

Part 199.15

Quality And Utilization Review Peer Review Organization Program

Revision:

Rule:

(a) General. (1) *Purpose.* The purpose of this section is to establish rules and procedures for the CHAMPUS Quality and Utilization Review Peer Review Organization program.

(2) *Applicability of program.* All claims submitted for health services under CHAMPUS are subject to review for quality of care and appropriate utilization. The Director, OCHAMPUS shall establish generally accepted standards, norms and criteria as are necessary for this program of utilization and quality review. These standards, norms and criteria shall include, but not be limited to, need for inpatient admission or inpatient or outpatient service, length of inpatient stay, intensity of care, appropriateness of treatment, and level of institutional care required. The Director, OCHAMPUS may issue implementing instructions, procedures and guidelines for retrospective, concurrent and prospective review.

(3) *Contractor implementation.* The CHAMPUS Quality and Utilization Review Peer Review Organization program may be implemented through contracts administered by the Director, OCHAMPUS. These contractors may include contractors that have exclusive functions in the area of utilization and quality review, fiscal intermediary contractors (which perform these functions along with a broad range of administrative services), and managed care contractors (which perform a range of functions concerning management of the delivery and financing of health care services under CHAMPUS). Regardless of the contractors involved, utilization and quality review activities follow the same standards, rules and procedures set forth in this section, unless otherwise specifically provided in this section or elsewhere in this part.

(4) *Medical issues affected.* The CHAMPUS Quality and Utilization Review Peer Review Organization program is distinguishable in purpose and impact from other activities relating to the administration and management of CHAMPUS in that the Peer Review Organization program is concerned primarily with medical judgments regarding the quality and appropriateness of health care services. Issues regarding such matters as benefit limitations are similar, but, if not determined on the basis of medical judgments, are governed by CHAMPUS rules and procedures other than those provided in this section. (See, for example, Sec. 199.7 regarding claims submission, review and payment.) Based on this purpose, a major attribute of the Peer Review Organization program is that medical judgments are made by (directly or pursuant to guidelines and subject to direct review) reviewers who are peers of the health care providers providing the services under review.

(5) *Provider responsibilities.* Because of the dominance of medical judgments in the quality and utilization review program, principal responsibility for complying with program rules and procedures rests with health care providers. For this reason, there are limitations, set forth in this section and in Sec. 199.4(h), on the extent to which beneficiaries may be held financially liable for health care services not

provided in conformity with rules and procedures of the quality and utilization review program concerning medical necessity of care.

(6) *Medicare rules used as model.* The CHAMPUS Quality and Utilization Review Peer Review Organization program, based on specific statutory authority, follows many of the quality and utilization review requirements and procedures in effect for the Medicare Peer Review Organization program, subject to adaptations appropriate for the CHAMPUS program. In recognition of the similarity of purpose and design between the Medicare and CHAMPUS PRO programs, and to avoid unnecessary duplication of effort, the CHAMPUS Quality and Utilization Review Peer Review Organization program will have special procedures applicable to supplies and services furnished to Medicare-eligible CHAMPUS beneficiaries. These procedures will enable CHAMPUS normally to rely upon Medicare determinations of medical necessity and appropriateness in the processing of CHAMPUS claims as a second payer to Medicare. As a general rule, only in cases involving Medicare-eligible CHAMPUS beneficiaries where Medicare payment for services and supplies is denied for reasons other than medical necessity and appropriateness will the CHAMPUS claim be subject to review for quality of care and appropriate utilization under the CHAMPUS PRO program. TRICARE will continue to perform a medical necessity and appropriateness review for quality of care and appropriate utilization under the CHAMPUS PRO program where required by statute.

(b) Objectives and general requirements of review system--(1) *In general.* Broadly, the program of quality and utilization review has as its objective to review the quality, completeness and adequacy of care provided, as well as its necessity, appropriateness and reasonableness.

(2) *Payment exclusion for services provided contrary to utilization and quality standards.* (i) In any case in which health care services are provided in a manner determined to be contrary to quality or necessity standards established under the quality and utilization review program, payment may be wholly or partially excluded.

(ii) In any case in which payment is excluded pursuant to paragraph (b)(2)(i) of this section, the patient (or the patient's family) may not be billed for the excluded services.

(iii) Limited exceptions and other special provisions pertaining to the requirements established in paragraphs (b)(2)(i) and (ii) of this section, are set forth in Sec. 199.4(h).

(3) *Review of services covered by DRG-based payment system.* Application of these objectives in the context of hospital services covered by the DRG-based payment system also includes a validation of diagnosis and procedural information that determines CHAMPUS reimbursement, and a review of the necessity and appropriateness of care for which payment is sought on an outlier basis.

(4) *Preauthorization and other utilization review procedures--*(i) *In general.* all health care services for which payment is sought under TRICARE are subject to review for appropriateness of utilization as determined by the Director, TRICARE Management Activity, or a designee.

(A) The procedures for this review may be prospective (before the care is provided), concurrent (while the care is in process), or retrospective (after the care has been provided). Regardless of the procedures of this utilization review, the same generally accepted standards, norms and criteria for evaluating the medical necessity, appropriateness and reasonableness of the care involved shall apply. The Director, TRICARE Management Activity, or a designee, shall establish procedures for conducting reviews, including types of health care services for which preauthorization or concurrent review shall be required. Preauthorization or concurrent review may be required for categories of health care

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services. Except where required by law, the categories of health care services for which preauthorization or concurrent review is required may vary in different geographical locations or for different types of providers.

(B) For healthcare services provided under TRICARE contracts entered into by the Department of Defense after October 30, 2000, medical necessity preauthorization will not be required for referrals for specialty consultation appointment services requested by primary care providers or specialty providers when referring TRICARE Prime beneficiaries for specialty consultation appointment services within the TRICARE contractor's network. However, the lack of medical necessity preauthorization requirements for consultative appointment services does not mean that non-emergent admissions or invasive diagnostic or therapeutic procedures which in and of themselves constitute categories of health care services related to, but beyond the level of the consultation appointment service, are not subject to medical necessity prior authorization. In fact many such health care services may continue to require medical necessity prior authorization as determined by the Director, TRICARE Management Activity, or a designee. TRICARE Prime beneficiaries are also required to obtain preauthorization before seeking health care services from a non-network provider.

(ii) *Preauthorization procedures.* With respect to categories of health care (inpatient or outpatient) for which preauthorization is required, the following procedures shall apply:

(A) The requirement for preauthorization shall be widely publicized to beneficiaries and providers.

(B) All requests for preauthorization shall be responded to in writing. Notification of approval or denial shall be sent to the beneficiary. Approvals shall specify the health care services and supplies approved and identify any special limits or further requirements applicable to the particular case.

(C) An approved preauthorization shall state the number of days, appropriate for the type of care involved, for which it is valid. In general, preauthorizations will be valid for 30 days. If the services or supplies are not obtained within the number of days specified, a new preauthorization request is required. For organ and stem cell transplants, the preauthorization shall remain in effect as long as the beneficiary continues to meet the specific transplant criteria set forth in the TRICARE/CHAMPUS Policy Manual, or until the approved transplant occurs.

(D) For healthcare services provided under TRICARE contracts entered into by the Department of Defense after October 30, 2000, medical necessity preauthorization for specialty consultation appointment services within the TRICARE contractor's network will not be required. However, the Director, TRICARE Management Activity, or designee, may continue to require or waive medical necessity prior (or pre) authorization for other categories of other health care services based on best business practice.

(iii) *Payment reduction for noncompliance with required utilization review procedures.* (A) Paragraph (b)(4)(iii) of this section applies to any case in which:

(1) A provider was required to obtain preauthorization or continued stay (in connection with required concurrent review procedures) approval.

(2) The provider failed to obtain the necessary approval; and

(3) The health care services have not been disallowed on the basis of necessity, appropriateness or reasonableness.

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In such a case, reimbursement will be reduced, unless such reduction is waived based on special circumstances.

(B) In a case described in paragraph (b)(4)(iii)(A) of this section, reimbursement will be reduced, unless such reduction is waived based on special circumstances. The amount of this reduction shall be at least ten percent of the amount otherwise allowable for services for which preauthorization (including preauthorization for continued stays in connection with concurrent review requirements) approval should have been obtained, but was not obtained.

(C) The payment reduction set forth in paragraph (b)(4)(iii)(B) of this section may be waived by the Director, OCHAMPUS when the provider could not reasonably have been expected to know of the preauthorization requirement or some other special circumstance justifies the waiver.

(D) Services for which payment is disallowed under paragraph (b)(4)(iii) of this section may not be billed to the patient (or the patient's family).

(c) Hospital cooperation. All hospitals which participate in CHAMPUS and submit CHAMPUS claims are required to provide all information necessary for CHAMPUS to properly process the claims. In order for CHAMPUS to be assured that services for which claims are submitted meet quality of care standards, hospitals are required to provide the Peer Review Organization (PRO) responsible for quality review with all the information, within timeframes to be established by OCHAMPUS, necessary to perform the review functions required by this paragraph. Additionally, all participating hospitals shall provide CHAMPUS beneficiaries, upon admission, with information about the admission and quality review system including their appeal rights. A hospital which does not cooperate in this activity shall be subject to termination as a CHAMPUS-authorized provider.

(1) Documentation that the beneficiary has received the required information about the CHAMPUS PRO program must be maintained in the same manner as is the notice required for the Medicare program by 42 CFR 466.78(b).

(2) The physician acknowledgment required for Medicare under 42 CFR 412.46 is also required for CHAMPUS as a condition for payment and may be satisfied by the same statement as required for Medicare, with substitution or addition of "CHAMPUS" when the word "Medicare" is used.

(3) Participating hospitals must execute a memorandum of understanding with the PRO providing appropriate procedures for implementation of the PRO program.

(4) Participating hospitals may not charge a CHAMPUS beneficiary for inpatient hospital services excluded on the basis of Sec. 199.4(g)(1) (not medically necessary), Sec. 199.4(g)(3) (inappropriate level), or Sec. 199.4(g)(7) (custodial care) unless all of the conditions established by 42 CFR 412.42(c) with respect to Medicare beneficiaries have been met with respect to the CHAMPUS beneficiary. In such cases in which the patient requests a PRO review while the patient is still an inpatient in the hospital, the hospital shall provide to the PRO the records required for the review by the close of business of the day the patient requests review, if such request was made before noon. If the hospital fails to provide the records by the close of business, that day and any subsequent working day during which the hospital continues to fail to provide the records shall not be counted for purposes of the two-day period of 42 CFR 412.42(c)(3)(ii).

(d) Areas of review--(1) Admissions. The following areas shall be subject to review to determine whether inpatient care was medically appropriate and necessary, was delivered in the most

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appropriate setting and met acceptable standards of quality. This review may include preadmission or prepayment review when appropriate.

(i) Transfers of CHAMPUS beneficiaries from a hospital or hospital unit subject to the CHAMPUS DRG-based payment system to another hospital or hospital unit.

(ii) CHAMPUS admissions to a hospital or hospital unit subject to the CHAMPUS DRG-based payment system which occur within a certain period (specified by OCHAMPUS) of discharge from a hospital or hospital unit subject to the CHAMPUS DRG-based payment system.

(iii) A random sample of other CHAMPUS admissions for each hospital subject to the CHAMPUS DRG-based payment system.

(iv) CHAMPUS admissions in any DRGs which have been specifically identified by OCHAMPUS for review or which are under review for any other reason.

(2) *DRG validation.* The review organization responsible for quality of care reviews shall be responsible for ensuring that the diagnostic and procedural information reported by hospitals on CHAMPUS claims which is used by the fiscal intermediary to assign claims to DRGs is correct and matches the information contained in the medical records. In order to accomplish this, the following review activities shall be done.

(i) Perform DRG validation reviews of each case under review.

(ii) Review of claim adjustments submitted by hospitals which result in the assignment of a higher weighted DRG.

(iii) Review for physician's acknowledgement of annual receipt of the penalty statement as contained in the Medicare regulation at 42 CFR 412.46.

(iv) Review of a sample of claims for each hospital reimbursed under the CHAMPUS DRG-based payment system. Sample size shall be determined based upon the volume of claims submitted.

(3) *Outlier review.* Claims which qualify for additional payment as a long-stay outlier or as a cost-outlier shall be subject to review to ensure that the additional days or costs were medically necessary and appropriate and met all other requirements for CHAMPUS coverage. In addition, claims which qualify as short-stay outliers shall be reviewed to ensure that the admission was medically necessary and appropriate and that the discharge was not premature.

(4) *Procedure review.* Claims for procedures identified by OCHAMPUS as subject to a pattern of abuse shall be the subject of intensified quality assurance review.

(5) *Other review.* Any other cases or types of cases identified by OCHAMPUS shall be subject to focused review.

(e) Actions as a result of review--(1) Findings related to individual claims. If it is determined, based upon information obtained during reviews, that a hospital has misrepresented admission, discharge, or billing information, or is found to have quality of care defects, or has taken an action that results in the unnecessary admissions of an individual entitled to benefits, unnecessary multiple admission of an individual, or other inappropriate medical or other practices with respect to beneficiaries or billing for

services furnished to beneficiaries, the PRO, in conjunction with the fiscal intermediary, shall, as appropriate:

- (i) Deny payment for or recoup (in whole or in part) any amount claimed or paid for the inpatient hospital and professional services related to such determination.
- (ii) Require the hospital to take other corrective action necessary to prevent or correct the inappropriate practice.
- (iii) Advise the provider and beneficiary of appeal rights, as required by Sec. 199.10 of this part.
- (iv) Notify OCHAMPUS of all such actions.

(2) *Findings related to a pattern of inappropriate practices.* In all cases where a pattern of inappropriate admissions and billing practices that have the effect of circumventing the CHAMPUS DRG-based payment system is identified, OCHAMPUS shall be notified of the hospital and practice involved.

(3) *Revision of coding relating to DRG validation.* The following provisions apply in connection with the DRG validation process set forth in paragraph (d)(2) of this section.

- (i) If the diagnostic and procedural information in the patient's medical record is found to be inconsistent with the hospital's coding or DRG assignment, the hospital's coding on the CHAMPUS claim will be appropriately changed and payments recalculated on the basis of the appropriate DRG assignment.
- (ii) If the information stipulated under paragraph (d)(2) of this section is found not to be correct, the PRO will change the coding and assign the appropriate DRG on the basis of the changed coding.

(f) Special procedures in connection with certain types of health care services or certain types of review activities--(1) *In general.* Many provisions of this section are directed to the context of services covered by the CHAMPUS DRG-based payment system. This section, however, is also applicable to other services. In addition, many provisions of this section relate to the context of peer review activities performed by Peer Review Organizations whose sole functions for CHAMPUS relate to the Quality and Utilization Review Peer Review Organization program. However, it also applies to review activities conducted by contractors who have responsibilities broader than those related to the quality and utilization review program. Paragraph (f) of this section authorizes certain special procedures that will apply in connection with such services and such review activities.

(2) *Services not covered by the DRG-based payment system.* In implementing the quality and utilization review program in the context of services not covered by the DRG-based payment system, the Director, OCHAMPUS may establish procedures, appropriate to the types of services being reviewed, substantively comparable to services covered by the DRG-based payment system regarding obligations of providers to cooperate in the quality and utilization review program, authority to require appropriate corrective actions and other procedures. The Director, OCHAMPUS may also establish such special, substantively comparable procedures in connection with review of health care services which, although covered by the DRG-based payment method, are also affected by some other special circumstances concerning payment method, nature of care, or other potential utilization or quality issue.

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(3) *Peer review activities by contractors also performing other administration or management functions--*

(i) *Sole-function PRO versus multi-function PRO.* In all cases, peer review activities under the Quality and Utilization Review Peer Review Organization program are carried out by physicians and other qualified health care professionals, usually under contract with OCHAMPUS. In some cases, the Peer Review Organization contractor's only functions are pursuant to the quality and utilization review program. In paragraph (f)(3) of this section, this type of contractor is referred to as a "sole function PRO." In other cases, the Peer Review Organization contractor is also performing other functions in connection with the administration and management of CHAMPUS. In paragraph (f)(3) of this section, this type of contractor is referred to as a "multi-function PRO." As an example of the latter type, managed care contractors may perform a wide range of functions regarding management of the delivery and financing of health care services under CHAMPUS, including but not limited to functions under the Quality and Utilization Review Peer Review Organization program.

(ii) *Special rules and procedures.* With respect to multi-function PROs, the Director, OCHAMPUS may establish special procedures to assure the independence of the Quality and Utilization Review Peer Review Organization program and otherwise advance the objectives of the program. These special rules and procedures include, but are not limited to, the following:

(A) A reconsidered determination that would be final in cases involving sole-function PROs under paragraph (i)(2) of this section will not be final in connection with multi-function PROs. Rather, in such cases (other than any case which is appealable under paragraph (i)(3) of this section), an opportunity for a second reconsideration shall be provided. The second reconsideration will be provided by OCHAMPUS or another contractor independent of the multi-function PRO that performed the review. The second reconsideration may not be further appealed by the provider.

(B) Procedures established by paragraphs (g) through (m) of this section shall not apply to any action of a multi-function PRO (or employee or other person or entity affiliated with the PRO) carried out in performance of functions other than functions under this section.

(g) Procedures regarding initial determinations. The CHAMPUS PROs shall establish and follow procedures for initial determinations that are substantively the same or comparable to the procedures applicable to Medicare under 42 CFR 466.83 to 466.104. In addition, these procedures shall provide that a PRO's determination that an admission is medically necessary is not a guarantee of payment by CHAMPUS; normal CHAMPUS benefit and procedural coverage requirements must also be applied.

(h) Procedures regarding reconsiderations. The CHAMPUS PROs shall establish and follow procedures for reconsiderations that are substantively the same or comparable to the procedures applicable to reconsiderations under Medicare pursuant to 42 CFR 473.15 to 473.34, except that the time limit for requesting reconsideration (see 42 CFR 473.20(a)(1)) shall be 90 days. A PRO reconsidered determination is final and binding upon all parties to the reconsideration except to the extent of any further appeal pursuant to paragraph (i) of this section.

(i) Appeals and hearings. (1) Beneficiaries may appeal a PRO reconsideration determination of OCHAMPUS and obtain a hearing on such appeal to the extent allowed and under the procedures set forth in Sec. 199.10(d).

(2) Except as provided in paragraph (i)(3), a PRO reconsidered determination may not be further appealed by a provider.

(3) A provider may appeal a PRO reconsideration determination to OCHAMPUS and obtain a hearing

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on such appeal to the extent allowed under the procedures set forth in Sec. 199.10(d) if it is a determination pursuant to Sec. 199.4(h) that the provider knew or could reasonably have been expected to know that the services were excludable.

(4) For purposes of the hearing process, a PRO reconsidered determination shall be considered as the procedural equivalent of a formal review determination under Sec. 199.10, unless revised at the initiative of the Director, OCHAMPUS prior to a hearing on the appeal, in which case the revised determination shall be considered as the procedural equivalent of a formal review determination under Sec. 199.10.

(5) The provisions of Sec. 199.10(e) concerning final action shall apply to hearings cases.

(j) Acquisition, protection and disclosure of peer review information. The provisions of 42 CFR part 476, except Sec. 476.108, shall be applicable to the CHAMPUS PRO program as they are to the Medicare PRO program.

(k) Limited immunity from liability for participants in PRO program. The provisions of section 1157 of the Social Security Act (42 U.S.C. 1320c-6) are applicable to the CHAMPUS PRO program in the same manner as they apply to the Medicare PRO program. Section 1102(g) of title 10, United States Code also applies to the CHAMPUS PRO program.

(l) Additional provision regarding confidentiality of records--(1) *General rule.* The provisions of 10 U.S.C. 1102 regarding the confidentiality of medical quality assurance records shall apply to the activities of the CHAMPUS PRO program as they do to the activities of the external civilian PRO program that reviews medical care provided in military hospitals.

(2) *Specific applications.* (i) Records concerning PRO deliberations are generally nondisclosable quality assurance records under 10 U.S.C. 1102.

(ii) Initial denial determinations by PROs pursuant to paragraph (g) of this section (concerning medical necessity determinations, DRG validation actions, etc.) and subsequent decisions regarding those determinations are not nondisclosable quality assurance records under 10 U.S.C. 1102.

(iii) Information the subject of mandatory PRO disclosure under 42 CFR part 476 is not a nondisclosable quality assurance record under 10 U.S.C. 1102.

(m) Obligations, sanctions and procedures. (1) The provisions of 42 CFR 1004.1-1004.80 shall apply to the CHAMPUS PRO program as they do the Medicare PRO program, except that the functions specified in those sections for the Office of Inspector General of the Department of Health and Human Services shall be the responsibility of OCHAMPUS.

(2) The provisions of 42 U.S.C. section 1395ww(f)(2) concerning circumvention by any hospital of the applicable payment methods for inpatient services shall apply to CHAMPUS payment methods as they do to Medicare payment methods.

(3) The Director, or a designee, of CHAMPUS shall determine whether to impose a sanction pursuant to paragraphs (m)(1) and (m)(2) of this section. Providers may appeal adverse sanctions decisions under the procedures set forth in Sec. 199.10(d).

(n) Authority to integrate CHAMPUS PRO and military medical treatment facility utilization

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review activities. (1) In the case of a military medical treatment facility (MTF) that has established utilization review requirements similar to those under the CHAMPUS PRO program, the contractor carrying out this function may, at the request of the MTF, utilize procedures comparable to the CHAMPUS PRO program procedures to render determinations or recommendations with respect to utilization review requirements.

(2) In any case in which such a contractor has comparable responsibility and authority regarding utilization review in both an MTF (or MTFs) and CHAMPUS, determinations as to medical necessity in connection with services from an MTF or CHAMPUS-authorized provider may be consolidated.

(3) In any case in which an MTF reserves authority to separate an MTF determination on medical necessity from a CHAMPUS PRO program determination on medical necessity, the MTF determination is not binding on CHAMPUS.

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