

**§ 476.80 Coordination with Medicare fiscal intermediaries and carriers.**

(a) *Procedures for agreements.* The Medicare fiscal intermediary or carrier must have a written agreement with the PRO. The PRO must take the initiative with the fiscal intermediary or carrier in developing the agreement. The following steps must be taken in developing the agreement.

(1) The PRO and the fiscal intermediary or carrier must negotiate in good faith in an effort to reach written agreement. If they cannot reach agreement, HCFA will assist them in resolving matters in dispute.

(2) The PRO must incorporate its administrative procedures into an agreement with the fiscal intermediary or carrier and obtain approval from HCFA, before it makes conclusive determinations for the Medicare program, unless HCFA finds that the fiscal intermediary or carrier has—

- (i) Refused to negotiate in good faith or in a timely manner, or
- (ii) Insisted on including in the agreement, provisions that are outside the scope of its authority under the Act.

(b) *Content of agreement.* The agreement must include procedures for—

(1) Informing the appropriate Medicare fiscal intermediaries and carriers of—

- (i) Changes as a result of DRG validations and revisions as a result of the review of these changes; and
- (ii) Initial denial determinations and revisions of these determinations as a result of reconsideration, or reopening all approvals and denials with respect to cases subject to preadmission review, and outlier claims in hospitals under a prospective payment system for health care services and items;

(2) Exchanging data or information;

(3) Modifying the procedures when additional review responsibility is authorized by HCFA; and

(4) Any other matters that are necessary for the coordination of functions.

(c) *Action by HCFA.* (1) Within the time specified in its contract, the PRO must submit to HCFA for approval its agreement with the Medicare fiscal intermediaries and carriers, or if an agreement has not been established,

the PRO's proposed administrative procedures, including any comments by the Medicare fiscal intermediaries and carriers.

(2) If HCFA approves the agreement or the administrative procedures (after a finding by HCFA as specified in paragraph (a)(2) of this section), the PRO may begin to make determinations under its contract with HCFA.

(3) If HCFA disapproves the agreement or procedures, it will—

(i) Notify the PRO and the appropriate fiscal agents in writing, stating the reasons for disapproval; and

(ii) Require the PRO and fiscal intermediary or carrier to revise its agreements or procedures.

(d) *Modification of agreements.* Agreements or procedures may be modified, with HCFA's approval—

(1) Through a revised agreement with the fiscal intermediary or carrier, or

(2) In the case of procedures, by the PRO, after providing opportunity for comment by the fiscal intermediary or carrier.

(e) *Role of the fiscal intermediary.* (1) The fiscal intermediary will not pay any claims for those cases which are subject to preadmission review by the PRO, until it receives notice that the PRO has approved the admission after preadmission or retrospective review.

(2) A PRO's determination that an admission is medically necessary is not a guarantee of payment by the fiscal intermediary. Medicare coverage requirements must also be applied.

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**§ 476.82 Continuation of functions not assumed by PROs.**

Any of the duties and functions under Part B of Title XI of the Act for which a PRO has not assumed responsibility under its contract with HCFA must be performed in the manner and to the extent otherwise provided for under the Act or in regulations.

PRO REVIEW FUNCTIONS

**§ 476.83 Initial denial determinations.**

A determination by a PRO that the health care services furnished or proposed to be furnished to a patient are

not medically necessary, are not reasonable, or are not at the appropriate level of care, is an initial denial determination and is appealable under part 473 of this chapter.

**§ 476.84 Changes as a result of DRG validation.**

A provider or practitioner may obtain a review by a PRO under part 473 of this chapter for changes in diagnostic and procedural coding that resulted in a change in DRG assignment as a result of PRO validation activities.

**§ 476.85 Conclusive effect of PRO initial denial determinations and changes as a result of DRG validations.**

A PRO initial denial determination or change as a result of DRG validation is final and binding unless, in accordance with the procedures in part 473—

- (a) The initial denial determination is reconsidered and revised; or
- (b) The change as a result of DRG validation is reviewed and revised.

**§ 476.86 Correlation of Title XI functions with Title XVIII functions.**

(a) *Payment determinations.* (1) PRO initial denial determinations under this part with regard to the reasonableness, medical necessity, and appropriateness of placement at an acute level of patient care as are also conclusive for payment purposes with regard to the following medical issues:

- (i) Whether inpatient care furnished in a psychiatric hospital meets the requirements of § 424.14 of this chapter.
- (ii) Whether payment for inpatient hospital or SNF care beyond 20 consecutive days is precluded under § 489.50 of this chapter because of failure to perform review of long-stay cases.
- (iii) Whether the care furnished was custodial care or care not reasonable and necessary and, as such, excluded under § 405.310(g) or § 405.310(k) of this chapter.

(iv) Whether the care was appropriately furnished in the inpatient or outpatient setting.

(2) Reviews with respect to determinations listed in paragraph (a)(1) of this section must not be conducted, for purposes of payment, by Medicare fis-

cal intermediaries or carriers except as outlined in paragraph (c) of this section.

(3) PROs make determinations as to the appropriateness of the location in which procedures are performed. A procedure may be medically necessary but denied if the PRO determines that it could, consistent with the provision of appropriate medical care, be effectively provided more economically on an outpatient basis or in an inpatient health care facility of a different type.

(4) PRO determinations as to whether the provider and the beneficiary knew or could reasonably be expected to have known that the services described in paragraph (a)(1) of this section were excluded are also conclusive for payment purposes.

(b) *Utilization review activities.* PRO review activities to determine whether inpatient hospital or SNF care services are reasonable and medically necessary and are furnished at the appropriate level of care fulfill the utilization review requirements set forth in §§ 405.1035, 405.1042, and 405.1137 of this chapter.

(c) *Coverage.* Nothing in paragraphs (a) (1) and (3) of this section will be construed as precluding HCFA or a Medicare fiscal intermediary or carrier, in the proper exercise of its duties and functions, from reviewing claims to determine:

(1) In the case of items or services not reviewed by a PRO, whether they meet coverage requirements of Title XVIII relating to medical necessity, reasonableness, or appropriateness of placement at an acute level of patient care. However, if a coverage determination pertains to medical necessity, reasonableness, or appropriateness of placement at an acute level of patient care, the fiscal intermediary or carrier must use a PRO to make a determination on those issues if a PRO is conducting review in the area and must abide by the PRO's determination.

(2) Whether any claim meets coverage requirements of Title XVIII relating to issues other than medical necessity, reasonableness or appropriateness of placement at an acute level of patient care.