers

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(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 Sec. 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 Secs. 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 Sec. 199.2 under the following circumstances:

(i) *Mandatory participation.* (A) An institutional provider in Sec. 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 Sec. 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 Sec. 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 Sec. 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 Sec. 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 Sec. 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 Sec. 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 Sec. 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 Sec. 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 Secs. 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 Sec. 199.9(f)(2).

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

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

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

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

(B) Maintains clinical records on all inpatients (and outpatients if the facility operates an outpatient department or emergency room).

(C) Has bylaws in effect with respect to its operations and medical staff.

(D) Has a requirement that every patient be under the care of a physician.

(E) Provides 24-hour nursing service rendered or supervised by a registered professional nurse, and has a licensed practical nurse or registered professional nurse on duty at all times.

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

(G) In the case of an institution in a state in which state or applicable local law provides for the licensing of hospitals, the hospital:

(1) Is licensed pursuant to such law, or

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

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

(I) Is accredited by the JCAH or meets such other requirements as the Secretary of Health and

Human Services, the Secretary of Transportation, or the Secretary of Defense finds necessary in the interest of the health and safety of patients who are admitted to and furnished services in the institution.

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, certain temporary hospitals and freestanding ambulatory surgical centers (ASCs) that enroll with Medicare as hospitals may be temporarily exempt from certain institutional requirements for acute care hospitals in this paragraph 199.6(b)(4)(i), as determined by the Director, Defense Health Agency (DHA), or designee, to ensure access to acute inpatient care during the COVID-19 outbreak.

(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 Sec. 199.7(b)(3). The hospital is responsible for assuring that patient services and all treatment are accurately documented and completed in a timely manner.
- (v) *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 Code¹ 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 full range of diagnostic and therapeutic services to establish and implement an effective plan of care which will reverse life-threatening and/or severely incapacitating symptoms;
- (ii) Partial hospitalization, which provides a less than 24-hour-per-day, seven-day-per-week treatment program for patients who continue to exhibit psychiatric problems but can function with support in some of the major life areas;
- (iii) A group home, which is a professionally directed living arrangement with the availability of psychiatric consultation and treatment for patients with significant family dysfunction and/or chronic

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but stable psychiatric disturbances;

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

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

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

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

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

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

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

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

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

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

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

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

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

(6) Submit claims for services provided to CHAMPUS beneficiaries at least every 30 days (except to

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

(7) Certify that:

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

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

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

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

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

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

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

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

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

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

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

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

(2) The RTC shall provide inpatient services to CHAMPUS beneficiaries in the same manner it

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

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

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

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

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

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

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

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

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

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

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

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

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

- (i) Require prior approval of all admissions to special institutional providers.
 - (ii) Set appropriate standards for special institutional providers in addition to or in the absence of JCAHO accreditation.
 - (iii) Monitor facility operations and treatment programs on a continuing basis and conduct onsite inspections on a scheduled and unscheduled basis.
 - (iv) Negotiate agreements of participation.
 - (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. (AAHC), 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) *Birth 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 Sec. 199.14, or such other method as determined by the Director;
- (3) Accept the CHAMPUS all-inclusive per diem rate as payment in full and collect from the CHAMPUS beneficiary or the family of the CHAMPUS beneficiary only those amounts that represent the beneficiary's liability, as defined in Sec. 199.4, and charges for services and supplies that are not a benefit of CHAMPUS;
- (4) Make all reasonable efforts acceptable to the Director to collect those amounts, which represent the beneficiary's liability, as defined in Sec. 199.4;
- (5) Comply with the provisions of Sec. 199.8, and submit claims first to all health insurance coverage to which the beneficiary is entitled that is primary to CHAMPUS;
- (6) Submit claims for services provided to CHAMPUS beneficiaries at least every 30 days (except to the extent a delay is necessitated by efforts to first collect from other health insurance). If claims are not submitted at least every 30 days, the PHP agrees not to bill the beneficiary or the beneficiary's family for any amounts disallowed by CHAMPUS;
- (7) Certify that:
 - (i) It is and will remain in compliance with the TRICARE standards and provisions of paragraph (b)(4)(xii) of this section establishing standards for psychiatric and substance use disorder partial hospitalization programs; and
 - (ii) It will maintain compliance with the CHAMPUS Standards for Psychiatric Substance Use Disorder Partial Hospitalization Programs, as issued by the Director, except for any such standards regarding which the facility notifies the Director, or designee, that it is not in compliance.
- (8) Designate an individual who will act as liaison for CHAMPUS inquiries. The PHP shall inform the Director, or designee, in writing of the designated individual;
- (9) Furnish OCHAMPUS, as requested by OCHAMPUS, with cost data certified by an independent accounting firm or other agency as authorized by the Director;
- (10) Comply with all requirements of this section applicable to institutional providers generally concerning accreditation requirements, preauthorization, concurrent care review, claims processing, beneficiary liability, double coverage, utilization and quality review, and other matters;
- (11) Grant the Director, or designee, the right to conduct quality assurance audits or accounting audits with full access to patients and records (including records relating to patients who are not CHAMPUS beneficiaries) to determine the quality and cost-effectiveness of care rendered. The audits may be conducted on a scheduled or unscheduled (unannounced) basis. This right to audit/review

includes, but is not limited to:

- (i) Examination of fiscal and all other records of the PHP which would confirm compliance with the participation agreement and designation as a TRICARE authorized PHP provider;
- (ii) Conducting such audits of PHP records including clinical, financial, and census records, as may be necessary to determine the nature of the services being provided, and the basis for charges and claims against the United States for services provided CHAMPUS beneficiaries;
- (iii) Examining reports of evaluations and inspections conducted by federal, state and local government, and private agencies and organizations;
- (iv) Conducting on-site inspections of the facilities of the PHP and interviewing employees, members of the staff, contractors, board members, volunteers, and patients, as required;
- (v) Audits conducted by the United States General Account Office.

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

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

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

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

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

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

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

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

employees.

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

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

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

(i) A physician;

(ii) A registered professional nurse;

(iii) A social worker; and

(iv) A pastoral or other counselor.

(5) Maintain central clinical records on all patients.

(6) Utilize volunteers.

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

(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 Sec. 199.14, or such other method as determined by the Director;
- (3) Accept the CHAMPUS-determined rate as payment in full and collect from the CHAMPUS beneficiary or the family of the CHAMPUS beneficiary only those amounts that represent the beneficiary's liability, as defined in Sec. 199.4, and charges for services and supplies that are not a benefit of CHAMPUS;
- (4) Make all reasonable efforts acceptable to the Director to collect those amounts which represent the beneficiary's liability, as defined in Sec. 199.4;
- (5) Comply with the provisions of Sec. 199.8, and submit claims first to all health insurance coverage to which the beneficiary is entitled that is primary to CHAMPUS;
- (6) Furnish OCHAMPUS with cost data, as requested by OCHAMPUS, certified to by an independent accounting firm or other agency as authorized by the Director;
- (7) Certify that:
 - (i) It is and will remain in compliance with the provisions of paragraph (b)(4)(xiv) of the section establishing standards for substance use disorder rehabilitation facilities; and
 - (ii) It has conducted a self-assessment of the facility's compliance with the CHAMPUS Standards for Substance Use Disorder Rehabilitation Facilities, as issued by the Director and notified the Director of any matter regarding which the facility is not in compliance with such standards; and
 - (iii) It will maintain compliance with the CHAMPUS Standards for Substance Use Disorder Rehabilitation Facilities, as issued by the Director, except for any such standards regarding which the facility notifies the Director that it is not in compliance.
- (8) Designate an individual who will act as liaison for CHAMPUS inquiries. The SUDRF shall inform OCHAMPUS in writing of the designated individual;
- (9) Furnish OCHAMPUS, as requested by OCHAMPUS, with cost data certified by an independent accounting firm or other agency as authorized by the Director;
- (10) Comply with all requirements of this section applicable to institutional providers generally concerning accreditation requirements, preauthorization, concurrent care review, claims processing, beneficiary liability, double coverage, utilization and quality review, and other matters;
- (11) Grant the Director, or designee, the right to conduct quality assurance audits or accounting audits with full access to patients and records (including records relating to patients who are not CHAMPUS beneficiaries) to determine the quality and cost effectiveness of care rendered. The audits may be conducted on a scheduled or unscheduled (unannounced) basis. This right to audit/review

included, but is not limited to:

- (i) Examination of fiscal and all other records of the center which would confirm compliance with the participation agreement and designation as an authorized TRICARE provider;
- (ii) Conducting such audits of center records including clinical, financial, and census records, as may be necessary to determine the nature of the services being provided, and the basis for charges and claims against the United States for services provided CHAMPUS beneficiaries;
- (iii) Examining reports of evaluations and inspection conducted by federal, state and local government, and private agencies and organizations;
- (iv) Conducting on-site inspections of the facilities of the SUDRF and interviewing employees, members of the staff, contractors, board members, volunteers, and patients, as required.
- (v) Audits conducted by the United States Government Accountability Office.

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

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

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

(xv) *Home health agencies (HHAs).* HHAs must be Medicare approved and meet all Medicare conditions of participation under sections 1861(o) and 1891 of the Social Security Act (42 U.S.C. 1395x(o) and 1395bbb) and 42 CFR part 484 in relation to TRICARE beneficiaries in order to receive payment under the TRICARE program. An HHA may be found to be out of compliance with a particular Medicare condition of participation and still participate in the TRICARE program as long as the HHA is allowed continued participation in Medicare while the condition of noncompliance is being corrected. An HHA is a public or private organization, or a subdivision of such an agency or organization, that meets the following requirements:

(A) Engaged in providing skilled nursing services and other therapeutic services, such as physical therapy, speech-language pathology services, or occupational therapy, medical services, and home health aide services.

(1) Makes available part-time or intermittent skilled nursing services and at least one other therapeutic service on a visiting basis in place of residence used as a patient's home.

(2) Furnishes at least one of the qualifying services directly through agency employees, but may furnish the second qualifying service and additional services under arrangement with another HHA or organization.

(B) Policies established by a professional group associated with the agency or organization (including at least one physician and one registered nurse) to govern the services and provides for supervision of such services by a physician or a registered nurse.

(C) Maintains clinical records for all patients.

(D) Licensed in accordance with State and local law or is approved by the State or local licensing agency as meeting the licensing standards, where applicable.

(E) Enters into an agreement with TRICARE in order to participate and to be eligible for payment under the program. In this agreement the HHA and TRICARE agree that the HHA will:

(1) Not charge the beneficiary or any other person for items or services for which the beneficiary is entitled to have payment under the TRICARE HHA prospective payment system.

(2) Be allowed to charge the beneficiary for items or services requested by the beneficiary in addition to those that are covered under the TRICARE HHA prospective payment system.

(F) Abide by the following consolidated billing requirements:

(1) The HHA must submit all TRICARE claims for all home health services, excluding durable medical equipment (DME), while the beneficiary is under the home health plan without regard to whether or not the item or service was furnished by the HHA, by others under arrangement with the HHA, or under any other contracting or consulting arrangement.

(2) Separate payment will be made for DME items and services provided under the home health benefit which are under the DME fee schedule. DME is excluded from the consolidated billing requirements.

(3) Home health services included in consolidated billing are:

(i) Part-time or intermittent skilled nursing;

(ii) Part-time or intermittent home health aide services;

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

(iv) Medical social services;

(v) Routine and non-routine medical supplies;

(vi) A covered osteoporosis drug (not paid under PPS rate) but excluding other drugs and biologicals;

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

(viii) Services at hospitals, SNFs or rehabilitation centers when they involve equipment too cumbersome to bring home.

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

(xvi) *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 Sec. 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 Sec. 199.2. IOP services consist of a comprehensive and complimentary schedule of recognized treatment approaches that may include day, evening, night, and weekend services consisting of individual and group counseling or therapy, and family counseling or therapy as clinically indicated for children and adolescents, or adults aged 18 and over, and may include case management to link patients and their families with community based support systems.

(2) *Eligibility. (i)* In order to qualify as a TRICARE authorized provider, every intensive outpatient program must meet the minimum basic standards set forth in paragraphs (b)(4)(xviii)(A) through (C) of this section, as well as additional elaborative criteria and standards as the Director determines are necessary to implement the basic standards. Each intensive outpatient program must be either a distinct part of an otherwise-authorized institutional provider or a free-standing psychiatric or substance use disorder intensive outpatient program. Approval of a hospital by TRICARE is sufficient for its IOP to be an authorized TRICARE provider. Such hospital-based intensive outpatient programs are not required to be separately authorized by TRICARE.

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

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

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

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

- (1) Render intensive outpatient program services to eligible TRICARE beneficiaries in need of such services, in accordance with the participation agreement and TRICARE regulation.
- (2) Accept payment for its services based upon the methodology provided in Sec. 199.14, or such other method as determined by the Director;
- (3) Collect from the TRICARE beneficiary or the family of the TRICARE beneficiary only those amounts that represent the beneficiary's liability, as defined in Sec. 199.4, and charges for services and supplies that are not a benefit of TRICARE;
- (4) Make all reasonable efforts acceptable to the Director to collect those amounts, which represent the beneficiary's liability, as defined in Sec. 199.4;
- (5) Comply with the provisions of Sec. 199.8, and submit claims first to all health insurance coverage to which the beneficiary is entitled that is primary to TRICARE;
- (6) Submit claims for services provided to TRICARE beneficiaries at least every 30 days (except to the extent a delay is necessitated by efforts to first collect from other health insurance). If claims are not submitted at least every 30 days, the IOP agrees not to bill the beneficiary or the beneficiary's family for any amounts disallowed by TRICARE;
- (7) Free-standing intensive outpatient programs shall certify that:
 - (i) It is and will remain in compliance with the provisions of paragraph (b)(4)(xii) of this section establishing standards for psychiatric and SUD IOPs;
 - (ii) It has conducted a self-assessment of the facility's compliance with the CHAMPUS Standards for Intensive Outpatient Programs, as issued by the Director, and notified the Director of any matter regarding which the facility is not in compliance with such standards; and
 - (iii) It will maintain compliance with the TRICARE standards for IOPs, as issued by the Director, except for any such standards regarding which the facility notifies the Director, or a designee that it is not in compliance.
- (8) Designate an individual who will act as liaison for TRICARE inquiries. The IOP shall inform TRICARE, or a designee in writing of the designated individual;
- (9) Furnish OCHAMPUS with cost data, as requested by OCHAMPUS, certified by an independent accounting firm or other agency as authorized by the Director.

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

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

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

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

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

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

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

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

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

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

(xix) *Opioid Treatment Programs (OTPs).* This paragraph (b)(4)(xix) establishes standards and requirements for Opioid Treatment Programs.

(A) *Organization and administration.* (1) *Definition.* Opioid Treatment Programs (OTPs) are defined in Sec. 199.2. Opioid Treatment Programs (OTPs) are organized, ambulatory, addiction treatment services for patients with an opioid use disorder. OTPs have the capacity to provide daily direct administration of medications without the prescribing of medications. Medication supplies for patients to take outside of OTPs originate from within OTPs. OTPs offer medication assisted treatment, patient-centered, recovery-oriented individualized treatment through addiction counseling, mental health therapy, case management, and health education.

(2) *Eligibility.* (i) Every free-standing Opioid Treatment Program must be accredited by an accrediting organization recognized by Director, under the current standards of an accrediting organization, as well as meet additional elaborative criteria and standards as the Director determines are necessary to implement the basic standards. OTPs adhere to requirements of the Department of Health and Human Services' 42 CFR part 8, the Substance Abuse and Mental Health Services Administration's Center for Substance Abuse Treatment, and the Drug Enforcement Agency. OTPs must be either a distinct part of an otherwise authorized institutional provider or a free-standing program. Approval of hospitals by TRICARE is sufficient for their OTPs to be authorized TRICARE providers. Such hospital-based OTPs, if certified under 42 CFR 8, are not required to be separately authorized by TRICARE.

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

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

(B) *Participation agreement requirements.* In addition to other requirements set forth in this paragraph (b)(4)(xix), in order for the services of OTPs to be authorized, OTPs shall have entered into a Participation Agreement with TRICARE. A single consolidated participation agreement is acceptable for all units of a TRICARE authorized facility. The period of a Participation Agreement shall be specified in the agreement, and will generally be for not more than five years. In addition to review of a facility's application and supporting documentation, an on-site inspection by DHA authorized personnel may be required prior to signing a participation agreement. The Participation Agreement shall include at least the following requirements:

(1) Render services from OTPs to eligible TRICARE beneficiaries in need of such services, in accordance with the participation agreement and TRICARE regulation.

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

(3) Collect from the TRICARE beneficiary or the family of the TRICARE beneficiary only those amounts that represent the beneficiary's liability, as defined in Sec. 199.4, and charges for services and supplies that are not a benefit of TRICARE;

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

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

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

(7) Free-standing opioid treatment programs shall certify that:

(i) It is and will remain in compliance with the provisions of paragraph (b)(4)(xii) of this section

establishing standards for opioid treatment programs;

(ii) It will maintain compliance with the TRICARE standards for OTPs, as issued by the Director, except for any such standards regarding which the facility notifies the Director, or a designee, that it is not in compliance.

(8) Designate an individual who will act as liaison for TRICARE inquiries. OTPs shall inform TRICARE, or a designee, in writing of the designated individual;

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

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

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

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

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

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

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

(2) OTPs may not discriminate against CHAMPUS beneficiaries in any manner, including admission practices or provisions of special or limited treatment.

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

(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 Sec. 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 Sec. 199.4(e) of this part, all otherwise covered services rendered by dentists require preauthorization.

(A) *Doctors of Dental Medicine (D.M.D.).*

(B) *Doctors of Dental Surgery (D.D.S.).*

(iii) *Other allied health professionals.* The services of the following individual professional providers of care are coverable on a fee-for-service basis provided such services are otherwise authorized in this or other sections of this part.

(A) *Clinical psychologist.* For purposes of CHAMPUS, a clinical psychologist is an individual who is licensed or certified by the state for the independent practice of psychology and:

(1) Possesses a doctoral degree in psychology from a regionally accredited university; and

(2) Has has 2 years of supervised clinical experience in psychological health services of which at least 1 year is post-doctoral and 1 year (may be the post-doctoral year) is in an organized psychological health service training program; or

(3) As an alternative to paragraphs (c)(3)(iii)(A)(1) and (2) of this section is listed in the National Register of Health Service Providers in Psychology.

(B) *Doctors of Optometry.*

(C) *Doctors of 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 speciality of practice, if the state does not offer specific licensure or certification for nurse practitioners.

(F) *Certified Clinical Social Worker.* A clinical social worker may provide covered services independent of physician referral and supervision, provided the clinical social worker:

(1) Is licensed or certified as a clinical social worker by the jurisdiction where practicing; or, if the jurisdiction does not provide for licensure or certification of clinical social workers, is certified by a national professional organization offering certification of clinical social workers; and

(2) Has at least a master's degree in social work from a graduate school of social work accredited by the Council on Social Work Education; and

(3) Has had a minimum of 2 years or 3,000 hours of post-master's degree supervised clinical social work practice under the supervision of a master's level social worker in an appropriate clinical setting, as determined by the Director, OCHAMPUS, or a designee.

Note: Patients' organic medical problems must receive appropriate concurrent management by a physician.

(G) *Certified psychiatric nurse specialist.* A certified psychiatric nurse specialist may provide covered care independent of physician referral and supervision. For purposes of CHAMPUS, a certified psychiatric nurse specialist is an individual who:

(1) Is a licensed, registered nurse; and

(2) Has at least a master's degree in nursing from a regionally accredited institution with a specialization in psychiatric and mental health nursing; and

(3) Has had at least 2 years of post-master's degree practice in the field of psychiatric and mental health nursing, including an average of 8 hours of direct patient contact per week; or

(4) Is listed in a CHAMPUS-recognized, professionally sanctioned listing of clinical specialists in psychiatric and mental health nursing.

(H) *Certified physician assistant.* A physician assistant may provide care under general supervision of a physician (see Sec. 199.14(j)(1)(ix) of this part for limitations on reimbursement). For purposes of CHAMPUS, a physician assistant must meet the applicable state requirements governing the qualifications of physician assistants and at least one of the following conditions:

(1) Is currently certified by the National Commission on Certification of Physician Assistants to assist primary care physicians, or

(2) Has satisfactorily completed a program for preparing physician assistants that:

(i) Was at least 1 academic year in length;

(ii) Consisted of supervised clinical practice and at least 4 months (in the aggregate) of classroom instruction directed toward preparing students to deliver health care; and

(iii) Was accredited by the American Medical Association's Committee on Allied Health Education and Accreditation; or

(3) Has satisfactorily completed a formal educational program for preparing program physician assistants that does not meet the requirement of paragraph (c)(3)(iii)(H)(2) of this section and had been assisting primary care physicians for a minimum of 12 months during the 18-month period immediately preceding January 1, 1987.

(l) *Anesthesiologist Assistant.* An anesthesiologist assistant may provide covered anesthesia services, if the anesthesiologist assistant:

(1) Works under the direct supervision of an anesthesiologist who bills for the services and for each patient;

(i) The anesthesiologist performs a pre-anesthetic examination and evaluation;

(ii) The anesthesiologist prescribes the anesthesia plan;

(iii) The anesthesiologist personally participates in the most demanding aspects of the anesthesia plan including, if applicable, induction and emergence;

(iv) The anesthesiologist ensures that any procedures in the anesthesia plan that he or she does not perform are performed by a qualified anesthesiologist assistant;

(v) The anesthesiologist monitors the course of anesthesia administration at frequent intervals;

(vi) The anesthesiologist remains physically present and available for immediate personal diagnosis and treatment of emergencies;

(vii) The anesthesiologist provides indicated post-anesthesia care; and

(viii) The anesthesiologist performs no other services while he or she supervises no more than four anesthesiologist assistants concurrently or a lesser number if so limited by the state in which the procedure is performed.

(2) Is in compliance with all applicable requirements of state law, including any licensure requirements the state imposes on nonphysician anesthetists; and

(3) Is a graduate of a Master's level anesthesiologist assistant educational program that is established under the auspices of an accredited medical school and that:

(i) Is accredited by the Committee on Allied Health Education and Accreditation, or its successor organization; and

(ii) Includes approximately two years of specialized basic science and clinical education in anesthesia at a level that builds on a premedical undergraduate science background.

(4) The Director, TMA, or a designee, shall issue TRICARE policies, instructions, procedures, guidelines, standards, and criteria as may be necessary to implement the intent of this section.

(J) *Certified Registered Nurse Anesthetist (CRNA).* A certified registered nurse anesthetist may provide covered care independent of physician referral and supervision as specified by state licensure. For purposes of CHAMPUS, a certified registered nurse anesthetist is an individual who:

- (1) Is a licensed, registered nurse; and
- (2) Is certified by the Council on Certification of Nurse Anesthetists, or its successor organization.

(K) *Other individual paramedical providers.*(1) The services of the following individual professional providers of care to be considered for benefits on a fee-for-service basis may be provided only if the beneficiary is referred by a physician for the treatment of a medically diagnosed condition and a physician must also provide continuing and ongoing oversight and supervision of the program or episode of treatment provided by these individual paramedical providers.

(i) Licensed registered nurses.

(ii) Audiologists.

(2) The services of the following individual 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.* A 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.* A dietician may 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 Sec. 199.7).

(5) Because of the similarity of the requirements for licensure, certification, experience, and education, a pastoral counselor may elect to be authorized under CHAMPUS as a certified marriage and family therapist, and as such, be subject to all previously defined criteria for the certified marriage and family therapist category, to include acceptance of the CHAMPUS determined allowable charge as payment in full, except for applicable deductibles and cost-shares (i.e., balance billing of a beneficiary above the allowable charge is prohibited; may not bill beneficiary for noncovered care). The pastoral counselor must also agree to enter into the same participation agreement as a certified marriage and family therapist with the Office of CHAMPUS within which the pastoral counselor agrees to all provisions including licensure, national association membership and conditions upon termination, outlined above for certified marriage and family therapist.

Note: No dual status will be recognized by the Office of CHAMPUS. Pastoral counselors must elect to become one of the categories of extramedical CHAMPUS provides specified above. Once authorized as either a pastoral counselor, or a certified marriage and family therapist, claims review and reimbursement will be in accordance with the criteria established for the elected provider category.

(C) *Supervised mental health counselor.* For the purposes of TRICARE, a supervised mental health counselor is an individual who does not meet the requirements of a TRICARE certified mental health counselor in paragraph (c)(3)(iii)(N) of this section, but meets all of the following requirements and conditions of practice:

(1) Minimum of a master's degree in mental health counseling or allied mental health field from a regionally accredited institution; and

(2) Two years of post-masters experience which includes 3,000 hours of clinical work and 100 hours of face-to-face supervision; and

(3) Is licensed or certified to practice as a mental health counselor by the jurisdiction where practicing (see paragraph (c)(3)(iv)(D) of this section for more specific information); and

(4) May only be reimbursed when:

(i) The TRICARE beneficiary is referred for therapy by a physician; and

(ii) A physician is providing ongoing oversight and supervision of the therapy being provided; and

(iii) The mental health counselor certifies on each claim for reimbursement that a written communication has been made or will be made to the referring physician of the results of the treatment. Such communication will be made at the end of the treatment, or more frequently, as required by the referring physician (refer to Sec. 199.7).

(D) The following additional information applies to each of the above categories of extramedical individual providers:

(1) These providers must also be licensed or certified to practice as a certified marriage and family therapist, pastoral counselor or mental health counselor by the jurisdiction where practicing. In jurisdictions that do not provide for licensure or certification, the provider must be certified by or eligible for full clinical membership in the appropriate national professional association that sets standards for the specific profession.

(2) Grace period for therapists or counselors in states where licensure/certification is optional. CHAMPUS is providing a grace period for those therapists or counselors who did not obtain optional licensure/certification in their jurisdiction, not realizing it was a CHAMPUS requirement for authorization. The exemption by state law for pastoral counselors may have misled this group into thinking licensure was not required. The same situation may have occurred with the other therapist or counselor categories where licensure was either not mandated by the state or was provided under a more general category such as "professional counselors." This grace period pertains only to the licensure/certification requirement, applies only to therapists or counselors who are already approved as of October 29, 1990, and only in those areas where the licensure/certification is optional. Any therapist or counselor who is not licensed/certified in the state in which he/she is practicing by August 1, 1991, will be terminated under the provisions of Sec. 199.9. This grace period does not change any of the other existing requirements which remain in effect. During this grace period, membership or proof of eligibility for full clinical membership in a recognized professional association is required for those therapists or counselors who are not licensed or certified by the state. The following organizations are recognized for therapists or counselors at the level indicated: Full clinical member of the American Association of Marriage and Family Therapy; membership at the fellow or diplomate level of the American Association of Pastoral Counselors; and membership in the National Academy of Certified Clinical Mental Health Counselors. Acceptable proof of eligibility for membership is a letter from the appropriate certifying organization. This opportunity for delayed certification/licensure is limited to the counselor or therapist category only as the language in all of the other provider categories has been consistent and unmodified from the time each of the other provider categories were added. The grace period does not apply in those states where licensure is mandatory.

(E) *Christian Science practitioners and Christian Science nurses.* CHAMPUS cost-shares the services of Christian Science practitioners and nurses. In order to bill as such, practitioners or nurses must be listed or be eligible for listing in the Christian Science Journal² at the time the service is provided.

(d) Other providers. Certain medical supplies and services of an ancillary or supplemental nature are coverable by CHAMPUS, subject to certain controls. This category of provider includes the following:

(1) *Independent laboratory.* Laboratory services of independent laboratories may be cost-shared if the laboratory is approved for participation under Medicare and certified by the Medicare Bureau, Health Care Financing Administration.

(2) *Suppliers of portable x-ray services.* Such suppliers must meet the conditions of coverage of the Medicare program, set forth in the Medicare regulations, or the Medicaid program in that state in which the covered service is provided.

(3) *Pharmacies.* Pharmacies must meet the applicable requirements of state law in the state in which the pharmacy is located. In addition to being subject to the policies and procedures for authorized providers established by this section, additional policies and procedures may be established for authorized pharmacies under Sec. 199.21 of this part implementing the Pharmacy Benefits Program.

(4) *Ambulance companies.* Such companies must meet the requirements of state and local laws in the jurisdiction in which the ambulance firm is licensed.

² Copies of this journal can be obtained through the Christian Science Publishing Company, 1 Norway Street, Boston, MA 02115-3122 or the Christian Science Publishing Society, P.O. Box 11369, Des Moines, IA 50340.

(5) *Medical equipment firms, medical supply firms, and Durable Medical Equipment, Prosthetic, Orthotic, Supplies providers/suppliers.* Any firm, supplier, or provider that is an authorized provider under Medicare or is otherwise designated an authorized provider by the Director, TRICARE Management Activity.

(6) *Mammography suppliers.* Mammography services may be cost-shared only if the supplier is certified by Medicare for participation as a mammography supplier, or is certified by the American College of Radiology as having met its mammography supplier standards.

(e) Extended Care Health Option Providers.--(1) *General.* (i) Services and items cost-shared through Sec. 199.5 must be rendered by a CHAMPUS-authorized provider.

(ii) A Program for Persons with Disabilities (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 Sec. 199.4, that meets all applicable licensing or other regulatory requirements of the state, county, municipality, or other political jurisdiction in which the ECHO service is rendered, or in the absence of such licensing or regulatory requirements, as determined by the Director, TRICARE Management Activity or designee.

(iii) *ECHO vendor.* A provider of an allowable ECHO item, such as supplies or equipment, shall be deemed to be a TRICARE-authorized vendor for the provision of the specific item, supply or equipment when the vendor supplies such information as the Director, TRICARE Management Activity or designee determines necessary to adjudicate a specific claim.

(3) *ECHO provider exclusion or suspension.* A provider of ECHO services or items may be excluded or suspended for a pattern of discrimination on the basis of disability. Such exclusion or suspension shall be accomplished according to the provisions of Sec. 199.9.

(f) Corporate services providers--(1) *General.* (i) This corporate services provider class is established to accommodate individuals who would meet the criteria for status as a CHAMPUS authorized individual professional provider as established by paragraph (c) of this section but for the fact that they are employed directly or contractually by a corporation or foundation that provides principally professional services which are within the scope of the CHAMPUS benefit.

(ii) Payment for otherwise allowable services may be made to a CHAMPUS-authorized corporate services provider subject to the applicable requirements, exclusions and limitations of this part.

(iii) The Director, OCHAMPUS, or designee, may create discrete types within any allowable category of provider established by this paragraph (f) to improve the efficiency of CHAMPUS management.

(iv) The Director, OCHAMPUS, or designee, may require, as a condition of authorization, that a specific category or type of provider established by this paragraph (f):

(A) Maintain certain accreditation in addition to or in lieu of the requirement of paragraph (f)(2)(v) of this section;

(B) Cooperate fully with a designated utilization and clinical quality management organization which has a contract with the Department of Defense for the geographic area in which the provider does business;

(C) Render services for which direct or indirect payment is expected to be made by CHAMPUS only after obtaining CHAMPUS written authorization; and

(D) Maintain Medicare approval for payment when the Director, OCHAMPUS, or designee, determines that a category, or type, of provider established by this paragraph (f) is substantially comparable to a provider or supplier for which Medicare has regulatory conditions of participation or conditions of coverage.

(v) Otherwise allowable services may be rendered at the authorized corporate services provider's place of business, or in the beneficiary's home under such circumstances as the Director, OCHAMPUS, or designee, determines to be necessary for the efficient delivery of such in-home services.

(vi) The Director, OCHAMPUS, or designee, may limit the term of a participation agreement for any category or type of provider established by this paragraph (f).

(vii) Corporate services providers shall be assigned to only one of the following allowable categories based upon the predominate type of procedure rendered by the organization;

(A) Medical treatment procedures;

(B) Surgical treatment procedures;

(C) Maternity management procedures;

(D) Rehabilitation and/or habilitation procedures; or

(E) Diagnostic technical procedures.

(viii) The Director, OCHAMPUS, or designee, shall determine the appropriate procedural category of a qualified organization and may change the category based upon the provider's CHAMPUS claim characteristics. The category determination of the Director, OCHAMPUS, designee, is conclusive and may not be appealed.

(2) *Conditions of authorization.* An applicant must meet the following conditions to be eligible for authorization as a CHAMPUS corporate services provider:

(i) Be a corporation or a foundation, but not a professional corporation or professional association; and

(ii) Be institution-affiliated or freestanding as defined in Sec. 199.2; and

(iii) Provide:

(A) Services and related supplies of a type rendered by CHAMPUS individual professional providers or diagnostic technical services and related supplies of a type which requires direct patient contact and a technologist who is licensed by the state in which the procedure is rendered or who is certified by a Qualified Accreditation Organization as defined in Sec. 199.2; and

(B) A level of care which does not necessitate that the beneficiary be provided with on-site sleeping accommodations and food in conjunction with the delivery of services; and

(iv) Complies with all applicable organizational and individual licensing or certification requirements that are extant in the state, county, municipality, or other political jurisdiction in which the provider renders services; and

(v) Be approved for Medicare payment when determined to be substantially comparable under the provisions of paragraph (f)(1)(iv)(D) of this section or, when Medicare approved status is not required, be accredited by a qualified accreditation organization, as defined in Sec. 199.2; and

(vi) Has entered into a participation agreement approved by the Director, OCHAMPUS, or designee, which at least complies with the minimum participation agreement requirements of this section.

(3) *Transfer of participation agreement.* In order to provide continuity of care for beneficiaries when there is a change of provider ownership, the provider agreement is automatically assigned to the new owner, subject to all the terms and conditions under which the original agreement was made.

(i) The merger of the provider corporation or foundation into another corporation or foundation, or the consolidation of two or more corporations or foundations resulting in the creation of a new corporation or foundation, constitutes a change of ownership.

(ii) Transfer of corporate stock or the merger of another corporation or foundation into the provider corporation or foundation does not constitute change of ownership.

(iii) The surviving corporation or foundation shall notify the Director, OCHAMPUS, or designee, in writing of the change of ownership promptly after the effective date of the transfer or change in ownership.

(4) *Pricing and payment methodology:* The pricing and payment of procedures rendered by a provider authorized under this paragraph (f) shall be limited to those methods for pricing and payment allowed by this part which the Director, OCHAMPUS, or designee, determines contribute to the efficient management of CHAMPUS.

(5) *Termination of participation agreement.* A provider may terminate a participation agreement upon 45 days written notice to the Director, OCHAMPUS, or designee, and to the public.

[51 FR 24008, Jul 1, 1986; 67 FR 40602, Jun 13, 2002; 67 FR 42720, Jun 25, 2002; 68 FR 65174, Nov 19, 2003; 69 FR 29229, May 21, 2004; 69 FR 44591, Jul 28, 2004; 69 FR 51568, Aug 20, 2004; 69 FR 55359, Sep 14, 2004; 70 FR 61378, Oct 24, 2005; 72 FR 63988, Nov 14, 2007; 74 FR 44755, Aug 31, 2009; 74 FR 55777, Oct 29, 2009; 74 FR 65438, Dec 10, 2009; 75 FR 47460, Aug 6, 2010; 75 FR 50882, Aug 18, 2010; 76 FR 41065, Jul 13, 2011; 76 FR 80743, Dec 27, 2011; 78 FR 48309, Aug 8, 2013; 79 FR 41641, Jul 17, 2014; 81 FR 61091, Sep 2, 2016; 81 FR 63695, Sep 16, 2016; 82 FR 45447, Sep 29, 2017; 82 FR 61692, Dec 29, 2017; 85 FR 15066, Mar 17, 2020; 85 FR 27927, May 12, 2020; 85 FR 54923, Sep 3, 2020; 85 FR 73196, Nov 17, 2020]

Editorial Note: For Federal Register citations affecting Sec. 199.6, see the List of Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.