

equipment be prorated. Equipment expense proration permits the allowable cost of an item of PFPWD authorized equipment to be apportioned so that no portion of the allowable cost exceeds the monthly benefit limit and allows each apportioned amount to be separately authorized as a benefit during subsequent contiguous months.

(i) *Maximum period.* The maximum number of contiguous months during which a prorated amount may be authorized for cost-share shall be the lesser of:

(A) The number of months calculated by dividing the initial allowable cost for the item of equipment by \$1,000 and doubling the resulting quotient; or

(B) The number of months of useful equipment life for the requesting beneficiary, as determined by the Director, OCHAMPUS, or designee.

(ii) *Cost-share.* A cost-share is applicable in any month in which a prorated amount is authorized, subject to the cost-share provisions for a sponsor with two or more PFPWD eligible beneficiaries.

(iii) *Termination.* Prorated payments shall be terminated as of the first day of the month following the death of a beneficiary or as of the effective date of a beneficiary's loss of PFPWD eligibility for any other reason.

(4) *For-profit institutional care provider.* Institutional care provided by a for-profit entity may be allowed only when the care for a specific PFPWD beneficiary:

(i) Is contracted for by a public facility, as defined in §199.2, as a part of a publicly funded long-term inpatient care program; and

(ii) Is provided based upon the PFPWD beneficiary's being eligible for the publicly funded program which has contracted for the care; and

(iii) Is authorized by the public facility as a part of a publicly funded program; and

(iv) Would cause a cost-share liability in the absence of CHAMPUS eligibility; and

(v) Produces a PFPWD beneficiary cost-share liability that does not exceed the maximum charge by the provider to the public facility for the contracted level of care.

(g) *Implementing instructions.* The Director, OCHAMPUS, or a designee, shall issue CHAMPUS policies, instructions, procedures, guidelines, standards, and criteria as may be necessary to implement the intent of this section.

[62 FR 35093, June 30, 1997, as amended at 62 FR 42904, Aug. 11, 1997]

§ 199.6 Authorized providers.

(a) *General.* This section sets forth general policies and procedures that are the basis for the CHAMPUS cost-sharing of medical services and supplies provided by institutions, individuals, or other types of providers. Providers seeking payment from the Federal Government through programs such as CHAMPUS have a duty to familiarize themselves with, and comply with, the program requirements.

(1) *Listing of provider does not guarantee payment of benefits.* The fact that a type of provider is listed in this section is not to be construed to mean that CHAMPUS will automatically pay a claim for services or supplies provided by such a provider. The provider who actually furnishes the service(s) must, in fact, meet all licensing and other requirements established by this part to be an authorized provider; the provider must not be the subject of sanction under §199.9; and, cost-sharing of the services must not otherwise be prohibited by this part. In addition, the patient must in fact be an eligible beneficiary and the services or supplies billed must be authorized and medically necessary, regardless of the standing of the provider.

(2) *Outside the United States or emergency situations within the United States.* Outside the United States or within the United States and Puerto Rico in emergency situations, the Director, OCHAMPUS, or a designee, after review of the facts, may provide payment to or on behalf of a beneficiary who receives otherwise covered services or supplies from a provider of service that does not meet the standards described in this part.

NOTE: Only the Secretary of Defense, the Secretary of Health and Human Services, or the Secretary of Transportation, or their designees, may authorize (in emergency situations) payment to civilian facilities in the

United States that are not in compliance with title VI of the Civil Rights Act of 1964. For the purpose of the Civil Rights Act only, the United States includes the 50 states, the District of Columbia, Puerto Rico, Virgin Islands, American Samoa, Guam, Wake Island, Canal Zone, and the territories and possessions of the United States.

(3) *Dual Compensation/Conflict of Interest.* Title 5, United States Code, section 5536 prohibits medical personnel who are active duty Uniformed Service members or civilian employees of the Government from receiving additional Government compensation above their normal pay and allowances for medical care furnished. In addition, Uniformed Service members and civilian employees of the Government are generally prohibited by law and agency regulations and policies from participating in apparent or actual conflict of interest situations in which a potential for personal gain exists or in which there is an appearance of impropriety or incompatibility with the performance of their official duties or responsibilities. The Departments of Defense, Health and Human Services, and Transportation have a responsibility, when disbursing appropriated funds in the payment of CHAMPUS benefits, to ensure that the laws and regulations are not violated. Therefore, active duty Uniformed Service members (including a reserve member while on active duty and civilian employees of the United States Government shall not be authorized to be CHAMPUS providers. While individual employees of the Government may be able to demonstrate that the furnishing of care to CHAMPUS beneficiaries may not be incompatible with their official duties and responsibilities, the processing of millions of CHAMPUS claims each year does not enable Program administrators to efficiently review the status of the provider on each claim to ensure that no conflict of interest or dual compensation situation exists. The problem is further complicated given the numerous interagency agreements (for example, resource sharing arrangements between the Department of Defense and the Veterans Administration in the provision of health care) and other unique arrangements which exist at individual treatment facilities around the country. While an individ-

ual provider may be prevented from being an authorized CHAMPUS provider even though no conflict of interest or dual compensation situation exists, it is essential for CHAMPUS to have an easily administered, uniform rule which will ensure compliance with the existing laws and regulations. Therefore, a provider who is an active duty Uniformed Service member or civilian employee of the Government shall not be an authorized CHAMPUS provider. In addition, a provider shall certify on each CHAMPUS claim that he/she is not an active duty Uniformed Service member or civilian employee of the Government.

(4) [Reserved]

(5) *Utilization review and quality assurance.* Providers approved as authorized CHAMPUS providers have certain obligations to provide services and supplies under CHAMPUS which are (i) furnished at the appropriate level and only when and to the extent medically necessary under the criteria of this part; (ii) of a quality that meets professionally recognized standards of health care; and, (iii) supported by adequate medical documentation as may be reasonably required under this part by the Director, OCHAMPUS, or designee, to evidence the medical necessity and quality of services furnished, as well as the appropriateness of the level of care. Therefore, the authorization of CHAMPUS benefits is contingent upon the services and supplies furnished by any provider being subject to pre-payment or post-payment utilization and quality assurance review under professionally recognized standards, norms, and criteria, as well as any standards or criteria issued by the Director, OCHAMPUS, or a designee, pursuant to this part. (Refer to §§ 199.4, 199.5, and 199.7 of this part.)

(6) *Exclusion of beneficiary liability.* In connection with certain utilization review, quality assurance and preauthorization requirements of section 199.4 of this part, providers may not hold patients liable for payment for certain services for which CHAMPUS payment is disallowed. With respect to such services, providers may not seek payment from the patient or the patient's family. Any such effort to seek payment is a basis for

termination of the provider's authorized status.

(7) *Provider required.* In order to be considered for benefits, all services and supplies shall be rendered by, prescribed by, or furnished at the direction of, or on the order of a CHAMPUS-authorized provider practicing within the scope of his or her license.

(8) *Participating Providers.* (i) *In general.* A Participating Provider is an individual or institutional provider that has agreed to accept the CHAMPUS-determined allowable amount as payment in full for the medical services and supplies provided to the CHAMPUS beneficiary, and has agreed to accept the amount paid by CHAMPUS or the CHAMPUS payment combined with the cost sharing and deductible amounts paid by, or on behalf of, the beneficiary as full payment for the covered medical services or supplies. In addition, Participating Providers submit the appropriate claims forms to the appropriate CHAMPUS contractor on behalf of the beneficiary. There are several circumstances under which providers are Participating Providers.

(ii) *Mandatory participation.* Medicare-participating hospitals are required by law to be Participating Providers on all inpatient claims under CHAMPUS. Hospitals that are not Medicare-participating providers but are subject to the CHAMPUS DRG-based payment system or the CHAMPUS mental health payment system (see §199.14(a)), must sign agreements to participate on all CHAMPUS inpatient claims in order to be authorized providers under CHAMPUS.

(iii) *Participating Provider Program.*

(A) *In general.* An institutional provider not required to participate pursuant to paragraph (a)(8)(ii) of this section and any individual provider may become a Participating Provider by signing a Participating Provider agreement. In such an agreement, the provider agrees that all CHAMPUS claims filed during the time period covered by the agreement will be on a participating basis.

(B) *Agreement required.* Under the Participating Provider Program, the provider must sign an agreement or memorandum of understanding under which the provider agrees to become a

Participating Provider. Such an agreement may be with the nearby military treatment facility, a CHAMPUS contractor, or other authorized official. Such agreement may include other provisions pertaining to the Participating Provider Program. The Director, OCHAMPUS shall establish a standard model agreement and other procedures to promote uniformity in the administration of the Participating Provider Program.

(C) *Relationship to other activities.* Participating Provider agreements may include other provisions, such as provisions regarding discounts (see §199.14(i)) or other provisions in connection with the delivery and financing of health care services, as authorized by this part or other DoD Directives or Instructions. Participating Provider agreement provisions may also be incorporated into other types of agreements, such as preferred provider arrangements where such arrangements are established under CHAMPUS.

(iv) *Claim-by-claim participation.* Institutional and individual providers that are not participating providers pursuant to paragraphs (a)(8)(ii) or (iii) 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 CHAMPUS contractor on behalf of the beneficiary.

(9) *Limitation to authorized institutional provider designation.* Authorized institutional provider status granted to a specific institutional provider applicant does not extend to any institution-affiliated provider, as defined in §199.2, of that specific applicant.

(10) *Authorized provider.* A hospital or institutional provider, physician, or other individual professional provider, or other provider of services or supplies specifically authorized in this chapter to provide benefits under CHAMPUS. In addition, to be an authorized CHAMPUS provider, any hospital which is a CHAMPUS participating provider under paragraph (a)(7) of this section, shall be a participating provider for all care, services, or supplies furnished to an active duty member of the uniformed services for which the active duty member is entitled under 10 U.S.C. 1074(c). As a participating

provider for active duty members, the CHAMPUS authorized hospital shall provide such care, services, and supplies in accordance with the payment rules of § 199.16 of this part. The failure of any CHAMPUS participating hospital to be a participating provider for any active duty member subjects the hospital to termination of the hospital's status as a CHAMPUS authorized provider for failure to meet the qualifications established by this part.

(11) *Submittal of claims by provider required.*—(i) *General rule.* Unless waived pursuant to paragraph (a)(11)(ii) of this section, every CHAMPUS-authorized institutional and individual provider is required to submit CHAMPUS claims to the appropriate CHAMPUS contractor on behalf of the beneficiary for all services and supplies. In addition, the provider may not impose any charge relating to completing and submitting the applicable claim form (or any other related information). (Although CHAMPUS encourages provider participation, paragraph (a)(11) of this section requires only the submission of claim forms by providers on behalf of beneficiaries; it does not require that providers accept assignment of beneficiaries' claims or become Participating Providers.)

(ii) *Waiver of claims submission requirement.* The requirement that providers submit claims on behalf of beneficiaries may be waived in circumstances set forth in paragraph (a)(11)(ii) of this section. A decision by the Director, OCHAMPUS to waive or not waive the requirement in any particular circumstance is not subject to the appeal and hearing procedures of § 199.10.

(A) *General requirement for waiver.* The requirement that providers submit claims on behalf of beneficiaries may be waived by the Director, OCHAMPUS when the Director determines that the waiver is necessary in order to ensure adequate access for CHAMPUS beneficiaries to health care services. However, the requirement may not be waived for Participating Providers (see paragraph (a)(8) of this section).

(B) *Blanket waiver for providers outside the United States.* The requirement that providers submit claims is waived with respect to providers outside the United

States (the United States includes Puerto Rico for this purpose).

(C) *Blanket waiver in double coverage cases.* The requirement that providers submit claims is waived in cases in which another insurance plan or program provides primary coverage for the services.

(D) *Waivers for particular categories of care.* The Director, OCHAMPUS may waive the requirement that providers submit claims if the Director determines that available evidence clearly shows that the requirement would impair adequate access. For this purpose, such evidence may include consideration of the number of providers in the locality who provide the affected services, the number of such providers who are CHAMPUS Participating Providers, the number of CHAMPUS beneficiaries in the area, and other relevant factors. Providers or beneficiaries in a locality may submit to the Director, OCHAMPUS a petition, together with appropriate documentation regarding relevant factors, for a determination that adequate access would be impaired. The Director, OCHAMPUS will consider and respond to all such petitions. The Director, OCHAMPUS may establish procedures for handling such petitions.

(E) *Case-by-case waivers.* On a case-by-case basis, the Director, OCHAMPUS may waive the provider's obligation to submit that claim if the Director determines that a waiver in that case is necessary in order to ensure adequate access for CHAMPUS beneficiaries to the health care services involved. Such case-by-case waivers may be requested by providers or beneficiaries pursuant to procedures established by the Director.

(iii) *Remedies for noncompliance.* (A) In any case in which a provider fails to submit a claim, or charges an administrative fee for filing a claim (or any other related information), in violation of the requirements of paragraph (a)(11) of this section, the amount that would otherwise be allowable for the claim shall be reduced by ten percent, unless the reduction is waived by the Director, OCHAMPUS based on special circumstances. The amount disallowed by such a reduction may not be billed to

the patient (or the patient's sponsor or family).

(B) Repeated failures by a provider to comply with the requirements of paragraph (a)(11) of this section shall be considered abuse and/or fraud and grounds for exclusion or suspension of the provider under § 199.9.

(12) *Balance billing limits.*

(i) *In general.* Individual providers who are not Participating Providers may not balance bill a beneficiary an amount which exceeds the applicable balance billing limit. The balance billing limit shall be the same percentage as the Medicare limiting charge percentage for nonparticipating physicians.

(ii) *Waiver.* The balance billing limit may be waived by the Director, OCHAMPUS on a case-by-case basis if requested by a CHAMPUS beneficiary. A decision by the Director, OCHAMPUS to waive or not waive the limit in any particular case is not subject to the appeal and hearing procedures of § 199.10.

(iii) *Compliance.* Failure to comply with the balance billing limit shall be considered abuse and/or fraud and grounds of exclusion or suspension of the provider under § 199.9.

(b) *Institutional providers—(1) General.* Institutional providers are those providers who bill for services in the name of an organizational entity (such as hospital and skilled nursing facility), rather than in the name of a person. The term "institutional provider" does not include professional corporations or associations qualifying as a domestic corporation under § 301.7701-5 of the Internal Revenue Service Regulations nor does it include other corporations that provide principally professional services. Institutional providers may provide medical services and supplies on either an inpatient or outpatient basis.

(i) *Preauthorization.* Preauthorization may be required by the Director, OCHAMPUS for any health care service for which payment is sought under CHAMPUS. (See §§ 199.4 and 199.15 for further information on preauthorization requirements.)

(ii) *Billing practices.*

(A) Each institutional billing, including those institutions subject to the

CHAMPUS DRG-based reimbursement method or a CHAMPUS-determined all-inclusive rate reimbursement method, must be itemized fully and sufficiently descriptive for the CHAMPUS to make a determination of benefits.

(B) Institutional claims subject to the CHAMPUS DRG-based reimbursement method or a CHAMPUS-determined all-inclusive rate reimbursement method, may be submitted only after the beneficiary has been discharged or transferred from the institutional provider's facility or program.

(C) Institutional claims for Residential Treatment Centers and all other institutional providers, except those listed in (B) above, should be submitted to the appropriate CHAMPUS fiscal intermediary at least every 30 days.

(iii) *Medical records.* Institutional providers must provide adequate contemporaneous clinical records to substantiate that specific care was actually furnished, was medically necessary, and appropriate, and to identify the individual(s) who provided the care. The minimum requirements for medical record documentation are set forth by the following:

(A) The cognizant state licensing authority;

(B) The Joint Commission on Accreditation of Healthcare Organizations (JCAHO), or other health care accreditation organizations as may be appropriate;

(C) Standards of practice established by national medical organizations; and

(D) This part.

(2) *Nondiscrimination policy.* Except as provided below, payment may not be made for inpatient or outpatient care provided and billed by an institutional provider found by the Federal Government to practice discrimination in the admission of patients to its services on the basis of race, color, or national origin. Reimbursement may not be made to a beneficiary who pays for care provided by such a facility and submits a claim for reimbursement. In the following circumstances, the Secretary of Defense, or a designee, may authorize payment for care obtained in an ineligible facility:

(i) *Emergency care.* Emergency inpatient or outpatient care.

(ii) *Care rendered before finding of a violation.* Care initiated before a finding of a violation and which continues after such violation when it is determined that a change in the treatment facility would be detrimental to the health of the patient, and the attending physician so certifies.

(iii) *Other facility not available.* Care provided in an ineligible facility because an eligible facility is not available within a reasonable distance.

(3) *Procedures for qualifying as a CHAMPUS-approved institutional provider.* General and special hospitals otherwise meeting the qualifications outlined in paragraphs (b)(4) (i), (ii), and (iii), of this section are not required to request CHAMPUS approval formally.

(i) *JCAH accreditation status.* Each CHAMPUS fiscal intermediary shall keep informed as to the current JCAH accreditation status of all hospitals and skilled nursing facilities in its area; and the provider's status under Medicare, particularly with regard to compliance with title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d(1)). The Director, OCHAMPUS, or a designee, shall specifically approve all other authorized institutional providers providing services to CHAMPUS beneficiaries. At the discretion of the Director, OCHAMPUS, any facility that is certified and participating as a provider of services under title XVIII of the Social Security Act (Medicare), may be deemed to meet CHAMPUS requirements. The facility must be providing a type and level of service that is authorized by this part.

(ii) *Required to comply with criteria.* Facilities seeking CHAMPUS approval will be expected to comply with appropriate criteria set forth in paragraph (b)(4) of this section. They also are required to complete and submit CHAMPUS Form 200, "Required Information, Facility Determination Instructions," and provide such additional information as may be requested by OCHAMPUS. An onsite evaluation, either scheduled or unscheduled, may be conducted at the discretion of the Director, OCHAMPUS, or a designee. The final determination regarding approval, reapproval, or disapproval of a facility will be provided in writing to

the facility and the appropriate CHAMPUS fiscal intermediary.

(iii) *Notice of peer review rights.* All health care facilities subject to the DRG-based payment system shall provide CHAMPUS beneficiaries, upon admission, with information about peer review including their appeal rights. The notices shall be in a form specified by the Director, OCHAMPUS.

(iv) *Surveying of facilities.* The surveying of newly established institutional providers and the periodic resurveying of all authorized institutional providers is a continuing process conducted by OCHAMPUS.

(v) *Institutions not in compliance with CHAMPUS standards.* If a determination is made that an institution is not in compliance with one or more of the standards applicable to its specific category of institution, CHAMPUS shall take immediate steps to bring about compliance or terminate the approval as an authorized institution in accordance with § 199.9(f)(2).

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

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

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

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

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

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

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

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

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

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

(1) Is licensed pursuant to such law, or

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

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

(I) Is accredited by the JCAH or meets such other requirements as the Secretary of Health and Human Services, the Secretary of Transportation, or the Secretary of Defense finds necessary in the interest of the health and safety of patients who are admitted to and furnished services in the institution.

(ii) *Liver transplantation centers.* (A) CHAMPUS shall provide coverage for liver transplantation procedures performed only by experienced transplant surgeons at centers complying with the provisions outlined in paragraph (b)(4)(i) of this section and meeting the following criteria:

(1) The center is a tertiary care facility affiliated with an academic health center. The center must have accredited programs in graduate medical education related to the function of liver transplantation such as internal medi-

cine, pediatrics, surgery, and anesthesiology;

(2) The center has an active solid organ transplantation program (involving liver transplants as well as other organs);

(3) The transplantation center must have at least a 50 percent one-year survival rate for ten cases. At the time CHAMPUS approval is requested, the transplant center must provide evidence that at least ten liver transplants have been performed at the center and that at least 50 percent of those transplanted patients have survived one year following surgery. A 50 percent one-year survival rate for all subsequent liver transplantations must be maintained for continued CHAMPUS approval;

(4) The center has allocated sufficient operating room, recovery room, laboratory, and blood bank support and a sufficient number of intensive care and general surgical beds and specialized staff for these areas;

(5) The center participates in a donor procurement program and network;

(6) The center systematically collects and shares data on its transplant program;

(7) The center has an interdisciplinary body to determine the suitability of candidates for transplantation on an equitable basis;

(8) The transplantation surgeon is specifically trained for liver grafting and must assemble and train a team to function whenever a donor liver is available;

(9) The transplantation center must have on staff board eligible or board certified physicians and other experts in the field of hepatology, pediatrics, infectious disease, nephrology with dialysis capability, pulmonary medicine with respiratory therapy support, pathology, immunology, and anesthesiology to complement a qualified transplantation team;

(10) The transplantation center has the assistance of appropriate microbiology, clinical chemistry, and radiology support;

(11) The transplantation center has blood bank support to accommodate normal demands and the transplant procedure; and

(12) The transplantation center includes the availability of psychiatric and social services support for patients and family.

(B) In order to receive approval as a CHAMPUS authorized liver transplant center, a center must submit a request to the Director, CHAMPUS, or a designee. The CHAMPUS authorized liver transplant center shall agree to the following:

(1) Bill for all services and supplies related to the liver transplantation performed by its staff and bill also for services rendered by the donor hospital following declaration of brain death and after all existing legal requirements for excision of the donor organ have been met; and

(2) The center shall agree to submit all charges on the basis of fully itemized bills. This means that each service and supply and the charge for each is individually identified.

(iii) *Heart transplantation centers.* (A) CHAMPUS shall provide coverage for heart transplantation procedures performed only by experienced transplant surgeons at centers complying with provisions outlined in paragraph (b)(4)(i) of this section and meeting the following criteria:

(1) The center has experts in the fields of cardiology, cardiovascular surgery, anesthesiology, immunology, infectious disease, nursing, social services and organ procurement to complement the transplant team;

(2) The center has an active cardiovascular medical and surgical program as evidenced by a minimum of 500 cardiac catheterizations and coronary arteriograms and 250 open heart procedures per year;

(3) The center has an anesthesia team that is available at all times;

(4) The center has infectious disease services with both the professional skills and the laboratory resources that are needed to discover, identify, and manage a whole range of organisms;

(5) The center has a nursing service team trained in the hemodynamic support of the patient and in managing immunosuppressed patients;

(6) The center has pathology resources that are available for studying

and reporting the pathological responses of transplantation;

(7) The center has legal counsel familiar with transplantation laws and regulations;

(8) The commitment of the transplant center must be at all levels and broadly evident throughout the facility;

(9) Responsible team members must be board certified or board eligible in their respective disciplines;

(10) Component teams must be integrated into a comprehensive transplant team with clearly defined leadership and responsibility;

(11) The center has adequate social service resources;

(12) The transplant center must comply with applicable State transplant laws and regulations;

(13) The transplant center must safeguard the rights and privacy of patients;

(14) The transplant center must have adequate patient management plans and protocols;

(15) The center participates in a donor procurement program and network;

(16) The center systematically collects and shares data on its transplant program;

(17) The center has an interdisciplinary body to determine the suitability of candidates for transplantation on an equitable basis;

(18) The center has extensive blood bank support;

(19) The center must have an established heart transplantation program with documented evidence of 12 or more heart transplants in each of the two consecutive preceding 12-month periods prior to application and 12 heart transplants prior to that; and

(20) The center must demonstrate actuarial survival rates of 73 percent for one year and 65 percent for two years for patients who have had heart transplants since January 1, 1982, at that facility.

(B) CHAMPUS approval will lapse if either the number of heart transplants falls below 8 in 12 months or if the one-year survival rate falls below 60 percent for a consecutive 24-month period.

(C) CHAMPUS-approval may also be extended for a heart transplant center

that meets other certification or accreditation standards provided the standards are equivalent to or exceed the criteria listed above and have been approved by the Director, OCHAMPUS.

(D) In order to receive approval as a CHAMPUS heart transplant center, a facility must submit a request to the Director, OCHAMPUS, or a designee. The CHAMPUS-authorized heart transplant center shall agree to the following:

(1) Bill for all services and supplies related to the heart transplantation performed by its staff and bill also for services rendered by the donor hospital following declaration of brain death;

(2) Submit all charges on the basis of fully itemized bills. Each service and supply must be individually identified and the first claim submitted for the heart transplantation must include a copy of the admission history and physical examination; and

(3) Report any significant decrease in the experience level or survival rates and loss of key members of the transplant team to the Director, OCHAMPUS.

(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 the JCAHO Accreditation Manual for Hospitals (AMH) standards in order for their services to be cost-shared under CHAMPUS. In the case of those psychiatric hospitals that are not JCAHO-accredited because they have not been

in operation a sufficient period of time to be eligible to request an accreditation survey by the JCAHO, the Director, OCHAMPUS, 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 the JCAHO.

(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 the JCAHO AMH standards, their medical records must be maintained in accordance with the JCAHO Consolidated Standard Manual for Child, Adolescent, and Adult Psychiatric, Alcoholism, and Drug Abuse Facilities and Facilities Serving the Mentally Retarded, along with the requirements set forth in § 199.7(b)(3). The hospital is responsible for assuring that patient services and all treatment are accurately documented and completed in a timely manner.

(v) *Hospitals, long-term (tuberculosis, chronic care, or rehabilitation).* To be considered a long-term hospital, an institution for patients that have tuberculosis or chronic diseases must be an institution (or distinct part of an institution) primarily engaged in providing by or under the supervision of a physician appropriate medical or surgical services for the diagnosis and active

treatment of the illness or condition in which the institution specializes.

(A) In order for the service of long-term hospitals to be covered, the hospital 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 CHAMPUS, they must be primarily for the treatment of the presenting illness.

(B) Custodial or domiciliary care is not coverable under CHAMPUS, even if rendered in an otherwise authorized long-term hospital.

(C) The controlling factor in determining whether a beneficiary's stay in a long-term hospital is coverable by CHAMPUS 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 CHAMPUS 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 poli-

cies 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 Code⁸ 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.

(vii) *Residential treatment centers.* This paragraph (b)(4)(vii) establishes 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. The extent and pervasiveness of the patient's problems require a protected and highly structured therapeutic environment. Residential treatment is differentiated from:

⁸Compiled and published by the National Fire Protection Association, Batterymarch Park, Quincy, Massachusetts 02269.

(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 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 chemical abuse or dependence; and

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

(2) Eligibility.

(i) Every RTC must be certified pursuant to CHAMPUS certification standards. Such standards shall incorporate the basic standards set forth in paragraphs (b)(4)(vii) (A) through (D) of this section, and shall include such additional elaborative criteria and standards as the Director, OCHAMPUS determines are necessary to implement the basic standards.

(ii) To be eligible for CHAMPUS certification, the facility is required to be licensed and fully operational for six months (with a minimum average daily census of 30 percent of total bed capacity) and operate in substantial compliance with state and federal regulations.

(iii) The facility is currently accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) under the current edition of the Manual for Mental Health, Chemical Dependency, and Mental Retardation/Developmental Disabilities Services which is available from

JCAHO, P.O. Box 75751, Chicago, IL 60675.

(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, OCHAMPUS.

(3) Governing body.

(i) The RTC shall have a governing body which is responsible for the policies, bylaws, and activities of the facility. If the RTC is owned by a partnership or single owner, the partners or single owner are regarded as the governing body. The facility will provide an up-to-date list of names, addresses, telephone numbers and titles of the members of the governing body.

(ii) The governing body ensures appropriate and adequate services for all patients and oversees continuing development and improvement of care. Where business relationships exist between the governing body and facility, appropriate conflict-of-interest policies are in place.

(iii) Board members are fully informed about facility services and the governing body conducts annual review of its performance in meeting purposes, responsibilities, goals and objectives.

(4) *Chief executive officer.* The chief executive officer, appointed by and subject to the direction of the governing body, shall assume overall administrative responsibility for the operation of the facility according to governing body policies. The chief executive officer shall have five years' administrative experience in the field of mental health. On October 1, 1997, the CEO shall possess a degree in business administration, public health, hospital administration, nursing, social work, or psychology, or meeting similar educational requirements as prescribed by the Director, OCHAMPUS.

(5) *Clinical Director.* The clinical director, appointed by the governing body, shall be a psychiatrist or doctoral level psychologist who meets applicable CHAMPUS requirements for individual professional providers and is licensed to practice in the state where

the residential treatment center is located. The clinical director shall possess requisite education and experience, credentials applicable under state practice and licensing laws appropriate to the professional discipline, and a minimum of five years' clinical experience in the treatment of children and adolescents. The clinical director shall be responsible for planning, development, implementation, and monitoring of all clinical activities.

(6) *Medical director.* The medical director, appointed by the governing body, shall be licensed to practice medicine in the state where the residential treatment center is located and shall possess requisite education and experience, including graduation from an accredited school of medicine or osteopathy, an approved residency in psychiatry and a minimum of five years clinical experience in the treatment of children and adolescents. The Medical Director shall be responsible for the planning, development, implementation, and monitoring of all activities relating to medical treatment of patients. If qualified, the Medical Director may also serve as Clinical Director.

(7) *Medical or professional staff organization.* The governing body shall establish a medical or professional staff organization to assure effective implementation of clinical privileging, professional conduct rules, and other activities directly affecting patient care.

(8) *Personnel policies and records.* The RTC shall maintain written personnel policies, updated job descriptions and personnel records to assure the selection of qualified personnel and successful job performance of those personnel.

(9) *Staff development.* The facility shall provide appropriate training and development programs for administrative, professional support, and direct care staff.

(10) *Fiscal accountability.* The RTC shall assure fiscal accountability to applicable government authorities and patients.

(11) *Designated teaching facilities.* Students, residents, interns or fellows providing direct clinical care are under the supervision of a qualified staff member approved by an accredited university. The teaching program is approved by the Director, OCHAMPUS.

(12) *Emergency reports and records.* The facility notifies OCHAMPUS of any serious occurrence involving CHAMPUS beneficiaries.

(B) *Treatment services.*

(1) *Staff composition.*

(i) The RTC shall follow written plans which assure that medical and clinical patient needs will be appropriately addressed 24 hours a day, seven days a week by a sufficient number of fully qualified (including license, registration or certification requirements, educational attainment, and professional experience) health care professionals and support staff in the respective disciplines. Clinicians providing individual, group, and family therapy meet CHAMPUS requirements as qualified mental health providers and operate within the scope of their licenses. The ultimate authority for planning, development, implementation, and monitoring of all clinical activities is vested in a psychiatrist or doctoral level psychologist. The management of medical care is vested in a physician.

(ii) The RTC shall ensure adequate coverage by fully qualified staff during all hours of operation, including physician availability, other professional staff coverage, and support staff in the respective disciplines.

(2) *Staff qualifications.* The RTC will have a sufficient number of qualified mental health providers, administrative, and support staff to address patients' clinical needs and to coordinate the services provided. RTCs which employ individuals with master's or doctoral level degrees in a mental health discipline who do not meet the licensure, certification and experience requirements for a qualified mental health provider but are actively working toward licensure or certification, may provide services within the all-inclusive per diem rate, provided the individual works under the clinical supervision of a fully qualified mental health provider employed by the RTC. All other program services shall be provided by trained, licensed staff.

(3) *Patient rights.*

(i) The RTC shall provide adequate protection for all patient rights, including rights provided by law, privacy, personnel rights, safety, confidentiality, informed consent, grievances, and personal dignity.

(ii) The facility has a written policy regarding patient abuse and neglect.

(iii) Facility marketing and advertising meets professional standards.

(4) *Behavioral management.* The RTC shall adhere to a comprehensive, written plan of behavioral management, developed by the clinical director and the medical or professional staff and approved by the governing body, including strictly limited procedures to assure that the restraint or seclusion are used only in extraordinary circumstances, are carefully monitored, and are fully documented. Only trained and clinically privileged RNs or qualified mental health professionals may be responsible for the implementation of seclusion and restraint procedures in an emergency situation.

(5) *Admission process.* The RTC shall maintain written policies and procedures to ensure that, prior to an admission, a determination is made, and approved pursuant to CHAMPUS preauthorization requirements, that the admission is medically and/or psychologically necessary and the program is appropriate to meet the patient's needs. Medical and/or psychological necessity determinations shall be rendered by qualified mental health professionals who meet CHAMPUS requirements for individual professional providers and who are permitted by law and by the facility to refer patients for admission.

(6) *Assessments.* The professional staff of the RTC shall complete a current multidisciplinary assessment which includes, but is not limited to physical, psychological, developmental, family, educational, social, spiritual and skills assessment of each patient admitted. Unless otherwise specified, all required clinical assessments are completed prior to development of the multidisciplinary treatment plan.

(7) *Clinical formulation.* A qualified mental health professional of the RTC will complete a clinical formulation on all patients. The clinical formulation will be reviewed and approved by the

responsible individual professional provider and will incorporate significant findings from each of the multidisciplinary assessments. It will provide the basis for development of an interdisciplinary treatment plan.

(8) *Treatment planning.* A qualified mental health professional shall be responsible for the development, supervision, implementation, and assessment of a written, individualized, interdisciplinary plan of treatment, which shall be completed within 10 days of admission and shall include individual, measurable, and observable goals for incremental progress and discharge. A preliminary treatment plan is completed within 24 hours of admission and includes at least an admission note and orders written by the admitting mental health professional. The master treatment plan is reviewed and revised at least every 30 days, or when major changes occur in treatment.

(9) *Discharge and transition planning.* The RTC shall maintain a transition planning process to address adequately the anticipated needs of the patient prior to the time of discharge. The planning involves determining necessary modifications in the treatment plan, facilitating the termination of treatment, and identifying resources to maintain therapeutic stability following discharge.

(10) *Clinical documentation.* Clinical records shall be maintained on each patient to plan care and treatment and provide ongoing evaluation of the patient's progress. All care is documented and each clinical record contains at least the following: demographic data, consent forms, pertinent legal documents, all treatment plans and patient assessments, consultation and laboratory reports, physician orders, progress notes, and a discharge summary. All documentation will adhere to applicable provisions of the JCAHO and requirements set forth in § 199.7(b)(3). An appropriately qualified records administrator or technician will supervise and maintain the quality of the records. These requirements are in addition to other records requirements of this part, and documentation requirements of the Joint Commission on Accreditation of Healthcare Organizations.

(11) *Progress notes.* RTC's shall document the course of treatment for patients and families using progress notes which provide information to review, analyze, and modify the treatment plans. Progress notes are legible, contemporaneous, sequential, signed and dated and adhere to applicable provisions of the Manual of Mental Health, Chemical Dependency, and Mental Retardation/Development Disabilities Services and requirements set forth in § 199.7(b)(3).

(12) *Therapeutic services.*

(i) Individual, group, and family psychotherapy are provided to all patients, consistent with each patient's treatment plan, by qualified mental health providers.

(ii) A range of therapeutic activities, directed and staffed by qualified personnel, are offered to help patients meet the goals of the treatment plan.

(iii) Therapeutic educational services are provided or arranged that are appropriate to the patients educational and therapeutic needs.

(13) *Ancillary services.* A full range of ancillary services is provided. Emergency services include policies and procedures for handling emergencies with qualified personnel and written agreements with each facility providing the service. Other ancillary services include physical health, pharmacy and dietary services.

(C) *Standards for physical plant and environment.*

(1) *Physical environment.* The buildings and grounds of the RTC shall be maintained so as to avoid health and safety hazards, be supportive of the services provided to patients, and promote patient comfort, dignity, privacy, personal hygiene, and personal safety.

(2) *Physical plant safety.* The RTC shall be of permanent construction and maintained in a manner that protects the lives and ensures the physical safety of patients, staff, and visitors, including conformity with all applicable building, fire, health, and safety codes.

(3) *Disaster planning.* The RTC shall maintain and rehearse written plan for taking care of casualties and handling other consequences arising from internal and external disasters.

(D) *Standards for evaluation system.*

(1) *Quality assessment and improvement.* The RTC shall develop and implement a comprehensive quality assurance and quality improvement program that monitors the quality, efficiency, appropriateness, and effectiveness of the care, treatments, and services it provides for patients and their families, primarily utilizing explicit clinical indicators to evaluate all functions of the RTC and contribute to an ongoing process of program improvement. The clinical director is responsible for developing and implementing quality assessment and improvement activities throughout the facility.

(2) *Utilization review.* The RTC shall implement a utilization review process, pursuant to a written plan approved by the professional staff, the administration, and the governing body, that assesses the appropriateness of admission, continued stay, and timeliness of discharge as part of an effort to provide quality patient care in a cost-effective manner. Findings of the utilization review process are used as a basis for revising the plan of operation, including a review of staff qualifications and staff composition.

(3) *Patient records review.* The RTC shall implement a process, including monthly reviews of a representative sample of patient records, to determine the completeness and accuracy of the patient records and the timeliness and pertinence of record entries, particularly with regard to regular recording of progress/non-progress in treatment.

(4) *Drug utilization review.* The RTC shall implement a comprehensive process for the monitoring and evaluating of the prophylactic, therapeutic, and empiric use of drugs to assure that medications are provided appropriately, safely, and effectively.

(5) *Risk management.* The RTC shall implement a comprehensive risk management program, fully coordinated with other aspects of the quality assurance and quality improvement program, to prevent and control risks to patients and staff and costs associated with clinical aspects of patient care and safety.

(6) *Infection control.* The RTC shall implement a comprehensive system for the surveillance, prevention, control,

and reporting of infections acquired or brought into the facility.

(7) *Safety.* The RTC shall implement an effective program to assure a safe environment for patients, staff, and visitors, including an incident report system, a continuous safety surveillance system, and an active multidisciplinary safety committee.

(8) *Facility evaluation.* The RTC annually evaluates accomplishment of the goals and objectives of each clinical program and service of the RTC and reports findings and recommendations to the governing body.

(E) *Participation agreement requirements.* In addition to other requirements set forth in paragraph (b)(4)(vii), of this section in order 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. Participation agreements entered into prior April 6, 1995 must be renewed not later than October 1, 1995. In addition to review of a facility's application and supporting documentation, an on-site inspection by OCHAMPUS authorized personnel may be required prior to signing a Participation Agreement. Retroactive approval is not given. In addition, the Participation Agreement shall include provisions that the RTC shall, at a minimum:

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

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

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

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

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

(6) Submit claims for services provided to CHAMPUS beneficiaries at least 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 provisions of paragraph (b)(4)(vii) of this section establishing standards for Residential Treatment Centers;

(ii) It has conducted a self assessment of the facility's compliance with the CHAMPUS Standards for Residential Treatment Centers Serving Children and Adolescents with Mental Disorders, as issued by the Director, OCHAMPUS and notified the Director, OCHAMPUS 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 Residential Treatment Centers Serving Children and Adolescents with Mental Disorders, as issued by the Director, OCHAMPUS, except for any such standards regarding which the facility notifies the Director, OCHAMPUS 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

preauthorization, concurrent care review, claims processing, beneficiary liability, double coverage, utilization and quality review and other matters;

(1) Grant the Director, OCHAMPUS, 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 an authorized CHAMPUS RTC provider;

(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 General Accounting Office.

(F) *Other requirements applicable to RTCs.*

(1) Even though an RTC may qualify as a CHAMPUS-authorized provider and may have entered into a participation agreement with CHAMPUS, payment by CHAMPUS for particular services provided is contingent upon the RTC also meeting all conditions set forth in §199.4 especially all requirements of paragraph (b)(4) of that section.

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

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

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

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

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

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

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

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

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

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

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

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

(i) Require prior approval of all admissions to special institutional providers.

(ii) Set appropriate standards for special institutional providers in addition to or in the absence of JCAHO accreditation.

(iii) Monitor facility operations and treatment programs on a continuing basis and conduct onsite inspections on a scheduled and unscheduled basis.

(iv) Negotiate agreements of participation.

(v) Terminate approval of a case when it is ascertained that a departure from the facts upon which the admission was based originally has occurred.

(vi) Declare a special institutional provider not eligible for CHAMPUS payment if that facility has been found to have engaged in fraudulent or deceptive practices.

(3) In general, the following disclaimers apply to treatment by special institutional providers:

(i) Just because one period or episode of treatment by a facility has been covered by CHAMPUS may not be construed to mean that later episodes of care by the same or similar facility will be covered automatically.

(ii) The fact that one case has been authorized for treatment by a specific facility or similar type of facility may not be construed to mean that similar cases or later periods of treatment will be extended CHAMPUS benefits automatically.

(B) *Types of providers.* The following is a list of facilities that have been designated specifically as special institutional providers.

(1) *Free-standing ambulatory surgical centers.* Care provided by freestanding ambulatory surgical centers may be cost-shared by CHAMPUS under the following circumstances:

(i) The treatment is prescribed and supervised by a physician.

(ii) The type and level of care and services rendered by the center are otherwise authorized by this part.

(iii) The center meets all licensing or other certification requirements of the jurisdiction in which the facility is located.

(iv) The center is accredited by the JCAH, the Accreditation Association for Ambulatory Health Care, Inc. (AAAHC), or such other standards as authorized by the Director, OCHAMPUS.

(v) A childbirth procedure provided by a CHAMPUS-approved free-standing ambulatory surgical center shall not be cost-shared by the CHAMPUS unless the surgical center is also a CHAMPUS-approved birthing center institutional provider as established by the birthing center provider certification requirement of this Regulation.

(2) [Reserved]

(xi) *Birthing centers.* A birthing center is a freestanding or institution-affiliated outpatient maternity care program which principally provides a planned course of outpatient prenatal care and outpatient childbirth service limited to low-risk pregnancies; excludes care for high-risk pregnancies; limits childbirth to the use of natural childbirth procedures; and provides immediate newborn care.

(A) *Certification requirements.* A birthing center which meets the following criteria may be designated as an authorized CHAMPUS institutional provider:

(1) The predominant type of service and level of care rendered by the center is otherwise authorized by this part.

(2) The center is licensed to operate as a birthing center where such license is available, or is specifically licensed as a type of ambulatory health care facility where birthing center specific license is not available, and meets all applicable licensing or certification requirements that are extant in the state, county, municipality, or other political jurisdiction in which the center is located.

(3) The center is accredited by a nationally recognized accreditation organization whose standards and procedures have been determined to be acceptable by the Director, OCHAMPUS, or a designee.

(4) The center complies with the CHAMPUS birthing center standards set forth in this part.

(5) The center has entered into a participation agreement with OCHAMPUS in which the center agrees, in part, to:

(i) Participate in CHAMPUS and accept payment for maternity services based upon the reimbursement methodology for birthing centers;

(ii) Collect from the CHAMPUS beneficiary only those amounts that represent the beneficiary's liability under the participation agreement and the reimbursement methodology for birthing centers, and the amounts for services and supplies that are not a benefit of the CHAMPUS;

(iii) Permit access by the Director, OCHAMPUS, or a designee, to the clinical record of any CHAMPUS beneficiary, to the financial and organizational records of the center, and to reports of evaluations and inspections conducted by state or private agencies or organizations;

(iv) Submit claims first to all health benefit and insurance plans primary to the CHAMPUS to which the beneficiary is entitled and to comply with the double coverage provisions of this part;

(v) Notify CHAMPUS in writing within 7 days of the emergency transport of

any CHAMPUS beneficiary from the center to an acute care hospital or of the death of any CHAMPUS beneficiary in the center.

(6) A birthing center shall not be a CHAMPUS-authorized institutional provider and CHAMPUS benefits shall not be paid for any service provided by a birthing center before the date the participation agreement is signed by the Director, OCHAMPUS, or a designee.

(B) *CHAMPUS birthing center standards.* (1) *Environment:* The center has a safe and sanitary environment, properly constructed, equipped, and maintained to protect health and safety and meets the applicable provisions of the "Life Safety Code" of the National Fire Protection Association.

(2) *Policies and procedures:* The center has written administrative, fiscal, personnel and clinical policies and procedures which collectively promote the provision of high-quality maternity care and childbirth services in an orderly, effective, and safe physical and organizational environment.

(3) *Informed consent:* Each CHAMPUS beneficiary admitted to the center will be informed in writing at the time of admission of the nature and scope of the center's program and of the possible risks associated with maternity care and childbirth in the center.

(4) *Beneficiary care:* Each woman admitted will be cared for by or under the direct supervision of a specific physician or a specific certified nurse-midwife who is otherwise eligible as a CHAMPUS individual professional provider.

(5) *Medical direction:* The center has written memoranda of understanding (MOU) for routine consultation and emergency care with an obstetrician-gynecologist who is certified or is eligible for certification by the American Board of Obstetrics and Gynecology or the American Osteopathic Board of Obstetrics and Gynecology and with a pediatrician who is certified or eligible for certification by the American Board of Pediatrics or by the American Osteopathic Board of Pediatrics, each of whom have admitting privileges to at least one backup hospital. In lieu of a required MOU, the center may employ a physician with the required

qualifications. Each MOU must be renewed annually.

(6) *Admission and emergency care criteria and procedures.* The center has written clinical criteria and administrative procedures, which are reviewed and approved annually by a physician related to the center as required by paragraph (b)(4)(xi)(B)(5) above, for the exclusion of a woman with a high-risk pregnancy from center care and for management of maternal and neonatal emergencies.

(7) *Emergency treatment.* The center has a written memorandum of understanding (MOU) with at least one backup hospital which documents that the hospital will accept and treat any woman or newborn transferred from the center who is in need of emergency obstetrical or neonatal medical care. In lieu of this MOU with a hospital, a birthing center may have an MOU with a physician, who otherwise meets the requirements as a CHAMPUS individual professional provider, and who has admitting privileges to a backup hospital capable of providing care for critical maternal and neonatal patients as demonstrated by a letter from that hospital certifying the scope and expected duration of the admitting privileges granted by the hospital to the physician. The MOU must be reviewed annually.

(8) *Emergency medical transportation.* The center has a written memorandum of understanding (MOU) with at least one ambulance service which documents that the ambulance service is routinely staffed by qualified personnel who are capable of the management of critical maternal and neonatal patients during transport and which specifies the estimated transport time to each backup hospital with which the center has arranged for emergency treatment as required in paragraph (b)(4)(xi)(B)(7) above. Each MOU must be renewed annually.

(9) *Professional staff.* The center's professional staff is legally and professionally qualified for the performance of their professional responsibilities.

(10) *Medical records.* The center maintains full and complete written documentation of the services rendered to each woman admitted and each newborn delivered. A copy of the informed

consent document required by paragraph (b)(4)(xi)(B)(3), above, which contains the original signature of the CHAMPUS beneficiary, signed and dated at the time of admission, must be maintained in the medical record of each CHAMPUS beneficiary admitted.

(11) *Quality assurance.* The center has an organized program for quality assurance which includes, but is not limited to, written procedures for regularly scheduled evaluation of each type of service provided, of each mother or newborn transferred to a hospital, and of each death within the facility.

(12) *Governance and administration.* The center has a governing body legally responsible for overall operation and maintenance of the center and a full-time employee who has authority and responsibility for the day-to-day operation of the center.

(xi) *Psychiatric partial hospitalization programs.* Paragraph (b)(4)(xii) of this section establishes standards and requirements for psychiatric 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.

(2) *Eligibility.*

(i) Every psychiatric partial hospitalization program must be certified pursuant to CHAMPUS certification standards. Such standards shall incorporate the basic standards set forth in paragraphs (b)(4)(xii) (A) through (D) of this section, and shall include such additional elaborative criteria and standards as the Director, OCHAMPUS determines are necessary to implement the basic standards. Each psychiatric partial hospitalization program must be either a distinct part of an otherwise authorized institutional provider or a freestanding program.

(ii) To be eligible for CHAMPUS certification, the facility is required to be

licensed and fully operational for a period of at least six months (with a minimum patient census of at least 30 percent of bed capacity) and operate in substantial compliance with state and federal regulations.

(iii) The facility is currently accredited by the Joint Commission on Accreditation of Healthcare Organizations under the current edition of the Accreditation Manual for Mental Health, Chemical Dependency, and Mental Retardation/Developmental Disabilities Services.

(iv) The facility has a written participation agreement with OCHAMPUS. On October 1, 1995, 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, OCHAMPUS. Partial hospitalization is capable of providing an interdisciplinary program of medical and therapeutic services a minimum of three hours per day, five days per week, and may include full- or half-day, evening, and weekend treatment programs.

(3) *Governing body.*

(i) The PHP shall have a governing body which is responsible for the policies, bylaws, and activities of the facilities. If the PHP is owned by a partnership or single owner, the partners or single owner are regarded as the governing body. The facility will provide an up-to-date list of names, addresses, telephone numbers, and titles of the members of the governing body.

(ii) The governing body ensures appropriate and adequate services for all patients and oversees continuing development and improvement of care. Where business relationships exist between the governing body and facility, appropriate conflict-of-interest policies are in place.

(iii) Board members are fully informed about facility services and the governing body conducts annual review of its performance in meeting purposes, responsibilities, goals and objectives.

(4) *Chief executive officer.* The Chief Executive Officer, appointed by and subject to the direction of the governing body, shall assume overall administrative responsibility for the operation of the facility according to governing

body policies. The chief executive officer shall have five years' administrative experience in the field of mental health. On October 1, 1997, the CEO shall possess a degree in business administration, public health, hospital administration, nursing, social work, or psychology, or meet similar educational requirements as prescribed by the Director, OCHAMPUS.

(5) *Clinical Director.* The clinical director, appointed by the governing body, shall be a psychiatrist or doctoral level psychologist who meets applicable CHAMPUS requirements for individual professional providers and is licensed to practice in the state where the PHP is located. The clinical director shall possess requisite education and experience, credentials applicable under state practice and licensing laws appropriate to the professional discipline, and a minimum of five years' clinical experience in the treatment of mental disorders specific to the ages and disabilities of the patients served. The clinical director shall be responsible for planning, development, implementation, and monitoring of all clinical activities.

(6) *Medical director.* The medical director, appointed by the governing body, shall be licensed to practice medicine in the state where the residential treatment center is located and shall possess requisite education and experience, including graduation from an accredited school of medicine or osteopathy, an approved residency in psychiatry and a minimum of five years clinical experience in the treatment of mental disorders specific to the ages and disabilities of the patients served. The Medical Director shall be responsible for the planning, development, implementation, and monitoring of all activities relating to medical treatment of patients. If qualified, the Medical Director may also serve as Clinical Director.

(7) *Medical or professional staff organization.* The governing body shall establish a medical or professional staff organization to assure effective implementation of clinical privileging, professional conduct rules, and other activities directly affecting patient care.

(8) *Personnel policies and records.* The PHP shall maintain written personnel

policies, updated job descriptions, personnel records to assure the selection of qualified personnel and successful job performance of those personnel.

(9) *Staff development.* The facility shall provide appropriate training and development programs for administrative, professional support, and direct care staff.

(10) *Fiscal accountability.* The PHP shall assure fiscal accountability to applicable government authorities and patients.

(11) *Designated teaching facilities.* Students, residents, interns, or fellows providing direct clinical care are under the supervision of a qualified staff member approved by an accredited university. The teaching program is approved by the Director, OCHAMPUS.

(12) *Emergency reports and records.* The facility notifies OCHAMPUS of any serious occurrence involving CHAMPUS beneficiaries.

(B) *Treatment services.*

(1) *Staff composition.*

(i) The PHP shall ensure that patient care needs will be appropriately addressed during all hours of operation by a sufficient number of fully qualified (including license, registration or certification requirements, educational attainment, and professional experience) health care professionals. Clinicians providing individual, group, and family therapy meet CHAMPUS requirements as qualified mental health providers, and operate within the scope of their licenses. The ultimate authority for managing care is vested in a psychiatrist or licensed doctor level psychologist. The management of medical care is vested in a physician.

(ii) The PHP shall establish and follow written plans to assure adequate staff coverage during all hours of operation, including physician availability, other professional staff coverage, and support staff in the respective disciplines.

(2) *Staff qualifications.* The PHP will have a sufficient number of qualified mental health providers, administrative, and support staff to address patients' clinical needs and to coordinate the services provided. PHPs which employ individuals with master's or doctoral level degrees in a mental health discipline who do not meet the licen-

sure, certification and experience requirements for a qualified mental health provider but are actively working toward licensure or certification, may provide services within the all-inclusive per diem rate, provided the individual works under the clinical supervision of a fully qualified mental health provider employed by the PHP. All other program services shall be provided by trained, licensed staff.

(3) *Patient rights.*

(i) The PHP shall provide adequate protection for all patient rights, including rights provided by law, privacy, personal rights, safety, confidentiality, informed consent, grievances, and personal dignity.

(ii) The facility has a written policy regarding patient abuse and neglect.

(iii) Facility marketing and advertising meets professional standards.

(4) *Behavioral management.* The PHP shall adhere to a comprehensive, written plan of behavior management, developed by the clinical director and the medical or professional staff and approved by the governing body, including strictly limited procedures to assure that restraint or seclusion are used only in extraordinary circumstances, are carefully monitored, and are fully documented. Only trained and clinically privileged RNs or qualified mental health professionals may be responsible for implementation of seclusion and restraint procedures in an emergency situation.

(5) *Admission process.* The PHP shall maintain written policies and procedures to ensure that prior to an admission, a determination is made, and approved pursuant to CHAMPUS preauthorization requirements, that the admission is medically and/or psychologically necessary and the program is appropriate to meet the patient's needs. Medical and/or psychological necessity determinations shall be rendered by qualified mental health professionals who meet CHAMPUS requirements for individual professional providers and who are permitted by law and by the facility to refer patients for admission.

(6) *Assessments.* The professional staff of the PHP shall complete a multidisciplinary assessment which includes, but

is not limited to physical health, psychological health, physiological, developmental, family, educational, spiritual, and skills assessment of each patient admitted. Unless otherwise specified, all required clinical assessment are completed prior to development of the interdisciplinary treatment plan.

(7) *Clinical formulation.* A qualified mental health provider of the PHP will complete a clinical formulation on all patients. The clinical formulation will be reviewed and approved by the responsible individual professional provider and will incorporate significant findings from each of the multidisciplinary assessments. It will provide the basis for development of an interdisciplinary treatment plan.

(8) *Treatment planning.* A qualified mental health professional with admitting privileges shall be responsible for the development, supervision, implementation, and assessment of a written, individualized, interdisciplinary plan of treatment, which shall be completed by the fifth day following admission to a full-day PHP, or by the seventh day following admission to a half-day PHP, and shall include measurable and observable goals for incremental progress and discharge. The treatment plan shall undergo review at least every two weeks, or when major changes occur in treatment.

(9) *Discharge and transition planning.* The PHP shall develop an individualized transition plan which addresses anticipated needs of the patient at discharge. The transition plan involves determining necessary modifications in the treatment plan, facilitating the termination of treatment, and identifying resources for maintaining therapeutic stability following discharge.

(10) *Clinical documentation.* Clinical records shall be maintained on each patient to plan care and treatment and provide ongoing evaluation of the patient's progress. All care is documented and each clinical record contains at least the following: demographic data, consent forms, pertinent legal documents, all treatment plans and patient assessments, consultation and laboratory reports, physician orders, progress notes, and a discharge summary. All documentation will adhere to applicable provisions of the JCAHO and re-

quirements set forth in §199.7(b)(3). An appropriately qualified records administrator or technician will supervise and maintain the quality of the records. These requirements are in addition to other records requirements of this part, and documentation requirements of the Joint Commission on Accreditation of Health Care Organization.

(11) *Progress notes.* PHPs shall document the course of treatment for patients and families using progress notes which provide information to review, analyze, and modify the treatment plans. Progress notes are legible, contemporaneous, sequential, signed and dated and adhere to applicable provisions of the Manual for Mental Health, Chemical Dependency, and Mental Retardation/Developmental Disabilities Services and requirements set forth in section 199.7(b)(3).

(12) *Therapeutic services.*

(i) Individual, group, and family therapy are provided to all patients, consistent with each patient's treatment plan by qualified mental health providers.

(ii) A range of therapeutic activities, directed and staffed by qualified personnel, are offered to help patients meet the goals of the treatment plan.

(iii) Educational services are provided or arranged that are appropriate to the patient's needs.

(13) *Ancillary services.* A full range of ancillary services are provided. Emergency services include policies and procedures for handling emergencies with qualified personnel and written agreements with each facility providing these services. Other ancillary services include physical health, pharmacy and dietary services.

(C) *Standards for physical plant and environment.*

(1) *Physical environment.* The buildings and grounds of the PHP shall be maintained so as to avoid health and safety hazards, be supportive of the services provided to patients, and promote patient comfort, dignity, privacy, personal hygiene, and personal safety.

(2) *Physical plant safety.* The PHP shall be of permanent construction and maintained in a manner that protects

the lives and ensures the physical safety of patients, staff, and visitors, including conformity with all applicable building, fire, health, and safety codes.

(3) *Disaster planning.* The PHP shall maintain and rehearse written plans for taking care of casualties and handling other consequences arising from internal and external disasters.

(D) *Standards for evaluation system.*

(1) *Quality assessment and improvement.* The PHP shall develop and implement a comprehensive quality assurance and quality improvement program that monitors the quality, efficiency, appropriateness, and effectiveness of care, treatments, and services the PHP provides for patients and their families. Explicit clinical indicators shall be used to be used to evaluate all functions of the PHP and contribute to an ongoing process of program improvement. The clinical director is responsible for developing and implementing quality assessment and improvement activities throughout the facility.

(2) *Utilization review.* The PHP shall implement a utilization review process, pursuant to a written plan approved by the professional staff, the administration and the governing body, that assesses distribution of services, clinical necessity of treatment, appropriateness of admission, continued stay, and timeliness of discharge, as part of an overall effort to provide quality patient care in a cost-effective manner. Findings of the utilization review process are used as a basis for revising the plan of operation, including a review of staff qualifications and staff composition.

(3) *Patient records.* The PHP shall implement a process, including regular monthly reviews of a representative sample of patient records, to determine completeness, accuracy, timeliness of entries, appropriate signatures, and pertinence of clinical entries. Conclusions, recommendations, actions taken, and the results of actions are monitored and reported.

(4) *Drug utilization review.* The PHP shall implement a comprehensive process for the monitoring and evaluating of the prophylactic, therapeutic, and empiric use of drugs to assure that medications are provided appropriately, safely, and effectively.

(5) *Risk management.* The PHP shall implement a comprehensive risk management program, fully coordinated with other aspects of the quality assurance and quality improvement program, to prevent and control risks to patients and staff, and to minimize costs associated with clinical aspects of patient care and safety.

(6) *Infection control.* The PHP shall implement a comprehensive system for the surveillance, prevention, control, and reporting of infections acquired or brought into the facility.

(7) *Safety.* The PHP shall implement an effective program to assure a safe environment for patients, staff, and visitors, including an incident reporting system, disaster training and safety education, a continuous safety surveillance system, and an active multidisciplinary safety committee.

(8) *Facility evaluation.* The PHP annually evaluates accomplishment of the goals and objectives of each clinical program component or facility service of the PHP and reports findings and recommendations to the governing body.

(E) *Participation agreement requirements.* In addition to other requirements set forth in paragraph (b)(4)(xii) of this section, in order for the services of a PHP to be authorized, the PHP 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. On October 1, 1995, 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, OCHAMPUS. In addition to review of a facility's application and supporting documentation, an on-site inspection by OCHAMPUS authorized personnel may be required prior to signing a participation agreement. The Participation Agreement shall include at least the following requirements:

(1) Render partial hospitalization program services to eligible CHAMPUS beneficiaries in need of such services, in accordance with the participation agreement and CHAMPUS regulation.

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

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

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

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

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

(7) Certify that:

(i) It is and will remain in compliance with the provisions of paragraph (b)(4)(xii) of this section establishing standards for psychiatric partial hospitalization programs;

(ii) It has conducted a self assessment of the facility's compliance with the CHAMPUS Standards for Psychiatric Partial Hospitalization Programs, as issued by the Director, OCHAMPUS, and notified the Director, OCHAMPUS 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 Psychiatric Partial Hospitalization Programs, as issued by the Director, OCHAMPUS, except for any such standards regarding which the facility notifies the Director, OCHAMPUS that it is not in compliance.

(8) Designate an individual who will act as liaison for CHAMPUS inquiries.

The PHP shall inform OCHAMPUS 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, OCHAMPUS;

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

(11) Grant the Director, OCHAMPUS, 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 an authorized CHAMPUS 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.

(F) *Other requirements applicable to PHPs.*

(I) Even though a PHP may qualify as a CHAMPUS-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 section 199.4 of this part.

(2) The PHP shall provide patient services to CHAMPUS beneficiaries in the same manner it provides inpatient services to all other patients. 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, OCHAMPUS 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 § 199.4(e)(19) and makes such services available on a 24-hour basis.

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

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

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

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

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

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

(i) A physician;

(ii) A registered professional nurse;

(iii) A social worker; and

(iv) A pastoral or other counselor.

(5) Maintain central clinical records on all patients.

(6) Utilize volunteers.

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

(8) The hospice must enter into an agreement with CHAMPUS in order to be qualified to participate and to be eligible for payment under the program. In this agreement the hospice and CHAMPUS agree that the hospice will:

(i) Not charge the beneficiary or any other person for items or services for which the beneficiary is entitled to have payment made under the CHAMPUS hospice benefit.

(ii) Be allowed to charge the beneficiary for items or services requested by the beneficiary in addition to those that are covered under the CHAMPUS hospice benefit.

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

(xiv) *Substance use disorder rehabilitation facilities.* Paragraph (b)(4)(xiv) of this section establishes standards and requirements for substance use disorder rehabilitation facilities (SUDRF). This

includes both inpatient rehabilitation centers for the treatment of substance use disorders and partial hospitalization centers for the treatment of substance use disorders.

(A) *Organization and administration.*

(1) *Definition of inpatient rehabilitation center.* An inpatient rehabilitation center is a 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, medically monitored assessment, treatment, and evaluation. An inpatient rehabilitation center is appropriate for patients whose addiction-related symptoms, or concomitant physical and emotional/behavioral problems reflect persistent dysfunction in several major life areas. 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) *Definition of partial hospitalization center for the treatment of substance use disorders.* A partial hospitalization center for the treatment of substance use disorders is an addiction-focused service that provides active treatment to

adolescents between the ages of 13 and 18 or adults aged 18 and over. Partial hospitalization is a generic term for day, evening, or weekend programs that treat patients with psychoactive substance use disorders according to a comprehensive, individualized, integrated schedule of care. A partial hospitalization center is organized, interdisciplinary, and medically monitored. Partial hospitalization is appropriate for those whose addiction-related symptoms or concomitant physical and emotional/behavioral problems can be managed outside the hospital environment for defined periods of time with support in one or more of the major life areas.

(3) *Eligibility.*

(i) Every inpatient rehabilitation center and partial hospitalization center for the treatment of substance use disorders must be certified pursuant to CHAMPUS certification standards. Such standards shall incorporate the basic standards set forth in paragraphs (b)(4)(xiv) (A) through (D) of this section, and shall include such additional elaborative criteria and standards as the Director, OCHAMPUS determines are necessary to implement the basic standards.

(ii) To be eligible for CHAMPUS certification, the SUDRF is required to be licensed and fully operational (with a minimum patient census of the lesser of: six patients or 30 percent of bed capacity) for a period of at least six months and operate in substantial compliance with state and federal regulations.

(iii) The SUDRF is currently accredited by the Joint Commission on Accreditation of Healthcare Organizations under the Accreditation Manual for Mental Health, Chemical Dependency, and Mental Retardation/Developmental Disabilities Services, or by the Commission on Accreditation of Rehabilitation Facilities as an alcoholism and other drug dependency rehabilitation program under the Standards Manual for Organizations Serving People with Disabilities, or other designated standards approved by the Director, OCHAMPUS.

(iv) The SUDRF has a written participation agreement with OCHAMPUS. On October 1, 1995, the

SUDRF is not considered 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, OCHAMPUS.

(4) *Governing body.*

(i) The SUDRF shall have a governing body which is responsible for the policies, bylaws, and activities of the facility. If the SUDRF is owned by a partnership or single owner, the partners or single owner are regarded as the governing body. The facility will provide an up-to-date list of names, addresses, telephone numbers and titles of the members of the governing body.

(ii) The governing body ensures appropriate and adequate services for all patients and oversees continuing development and improvement of care. Where business relationships exist between the governing body and facility, appropriate conflict-of-interest policies are in place.

(iii) Board members are fully informed about facility services and the governing body conducts annual reviews of its performance in meeting purposes, responsibilities, goals and objectives.

(5) *Chief executive officer.* The chief executive officer, appointed by and subject to the direction of the governing body, shall assume overall administrative responsibility for the operation of the facility according to governing body policies. The chief executive officer shall have five years' administrative experience in the field of mental health or addictions. On October 1, 1997 the CEO shall possess a degree in business administration, public health, hospital administration, nursing, social work, or psychology, or meet similar educational requirements as prescribed by the Director, OCHAMPUS.

(6) *Clinical Director.* The clinical director, appointed by the governing body, shall be a qualified psychiatrist or doctoral level psychologist who meets applicable CHAMPUS requirements for individual professional providers and is licensed to practice in the state where the SUDRF is located. The clinical director shall possess requisite education and experience, including credentials applicable under state practice and licensing laws appropriate to

the professional discipline. The clinical director shall satisfy at least one of the following requirements: certification by the American Society of Addiction Medicine; one year or 1,000 hours of experience in the treatment of psychoactive substance use disorders; or is a psychiatrist or doctoral level psychologist with experience in the treatment of substance use disorders. The clinical director shall be responsible for planning, development, implementation, and monitoring of all clinical activities.

(7) *Medical director.* The medical director, appointed by the governing body, shall be licensed to practice medicine in the state where the center is located and shall possess requisite education including graduation from an accredited school of medicine or osteopathy. The medical director shall satisfy at least one of the following requirements: certification by the American Society of Addiction Medicine; one year or 1,000 hours of experience in the treatment of psychoactive substance use disorders; or is a psychiatrist with experience in the treatment of substance use disorders. The medical director shall be responsible for the planning, development, implementation, and monitoring of all activities relating to medical treatment of patients. If qualified, the Medical Director may also serve as Clinical Director.

(8) *Medical or professional staff organization.* The governing body shall establish a medical or professional staff organization to assure effective implementation of clinical privileging, professional conduct rules, and other activities directly affecting patient care.

(9) *Personnel policies and records.* The SUDRF shall maintain written personnel policies, updated job descriptions, personnel records to assure the selection of qualified personnel and successful job performance of those personnel.

(10) *Staff development.* The SUDRF shall provide appropriate training and development programs for administrative, support, and direct care staff.

(11) *Fiscal accountability.* The SUDRF shall assure fiscal accountability to applicable government authorities and patients.

(12) *Designated teaching facilities.* Students, residents, interns, or fellows

providing direct clinical care are under the supervision of a qualified staff member approved by an accredited university or approved training program. The teaching program is approved by the Director, OCHAMPUS.

(13) *Emergency reports and records.* The facility notifies OCHAMPUS of any serious occurrence involving CHAMPUS beneficiaries.

(B) *Treatment services.*

(1) *Staff composition.*

(i) The SUDRF shall follow written plans which assure that medical and clinical patient needs will be appropriately addressed during all hours of operation by a sufficient number of fully qualified (including license, registration or certification requirements, educational attainment, and professional experience) health care professionals and support staff in the respective disciplines. Clinicians providing individual, group and family therapy meet CHAMPUS requirements as qualified mental health providers and operate within the scope of their licenses. The ultimate authority for planning, development, implementation, and monitoring of all clinical activities is vested in a psychiatrist or doctoral level clinical psychologist. The management of medical care is vested in a physician.

(ii) The SUDRF shall establish and follow written plans to assure adequate staff coverage during all hours of operation of the center, including physician availability and other professional staff coverage 24 hours per day, seven days per week for an inpatient rehabilitation center and during all hours of operation for a partial hospitalization center.

(2) *Staff qualifications.* Within the scope of its programs and services, the SUDRF has a sufficient number of professional, administrative, and support staff to address the medical and clinical needs of patients and to coordinate the services provided. SUDRFs that employ individuals with master's or doctoral level degrees in a mental health discipline who do not meet the licensure, certification and experience requirements for a qualified mental health provider but are actively working toward licensure or certification, may provide services within the DRG,

provided the individual works under the clinical supervision of a fully qualified mental health provider employed by the SUDRF.

(3) *Patient rights.*

(i) The SUDRF shall provide adequate protection for all patient rights, safety, confidentiality, informed consent, grievances, and personal dignity.

(ii) The SUDRF has a written policy regarding patient abuse and neglect.

(iii) SUDRF marketing and advertising meets professional standards.

(4) *Behavioral management.* When a SUDRF uses a behavioral management program, the center shall adhere to a comprehensive, written plan of behavioral management, developed by the clinical director and the medical or professional staff and approved by the governing body. It shall be based on positive reinforcement methods and, except for infrequent use of temporary physical holds or time outs, does not include the use of restraint or seclusion. Only trained and clinically privileged RNs or qualified mental health professionals may be responsible for the implementation of seclusion and restraint in an emergency situation.

(5) *Admission process.* The SUDRF shall maintain written policies and procedures to ensure that, prior to an admission, a determination is made, and approved pursuant to CHAMPUS preauthorization requirements, that the admission is medically and/or psychologically necessary and the program is appropriate to meet the patient's needs. Medical and/or psychological necessity determinations shall be rendered by qualified mental health professionals who meet CHAMPUS requirements for individual professional providers and who are permitted by law and by the facility to refer patients for admission.

(6) *Assessment.* The professional staff of the SUDRF shall provide a complete, multidisciplinary assessment of each patient which includes, but is not limited to, medical history, physical health, nursing needs, alcohol and drug history, emotional and behavioral factors, age-appropriate social circumstances, psychological condition, education status, and skills. Unless otherwise specified, all required clinical assessments are completed prior to

development of the multidisciplinary treatment plan.

(7) *Clinical formulation.* A qualified mental health care professional of the SUDRF will complete a clinical formulation on all patients. The clinical formulation will be reviewed and approved by the responsible individual professional provider and will incorporate significant findings from each of the multidisciplinary assessments. It will provide the basis for development of an interdisciplinary treatment plan.

(8) *Treatment planning.* A qualified health care professional with admitting privileges shall be responsible for the development, supervision, implementation, and assessment of a written, individualized, and interdisciplinary plan of treatment, which shall be completed within 10 days of admission to an inpatient rehabilitation center or by the fifth day following admission to full day partial hospitalization center, and by the seventh day of treatment for half day partial hospitalization. The treatment plan shall include individual, measurable, and observable goals for incremental progress towards the treatment plan objectives and goals and discharge. A preliminary treatment plan is completed within 24 hours of admission and includes at least a physician's admission note and orders. The master treatment plan is regularly reviewed for effectiveness and revised when major changes occur in treatment.

(9) *Discharge and transition planning.* The SUDRF shall maintain a transition planning process to address adequately the anticipated needs of the patient prior to the time of discharge.

(10) *Clinical documentation.* Clinical records shall be maintained on each patient to plan care and treatment and provide ongoing evaluation of the patient's progress. All care is documented and each clinical record contains at least the following: demographic data, consent forms, pertinent legal documents, all treatment plans and patient assessments, consultation and laboratory reports, physician orders, progress notes, and a discharge summary. All documentation will adhere to applicable provisions of the JCAHO and requirements set forth in § 199.7(b)(3). An appropriately qualified records admin-

istrator or technician will supervise and maintain the quality of the records. These requirements are in addition to other records requirements of this part, and provisions of the JCAHO Manual for Mental Health, Chemical Dependency, and Mental Retardation/Developmental Disabilities Services.

(11) *Progress notes.* Timely and complete progress notes shall be maintained to document the course of treatment for the patient and family.

(12) *Therapeutic services.*

(i) Individual, group, and family psychotherapy and addiction counseling services are provided to all patients, consistent with each patient's treatment plan by qualified mental health providers.

(ii) A range of therapeutic activities, directed and staffed by qualified personnel, are offered to help patients meet the goals of the treatment plan.

(iii) Therapeutic educational services are provided or arranged that are appropriate to the patient's educational and therapeutic needs.

(13) *Ancillary services.* A full range of ancillary services is provided. Emergency services include policies and procedures for handling emergencies with qualified personnel and written agreements with each facility providing the service. Other ancillary services include physical health, pharmacy and dietary services.

(C) *Standards for physical plant and environment.*

(1) *Physical environment.* The buildings and grounds of the SUDRF shall be maintained so as to avoid health and safety hazards, be supportive of the services provided to patients, and promote patient comfort, dignity, privacy, personal hygiene, and personal safety.

(2) *Physical plant safety.* The SUDRF shall be maintained in a manner that protects the lives and ensures the physical safety of patients, staff, and visitors, including conformity with all applicable building, fire, health, and safety codes.

(3) *Disaster planning.* The SUDRF shall maintain and rehearse written plans for taking care of casualties and handling other consequences arising from internal or external disasters.

(D) *Standards for evaluation system.*

(1) *Quality assessment and improvement.* The SUDRF develop and implement a comprehensive quality assurance and quality improvement program that monitors the quality, efficiency, appropriateness, and effectiveness of the care, treatments, and services it provides for patients and their families, utilizing clinical indicators of effectiveness to contribute to an ongoing process of program improvement. The clinical director is responsible for developing and implementing quality assessment and improvement activities throughout the facility.

(2) *Utilization review.* The SUDRF shall implement a utilization review process, pursuant to a written plan approved by the professional staff, the administration, and the governing body, that assesses the appropriateness of admissions, continued stay, and timeliness of discharge as part of an effort to provide quality patient care in a cost-effective manner. Findings of the utilization review process are used as a basis for revising the plan of operation, including a review of staff qualifications and staff composition.

(3) *Patient records review.* The center shall implement a process, including monthly reviews of a representative sample of patient records, to determine the completeness and accuracy of the patient records and the timeliness and pertinence of record entries, particularly with regard to regular recording of progress/non-progress in treatment plan.

(4) *Drug utilization review.* An inpatient rehabilitation center and, when applicable, a partial hospitalization center, shall implement a comprehensive process for the monitoring and evaluating of the prophylactic, therapeutic, and empiric use of drugs to assure that medications are provided appropriately, safely, and effectively.

(5) *Risk management.* The SUDRF shall implement a comprehensive risk management program, fully coordinated with other aspects of the quality assurance and quality improvement program, to prevent and control risks to patients and staff and costs associated with clinical aspects of patient care and safety.

(6) *Infection control.* The SUDRF shall implement a comprehensive system for

the surveillance, prevention, control, and reporting of infections acquired or brought into the facility.

(7) *Safety.* The SUDRF shall implement an effective program to assure a safe environment for patients, staff, and visitors.

(8) *Facility evaluation.* The SUDRF annually evaluates accomplishment of the goals and objectives of each clinical program and service of the SUDRF and reports findings and recommendations to the governing body.

(E) *Participation agreement requirements.* In addition to other requirements set forth in paragraph (b)(4)(xiv) of this section, in order for the services of an inpatient rehabilitation center or partial hospitalization center for the treatment of substance abuse disorders to be authorized, the center 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. On October 1, 1995, 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, OCHAMPUS. 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. In addition, such a Participation Agreement may not be signed until an SUDRF has been licensed and operational for at least six months. The Participation Agreement shall include at least the following requirements:

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

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

(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

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§ 199.4, and charges for services and supplies that are not a benefit of CHAMPUS;

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

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

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

(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;

(ii) It has conducted a self assessment of the SUDRF'S compliance with the CHAMPUS Standards for Substance Use Disorder Rehabilitation Facilities, as issued by the Director, OCHAMPUS, and notified the Director, OCHAMPUS 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, OCHAMPUS, except for any such standards regarding which the facility notifies the Director, OCHAMPUS that it is not in compliance.

(8) Grant the Director, OCHAMPUS, 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 CHAMPUS 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 General Accounting Office.

(F) *Other requirements applicable to substance use disorder rehabilitation facilities.*

(1) Even though a SUDRF may qualify as a CHAMPUS-authorized provider and may have entered into a participation agreement with CHAMPUS, payment by CHAMPUS for particular services provided is contingent upon the SUDRF also meeting all conditions set forth in § 199.4.

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

(3) The substance use disorder facility shall assure that all certifications and information provided to the Director, OCHAMPUS 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.

(c) *Individual professional providers of care.* (1) *General.* Individual professional providers of care are those providers who bill for their services on a fee-for-service basis and who are not employed

by an institutional provider or under a contract which provides for payment to the individual professional provider by an institutional provider. This category also includes those individuals who have formed professional corporations or associations qualifying as a domestic corporation under 26 CFR 301.7701-5. Such individual professional providers must be licensed or certified by the local licensing or certifying agency for the jurisdiction in which the care is provided; or in the absence of state licensure/certification, be a member of, or demonstrate eligibility for full clinical membership in, the appropriate national or professional certifying association that sets standards for the profession of which the provider is a member. Services provided must be in accordance with good medical practice and prevailing standards of quality of care and within recognized utilization norms.

(i) *Licensing/certification required, scope of license.* Otherwise covered services shall be cost-shared only if the individual professional provider holds a current, valid license or certification to practice his or her profession in the jurisdiction where the service is rendered. Licensure/certification must be at the full clinical practice level. The services provided must be within the scope of the license, certification or other legal authorization. Licensure or certification is required to be a CHAMPUS authorized provider if offered in the jurisdiction where the service is rendered, whether such licensure or certification is required by law or available on a voluntary basis. The requirement also applies for those categories of providers that would otherwise be exempt by the state because the provider is working in a non-profit, state-owned or church setting. Licensure/certification is mandatory for a provider to become a CHAMPUS-authorized provider.

(ii) *Monitoring required.* The Director, OCHAMPUS, or a designee, shall develop appropriate monitoring programs and issues guidelines, criteria, or norms necessary to ensure that CHAMPUS expenditures are limited to necessary medical supplies and services at the most reasonable cost to the government and beneficiary. The Director,

OCHAMPUS, or a designee, also will take such steps as necessary to deter overutilization of services.

(iii) *Christian Science.* Christian Science practitioners and Christian Science nurses are authorized to provide services under CHAMPUS. Inasmuch as they provide services of an extramedical nature, the general criteria outlined above do not apply to Christian Science services (refer to paragraph (c)(3)(iv)(B) regarding services of Christian Science practitioners and nurses).

(iv) *Physician referral and supervision.* Physician referral and supervision is required for the services of paramedical providers as listed in paragraph (c)(3)(iii)(H) of this section and for pastoral counselors and mental health counselors. Physician referral means that the physician must actually see the patient, perform an evaluation, and arrive at an initial diagnostic impression prior to referring the patient. Documentation is required of the physician's examination, diagnostic impression, and referral. Physician supervision means that the physician provides overall medical management of the case. The physician does not have to be physically located on the premises of the provider to whom the referral is made. Communication back to the referring physician is an indication of medical management.

(v) *Medical records:* Individual professional providers must 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 the following:

(A) The cognizant state licensing authority;

(B) The Joint Commission on Accreditation of Healthcare Organizations, or other health care accreditation organizations as may be appropriate;

(C) Standards of practice established by national medical organizations; and

(D) This part.

(2) *Interns and residents.* Interns and residents may not be paid directly by CHAMPUS for services rendered to a

beneficiary when their services are provided as part of their employment (either salaried or contractual) by a hospital or other institutional provider.

(3) *Types of providers.* Subject to the standards of participation provisions of this part, the following individual professional providers of medical care are authorized to provide services to CHAMPUS beneficiaries:

(i) *Physicians.* (A) Doctors of Medicine (M.D.).

(B) Doctors of Osteopathy (D.O.).

(ii) *Dentists.* Except for covered oral surgery as specified in §199.4(e) of this part, all otherwise covered services rendered by dentists require preauthorization.

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

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

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

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

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

(2) Has 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 Podiatry or Surgical Chiropody.*

(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 §199.14(g)(1)(iii) of this part for limitations on reimbursement). For purposes of CHAMPUS, a physician assistant must meet the applicable state requirements governing the qualifications of physician assistants and at least one of the following conditions:

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

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

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

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

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

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

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

(1) Licensed registered nurses.

(2) Licensed registered physical therapists and occupational therapists.

(3) Licensed registered physical therapists.

(4) Audiologists.

(5) Speech therapists (speech pathologists).

(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 patient's 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 recog-

nized as an authorized provider under CHAMPUS. Subsequent to termination, the certified marriage and family therapist may only be reinstated as an authorized CHAMPUS extramedical provider by entering into a new participation agreement as a certified marriage and family therapist.

(B) *Pastoral counselors.* For the purposes of CHAMPUS, a pastoral counselor is an individual who meets the following requirements:

(1) Recognized graduate professional education with the minimum of an earned master's degree from a regionally accredited educational institution in an appropriate behavioral science field, mental health discipline; and

(2) The following experience:

(i) Either 200 hours of approved supervision in the practice of pastoral counseling, ordinarily to be completed in a 2- to 3-year period, of which at least 100 hours must be in individual supervision. This supervision will occur preferably with more than one supervisor and should include a continuous process of supervision with at least three cases; and

(ii) 1,000 hours of clinical experience in the practice of pastoral counseling under approved supervision, involving at least 50 different cases; or

(iii) 150 hours of approved supervision in the practice of psychotherapy, ordinarily to be completed in a 2- to 3-year period, of which at least 50 hours must be individual supervision; plus at least 50 hours of approved individual supervision in the practice of pastoral counseling, ordinarily to be completed within a period of not less than 1 nor more than 2 years; and

(iv) 750 hours of clinical experience in the practice of psychotherapy under approved supervision involving at least 30 cases; plus at least 250 hours of clinical practice in pastoral counseling under approved supervision, involving at least 20 cases; and

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

(4) The services of a pastoral counselor meeting the above requirements are coverable following the CHAMPUS

determined allowable charge methodology, under the following specified conditions:

(i) The CHAMPUS beneficiary must be referred for therapy by a physician; and

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

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

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

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

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

(1) Minimum of a master's degree in mental health counseling or allied

mental health field from a regionally accredited institution; and

(2) Two years of post-masters experience which includes 3000 hours of clinical work and 100 hours of face-to-face supervision; and

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

(4) May only be reimbursed when:

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

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

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

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

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

(2) Grace period for therapists or counselors in states where licensure/certification is optional. CHAMPUS is providing a grace period for those therapists or counselors who did not obtain optional licensure/certification in their jurisdiction, not realizing it was a CHAMPUS requirement for authorization. The exemption by state law for pastoral counselors may have misled this group into thinking licensure was not required. The same situation may have occurred with the other therapist or counselor categories where licensure was either not mandated by the state or was provided under a more general category such as "professional

counselors.” This grace period pertains only to the licensure/certification requirement, applies only to therapists or counselors who are already approved as of October 29, 1990, and only in those areas where the licensure/certification is optional. Any therapist or counselor who is not licensed/certified in the state in which he/she is practicing by August 1, 1991, will be terminated under the provisions of § 199.9. This grace period does not change any of the other existing requirements which remain in effect. During this grace period, membership or proof of eligibility for full clinical membership in a recognized professional association is required for those therapists or counselors who are not licensed or certified by the state. The following organizations are recognized for therapists or counselors at the level indicated: Full clinical member of the American Association of Marriage and Family Therapy; membership at the fellow or diplomate level of the American Association of Pastoral Counselors; and membership in the National Academy of Certified Clinical Mental Health Counselors. Acceptable proof of eligibility for membership is a letter from the appropriate certifying organization. This opportunity for delayed certification/licensure is limited to the counselor or therapist category only as the language in all of the other provider categories has been consistent and unmodified from the time each of the other provider categories were added. The grace period does not apply in those states where licensure is mandatory.

(E) *Christian Science practitioners and Christian Science nurses.* CHAMPUS cost-shares the services of Christian Science practitioners and nurses. In order to bill as such, practitioners or nurses must be listed or be eligible for listing in the Christian Science Journal¹ 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.

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

(5) *Medical equipment firms, medical supply firms.* As determined by the Director, OCHAMPUS, or a designee.

(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) *Program for Persons with Disabilities Providers.*—(1) *General.* (i) Services and items cost-shared through § 199.5 must be rendered by a CHAMPUS-authorized provider.

(ii) A Program for the Handicapped (PFTH) provider with CHAMPUS-authorized status on the effective date for the Program for Persons with Disabilities (PFPWD) shall be deemed to be a CHAMPUS-authorized PFPWD provider until all outstanding PFTH benefit authorizations for services or items being rendered by the provider expire.

(2) *PFPWD provider categories.*—(i) *PFPWD inpatient care provider.* A provider of residential institutional care which is otherwise a PFPWD benefit shall be:

(A) A not-for-profit entity or a public facility, as defined in § 199.2; and

¹Copies 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.

(B) Located within a State, as defined in § 199.2; 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 CHAMPUS-authorized Institutional Provider as defined in paragraph (b) of this section, or be approved by a State educational agency as a training institution.

(ii) *PFPWD outpatient care provider.* A provider of PFPWD outpatient, ambulatory, or in-home services shall be:

(A) A CHAMPUS-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 a PFPWD benefit and not otherwise allowable as a benefit of § 199.4, that meets all applicable licensing or other regulatory requirements that are extant in the state, county, municipality, or other political jurisdiction in which the PFPWD service is rendered.

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

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

(f) *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.

(g) *Exclusion.* Regardless of any provision in this section, a provider who is suspended, excluded, or terminated under § 199.9 of this part is specifically

excluded as an authorized CHAMPUS provider.

[51 FR 24008, July 1, 1986]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 199.6, see the List of Sections Affected in the Finding Aids section of this volume.

§ 199.7 Claims submission, review, and payment.

(a) *General.* The Director, OCHAMPUS, or a designee, is responsible for ensuring that benefits under CHAMPUS are paid only to the extent described in this part. Before benefits can be paid, an appropriate claim must be submitted that includes sufficient information as to beneficiary identification, the medical services and supplies provided, and double coverage information, to permit proper, accurate, and timely adjudication of the claim by the CHAMPUS contractor or OCHAMPUS. Providers must be able to document that the care or service shown on the claim was rendered. This section sets forth minimum medical record requirements for verification of services. Subject to such definitions, conditions, limitations, exclusions, and requirements as may be set forth in this part, the following are the CHAMPUS claim filing requirements:

(1) *CHAMPUS identification card required.* A patient shall present his or her applicable CHAMPUS identification card (that is, Uniformed Services identification card) to the authorized provider of care that identifies the patient as an eligible CHAMPUS beneficiary (refer to § 199.3 of this part).

(2) *Claim required.* No benefit may be extended under the Basic Program or Program for Persons with Disabilities (PFPWD) without the submission of a complete and properly executed appropriate claim form.

(3) *Responsibility for perfecting claim.* It is the responsibility of the CHAMPUS beneficiary or sponsor or the authorized provider acting on behalf of the CHAMPUS beneficiary to perfect a claim for submission to the appropriate CHAMPUS fiscal intermediary. Neither a CHAMPUS fiscal intermediary nor OCHAMPUS is authorized to prepare a claim on behalf of a CHAMPUS beneficiary.