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objectives and perform the utilization and quality review functions established under section 1154 of the Social Security Act in an efficient and effective manner.

(b) HCFA will determine that the organization is capable of conducting utilization and quality review if—

(1) The organization's proposed review system is adequate; and

(2) The organization has available sufficient resources (including access to medical review skills) to implement that system; and

(3) The organization's quantifiable objectives are acceptable.

(c) HCFA may consider prior similar review experience in making determinations under paragraph (b) of this section.

(d) A State government that operates a Medicaid program will be considered incapable of performing utilization and quality review functions in an effective manner, unless the State demonstrates to the satisfaction of HCFA that it will act with complete independence and objectivity.

§ 462.105 Prohibition against contracting with health care facilities.

(a) *Basic rule.* Except as permitted under paragraph (b) of this section, the following are not eligible for PRO contracts:

(1) A health care facility in the PRO area.

(2) An association of health care facilities in the PRO area.

(3) A health care facility affiliate; that is, an organization in which more than 20 percent of the members of the governing body are also either a governing body member, officer, partner, five percent or more owner, or managing employee in a health care facility or association of health care facilities in the PRO area.

(b) *Exceptions.* Effective November 15, 1984, the prohibition stated in paragraph (a) of this section will not apply to a payor organization if HCFA determines under § 462.106 that there is no other eligible organization available.

(c) *Subcontracting.* A PRO must not subcontract with a facility to conduct any review activities except for the review of the quality of care.

[50 FR 15328, Apr. 17, 1985]

§ 462.106 Prohibition against contracting with payor organizations.

Payor organizations are not eligible to become PROs for the area in which they make payments until November 15, 1984. If no PRO contract for an area is awarded before November 15, 1984, a payor organization will be determined eligible by HCFA, if an eligible organization that is not a payor organization is unavailable at that time. HCFA may determine the unavailability of nonpayor organizations based on the lack of response to an appropriate Request for Proposal.

[50 FR 15328, Apr. 17, 1985]

§ 462.107 PRO contract award.

HCFA, in awarding PRO contracts, will take the following actions—

(a) Identify from among all proposals submitted in response to an RFP for a given PRO area all proposals submitted by organizations that meet the requirements of § 462.102 or § 462.103;

(b) Identify from among all proposals identified in paragraph (a) of this section all proposals that set forth minimally acceptable plans in accordance with the requirements of § 462.104 and the RFPs;

(c) Assign bonus points not to exceed 10% of the total points available to all physician-sponsored organizations identified in paragraph (b) of this section, consistent with statute; and

(d) Subject to the limitations established by §§ 462.105 and 462.106, award the contract for the given PRO area to the selected organization for a period of two years.

[49 FR 7207, Feb. 27, 1984. Redesignated and amended at 50 FR 15327, 15328, Apr. 17, 1985]

PART 466—UTILIZATION AND QUALITY CONTROL REVIEW

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 44 FR 32081, June 4, 1979, unless otherwise noted.

Subpart A—General Provisions

§ 466.1 Definitions.

As used in this part, unless the context indicates otherwise:

Active staff privileges means: (a) That a physician is authorized on a regular, rather than infrequent or courtesy, basis: (1) to order the admission of patients to a facility; (2) to perform diagnostic services in a facility; or (3) to care for and treat patients in a facility; or (b) that a health care practitioner other than a physician is authorized on a regular, rather than infrequent or courtesy, basis to order the admission of patients to a facility.

Admission review means a review and determination by a PRO of the medical necessity and appropriateness of a patient's admission to a specific facility.

Continued stay review means PRO review that is performed after admission review and during a patient's hospitalization to determine the medical necessity and appropriateness of continuing the patient's stay at a hospital level of care.

Criteria means predetermined elements of health care, developed by health professionals relying on professional expertise, prior experience, and the professional literature, with which aspects of the quality, medical necessity, and appropriateness of a health care service may be compared.

Diagnosis related group (DRG) means a system for classifying inpatient hospital discharges. DRGs are used for purposes of determining payment to hospitals for inpatient hospital services under the Medicare prospective payment system.

DRG validation means a part of the prospective payment system in which a PRO validates that DRG assignments are based on the correct diagnostic and procedural information.

Elective, when applied to admission or to a health care service, means an admission or a service that can be delayed without substantial risk to the health of the individual.

Five percent or more owner means a person (including, where appropriate, a corporation) who:

(a) Has an ownership interest of 5 percent or more;

(b) Has an indirect ownership interest equal to 5 percent or more;

(c) Has a combination of direct and indirect ownership interests (the possession of equity in the capital, the stock, or the profits of an entity) equal to five percent or more; or

(d) Is the owner of an interest of five percent or more in any obligation secured by an entity, if the interest equals at least five percent of the value of the property or assets of the entity.

Health care facility or *facility* means an organization involved in the delivery of health care services for which reimbursement may be made in whole or in part under Title XVIII of the Act.

Health care practitioners other than physicians means those health professionals who do not hold a doctor of medicine or doctor of osteopathy degree, who meet all applicable State or Federal requirements for practice of their professions, and who are in active practice.

Hospital means a health care institution or distinct part of a health care institution, as defined in Section 1861(e)–(g) of the Act, other than a Christian Science sanatorium operated, or listed and certified, by the First Church of Christ, Scientist, Boston, Massachusetts.

Initial denial determination means an initial negative decision by a PRO, regarding the medical necessity, quality, or appropriateness of health care services furnished, or proposed to be furnished, to a patient.

Major clinical area means medicine, surgery, pediatrics, obstetrics and gynecology, or psychiatry.

Major procedure means a diagnostic or therapeutic procedure which involves a surgical or anesthetic risk or requires highly trained personnel or special facilities or equipment.

Non-facility organization means a corporate entity that (1) is not a health care facility; (2) is not a 5 percent or more owner of a facility; and (3) is not owned by one or more health care facilities or association of facilities in the PRO area.

Norm means a pattern of performance in the delivery of health care services that is typical for a specified group.

Norms means numerical or statistical measures of average observed performance in the delivery of health care services.

Outliers means those cases that have either an extremely long length of stay or extraordinarily high costs when compared to most discharges classified in the same DRG.

Peer review means review by health care practitioners of services ordered or furnished by other practitioners in the same professional field.

Physician means a doctor of medicine or osteopathy or another individual who is authorized under State or Federal law to practice medicine and surgery, or osteopathy. This includes medical officers in American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands.

Practitioner means an individual credentialed within a recognized health care discipline and involved in providing the services of that discipline to patients.

Preadmission certification means a favorable determination, transmitted to the hospital and the fiscal intermediary, approving the patient's admission for payment purposes.

Preadmission review means review prior to a patient's admission to a hospital to determine, for payment purposes, the reasonableness, medical necessity and appropriateness of placement at an acute level of care.

Preprocedure review means review of a surgical or other invasive procedure prior to the conduct of the procedure.

PRO review means review performed in fulfillment of a contract with HCFA, either by the PRO or its subcontractors.

Profile means aggregated data in formats that display patterns of health care services over a defined period of time.

Profile analysis means review and analysis of profiles to identify and consider patterns of health care services.

Quality review study means an assessment conducted by or for a PRO of a patient care problem for the purpose of improving patient care through peer analysis, intervention, resolution of the problem and follow-up.

Regional norms, criteria, and standards means norms, criteria, and standards that apply to a geographic division which is larger than a PRO area.

Retrospective review means review that is conducted after services are provided to a patient. The review is focused on determining the appropriateness, necessity, quality, and reasonableness of health care services provided.

Review responsibility means (1) the responsibility of the PRO to perform review functions prescribed under Part B of Title XI of the Act and the Social Security Amendments of 1983 (Pub. L. No. 98–21) and the regulations of this part; (2) the responsibility to fulfill the terms and meet the objectives set forth in the negotiated contract between HCFA and the PRO; and (3) the authority of a PRO to make conclusive initial denial determinations regarding the medical necessity and appropriateness of health care and changes as a result of DRG validations.

Skilled nursing facility (SNF) means a health care institution or distinct part of an institution that (a) is primarily engaged in providing skilled nursing care or rehabilitative services to injured, disabled, or sick persons, and (b) has an agreement to participate in Medicare or Medicaid or both, and (c) is not a Christian Science sanatorium operated or listed and certified by the First Church of Christ Scientist, Boston, Massachusetts.

Standards means professionally developed expressions of the range of acceptable variation from a norm or criterion.

Subcontractor means a facility or a non-facility organization under contract with a PRO to perform PRO review functions.

Working day means any one of at least five days of each week (excluding, at the option of each PRO, legal holidays) on which the necessary personnel are available to perform review.

[44 FR 32081, June 4, 1979, as amended at 45 FR 67545, Oct. 10, 1980; 46 FR 48569, Oct. 1, 1981. Redesignated and amended at 50 FR 15328, 15329, Apr. 17, 1985; 51 FR 43197, Dec. 1, 1986]

Subpart B [Reserved]

Subpart C—Review Responsibilities of Utilization and Quality Control Peer Review Organizations (PROs)

SOURCE: 50 FR 15330, Apr. 17, 1985, unless otherwise noted.

GENERAL PROVISIONS

§ 466.70 Statutory bases and applicability.

(a) *Statutory basis.* Sections 1154, 1866(a)(1)(F) and 1886(f)(2) of the Act require that a PRO review those services furnished by physicians, other health care professionals, providers and suppliers as specified in its contract with the Secretary. Section 1154(a)(4) of the Act requires PROs, or, in certain circumstances, non-PRO entities, to perform quality of care reviews of services furnished under risk-basis contracts by health maintenance organizations (HMOs) and competitive medical plans (CMPs) that are covered under subpart C of part 417 of this chapter.

(b) *Applicability.* The regulations in this subpart apply to review conducted by a PRO and its subcontractors. Section 466.72 of this part also applies, for purposes of quality of care reviews under section 1154(a)(4) of the Act, to non-PRO entities that enter into contracts to perform reviews of services furnished under risk-basis contracts by HMOs and CMPs under subpart C of part 417 of this chapter.

[52 FR 37457, Oct. 7, 1987]

§ 466.71 PRO review requirements.

(a) *Scope of PRO review.* In its review, the PRO must determine (in accordance with the terms of its contract)—

(1) Whether the services are or were reasonable and medically necessary for the diagnosis and treatment of illness or injury or to improve functioning of a malformed body member, or (with respect to pneumococcal vaccine) for prevention of illness or (in the case of hospice care) for the palliation and management of terminal illness;

(2) Whether the quality of the services meets professionally recognized standards of health care;

(3) Whether those services furnished or proposed to be furnished on an inpatient basis could, consistent with the provisions of appropriate medical care, be effectively furnished more economically on an outpatient basis or in an inpatient health care facility of a different type;

(4) Through DRG validation, the validity of diagnostic and procedural information supplied by the hospital;

(5) The completeness, adequacy and quality of hospital care provided;

(6) The medical necessity, reasonableness and appropriateness of hospital admissions and discharges;

(7) The medical necessity, reasonableness and appropriateness of inpatient hospital care for which additional payment is sought under the outlier provisions of §§ 412.82 and 412.84 of this chapter; and

(8) Whether a hospital has misrepresented admission or discharge information or has taken an action that results in—

(i) The unnecessary admission of an individual entitled to benefits under part A;

(ii) Unnecessary multiple admissions of an individual; or

(iii) Other inappropriate medical or other practices with respect to beneficiaries or billing for services furnished to beneficiaries.

(b) *Payment determinations.* On the basis of the review specified under paragraphs (a) (1), (3), (6), (7), and (8) of this section, the PRO must determine whether payment may be made for these services. A PRO may grant a period of not more than two days (grace days) for the purpose of arranging post discharge care when the provider did not know or could not reasonably be expected to have known that payment for the service(s) would not be made under the Medicare program as specified in § 405.330(b).

(c) *Other duties and functions.* (1) The PRO must review at least a random sample of hospital discharges each quarter and submit new diagnostic and procedural information to the Medicare fiscal intermediary or carrier if it determines that the information submitted by the hospital was incorrect.

(2) As directed by HCFA, the PRO must review changes in DRG assignment made by the intermediary under the provisions of § 412.60(d) that result in the assignment of a higher-weighted DRG. The PRO's review must verify that the diagnostic and procedural information supplied by the hospital is substantiated by the information in the medical record.

(d) *Coordination of sanction activities.* The PRO must carry out the responsibilities specified in subpart C of part 1004 of this title regarding imposition of sanctions on providers and practitioners who violate their statutory obligations under section 1156 of the Act.

[52 FR 37457, Oct. 7, 1987; 52 FR 47003, Dec. 11, 1987, as amended at 59 FR 45402, Sept. 1, 1994]

§ 466.72 Review of the quality of care of risk-basis health maintenance organizations and competitive medical plans.

(a) (1) For purposes of a review under section 1154(a)(4) of the Act, a PRO must determine whether the quality of services (including both inpatient and outpatient services) provided by an HMO or CMP meets professionally recognized standards of health care, including whether appropriate health care services have not been provided or have been provided in inappropriate settings.

(2) Paragraph (a)(1) of this section will not apply with respect to a contract year if another entity has been awarded a contract to perform those reviews under section 1154(a)(4)(C) of the Act.

(b) For purposes of reviews under this section, non-PRO entities selected to perform these reviews under section 1154(a)(4)(C) of the Act are subject to the requirements of paragraph (a)(1) of this section and—

(1) Part 476 of this chapter regarding acquisition, protection, and disclosure of peer review information; and

(2) Part 1004 of Chapter V regarding a PRO's responsibilities, and sanctions on health care practitioners and providers.

[52 FR 37457, Oct. 7, 1987]

§ 466.73 Notification of PRO designation and implementation of review.

(a) *Notice of HCFA's decision.* HCFA sends written notification of a PRO contract award to the State survey agency and Medicare fiscal intermediaries and carriers. The notification includes the effective dates of the PRO contract and specifies the area and types of health care facilities to be reviewed by the PRO. The PRO must make a similar notification when review responsibilities are subcontracted.

(b) *Notification to health care facilities and the public.* As specified in its contract with HCFA, the PRO must—

(1) Provide, to each health care facility scheduled to come under review, a timely written notice that specifies the date and manner in which the PRO proposes to implement review, and the information to be furnished by the facility to each Medicare beneficiary upon admission as specified in § 466.78(b)(3) of this part.

(2) Publish, in at least one local newspaper of general circulation in the PRO area, a notice that states the date the PRO will assume review responsibilities and lists each area health care facility to be under review. The PRO must indicate that its plan for the review of health care services as approved in its contract with HCFA is available for public inspection in the PRO's business office and give the address, telephone number and usual hours of business.

[50 FR 15330, Apr. 17, 1985. Redesignated at 52 FR 37457, Oct. 7, 1987]

§ 466.74 General requirements for the assumption of review.

(a) A PRO must assume review responsibility in accordance with the schedule, functions and negotiated objectives specified in its contract with HCFA.

(b) A PRO must notify the appropriate Medicare fiscal intermediary or carrier of its assumption of review in specific health care facilities no later than five working days after the day that review is assumed in the facility.

(c) A PRO must maintain and make available for public inspection at its principal business office—

(1) A copy of each agreement with Medicare fiscal intermediaries and carriers;

(2) A copy of its currently approved review plan that includes the PRO's method for implementing review; and

(3) Copies of all subcontracts for the conduct of review.

(d) A PRO must not subcontract with a facility to conduct any review activities except for the review of the quality of care. The PRO may subcontract with a non-facility organization to conduct review in a facility.

(e) If required by HCFA, a PRO is responsible for compiling statistics based on the criteria contained in § 405.332 of this chapter and making limitation of liability determinations on excluded coverage of certain services that are made under section 1879 of the Act. If required by HCFA, PROs must also notify a provider of these determinations. These determinations and further appeals are governed by the reconsideration and appeals procedures in part 405, subpart G of this chapter for Medicare Part A related determinations and part 405, subpart H of this chapter for Medicare Part B related determinations.

(f) A PRO must make its responsibilities under its contract with HCFA, primary to all other interests and activities that the PRO undertakes.

§ 466.76 Cooperation with health care facilities.

Before implementation of review, a PRO must make a good faith effort to discuss the PRO's administrative and review procedures with each involved health care facility.

§ 466.78 Responsibilities of health care facilities.

(a) Every hospital seeking payment for services furnished to Medicare beneficiaries must maintain a written agreement with a PRO operating in the area in which the hospital is located. These agreements must provide for the PRO review specified in § 466.71.

(b) *Cooperation with PROs.* Health care facilities that submit Medicare claims must cooperate in the assumption and conduct of PRO review. Facilities must—

(1) Allocate adequate space to the PRO for its conduct of review at the times the PRO is conducting review.

(2) Provide patient care data and other pertinent data to the PRO at the time the PRO is collecting review information that is required for the PRO to make its determinations. The facility must photocopy and deliver to the PRO all required information within 30 days of a request. PROs pay hospitals paid under the prospective payment system for the costs of photocopying

records requested by the PRO in accordance with the payment rate determined under the methodology described in paragraph (c) of this section and for first class postage for mailing the records to the PRO. When the PRO does post-admission, preprocedure review, the facility must provide the necessary information before the procedure is performed, unless it must be performed on an emergency basis.

(3) Inform Medicare beneficiaries at the time of admission, in writing, that the care for which Medicare payment is sought will be subject to PRO review and indicate the potential outcomes of that review. Furnishing this information to the patient does not constitute notice, under § 405.332(a) of this chapter, that can support a finding that the beneficiary knew the services were not covered.

(4) When the facility has issued a written determination in accordance with § 412.42(c)(3) of this chapter that a beneficiary no longer requries inpatient hospital care, it must submit a copy of its determination to the PRO within 3 working days.

(5) Assure, in accordance with the provisions of its agreement with the PRO, that each case subject to preadmission review has been reviewed and approved by the PRO before admission to the hospital or a timely request has been made for PRO review.

(6)(i) Agree to accept financial liability for any admission subject to preadmission review that was not reviewed by the PRO and is subsequently determined to be inappropriate or not medically necessary.

(ii) The provisions of paragraph (b)(6)(i) of this section do not apply if a facility, in accordance with its agreement with a PRO, makes a timely request for preadmission review and the PRO does not review the case timely. Cases of this type are subject to retrospective prepayment review under paragraph (b)(7) of this section.

(7) Agree that, if the hospital admits a case subject to preadmission review without certification, the case must receive retrospective prepayment review, according to the review priority established by the PRO.

(c) *Photocopying reimbursement methodology for prospective payment system hospitals.* Hospitals subject to the prospective payment system are paid for the photocopying costs that are directly attributable to the hospitals' responsibility to the PROs to provide photocopies of requested hospital records. The payment is in addition to payment already provided for these costs under other provisions of the Social Security Act and is based on a fixed amount per page as determined by HCFA as follows:

(1) *Step one.* HCFA adds the annual salary of a photocopy machine operator and the costs of fringe benefits as determined in accordance with the principles set forth in OMB Circular A–76.

(2) *Step two.* HCFA divides the amount determined in paragraph (c)(1) of this section by the number of pages that can be reasonably expected to be made annually by the photocopy machine operator to establish the labor cost per page.

(3) HCFA adds to the per-page labor cost determined in paragraph (c)(2) of this section the per-page costs of supplies.

(d) *Appeals.* Reimbursement for the costs of photocopying and mailing records for PRO review is an additional payment to hospitals under the prospective system, as specified in § 412.115 of this chapter. Thus, appeals concerning these costs are subject to the review process specified in part 405, subpart R of this chapter.

[50 FR 15330, Apr. 17, 1985, as amended at 57 FR 47787, Oct. 20, 1992; 59 FR 45402, Sept. 1, 1994]

§ 466.80 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.

[50 FR 15330, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985]

§ 466.82 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

§ 466.83 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.

§ 466.84 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.

§ 466.85 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.

§ 466.86 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 fiscal 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.

(d) *Payment.* Medicare fiscal intermediaries and carriers are not precluded from making payment determinations with regard to coverage determinations made under paragraph (c) of this section.

(e) *Survey, compliance and assistance activities.* PRO review and monitoring activities fulfill the requirements for compliance and assistance activities of State survey agencies under section 1864(a) with respect to sections 1861(e)(6), 1861(j)(8), 1861(j)(12), and 1861(k) of the Act, and activities required of intermediaries and carriers under §§ 421.100(d) and 421.200(f) of this chapter.

(f) *Appeals.* The requirements and procedures for PRO review of changes as a result of DRG validation and the reconsideration, hearing and judicial review of PRO initial denial determinations are set forth in part 473 of this chapter.

[50 FR 15330, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985, as amended at 53 FR 6648, Mar. 2, 1988]

§ 466.88 Examination of the operations and records of health care facilities and practitioners.

(a) *Authorization to examine records.* A facility claiming Medicare payment must permit a PRO or its subcontractor to examine its operation and records (including information on charges) that are pertinent to health care services furnished to Medicare beneficiaries and are necessary for the PRO or its subcontractor to—

(1) Perform review functions including, but not limited to—

(i) DRG validation;

(ii) Outlier review in facilities under a prospective payment system; and

(iii) Implementation of corrective action and fraud and abuse prevention activities;

(2) Evaluate cases that have been identified as deviating from the PRO norms and criteria, or standards; and

(3) Evaluate the capability of the facility to perform quality review functions under a subcontract with the PRO.

(b) *Limitations on access to records.* A PRO has access to the records of non-Medicare patients if—

(1) The records relate to review performed under a non-Medicare PRO contract and if authorized by those patients in accordance with State law; or

(2) The PRO needs the records to perform its quality review responsibilities under the Act and receives authorization from the facility or practitioner.

(c) *Conditions of examination.* When examining a facility's operation or records the PRO must—

(1) Examine only those operations and records (including information on charges) required to fulfill the purposes of paragraph (a) of this section;

(2) Cooperate with agencies responsible for other examination functions under Federal or Federally assisted programs in order to minimize duplication of effort;

(3) Conduct the examinations during reasonable hours; and

(4) Maintain in its principal office written records of the results of the examination of the facility.

§ 466.90 Lack of cooperation by a health care facility or practitioner.

(a) If a health care facility or practitioner refuses to allow a PRO to enter and perform the duties and functions required under its contract with HCFA, the PRO may—

(1) Determine that the health care facility or practitioner has failed to comply with the requirements of § 474.30(c) of this chapter and report the matter to the HHS Inspector General; or

(2) Issue initial denial determinations for those claims it is unable to review, make the determination that financial liability will be assigned to the health care facility, and report the matter to the HHS Inspector General.

(b) If a PRO provides a facility with sufficient notice and a reasonable amount of time to respond to a request for information about a claim, and if the facility does not respond in a timely manner, the PRO will deny the claim.

§ 466.93 Opportunity to discuss proposed initial denial determination and changes as a result of a DRG validation.

Before a PRO reaches an initial denial determination or makes a change as a result of a DRG validation, it must—

(a) Promptly notify the provider or supplier and the patient's attending physician (or other attending health care practitioner) of the proposed determination or DRG change; and

(b) Afford an opportunity for the provider or supplier and the physician (or other attending health care practitioner) to discuss the matter with the PRO physician advisor and to explain the nature of the patient's need for health care services, including all factors which preclude treatment of the patient as an outpatient or in an alternative level of inpatient care.

§ 466.94 Notice of PRO initial denial determination and changes as a result of a DRG validation.

(a) *Notice of initial denial determination*—(1) *Parties to be notified.* A PRO must provide written notice of an initial denial determination to—

(i) The patient, or if the patient is expected to be unable to comprehend the notice, the patient's next of kin, guardian or other representative or sponsor;

(ii) The attending physician, or other attending health care practitioner;

(iii) The facility; and

(iv) The fiscal intermediary or carrier.

(2) *Timing of the notice.* The notice must be delivered to beneficiaries in the facility or mailed to those no longer in the facility, within the following time periods—

(i) For admission, on the first working day after the initial denial determination;

(ii) For continued stay (e.g., outliers in facilities under a prospective payment system), by the first working day after the initial denial determination if the beneficiary is still in the facility, and within 3 working days if the beneficiary has been discharged;

(iii) For preprocedure review, before the procedure is performed;

(iv) For preadmission review, before admission;

(v) If identification as a Medicare program patient has been delayed, within three working days of identification;

(vi) For retrospective review, (excluding DRG validation and post procedure review), within 3 working days of the initial denial determination; and

(vii) For post-procedure review, within 3 working days of the initial denial determination.

(3) *Preadmission review.* In the case of preadmission review, the PRO must document that the patient and the facility received notice of the initial denial determination.

(b) *Notice of changes as a result of a DRG validation.* The PRO must notify the provider and practitioner of changes to procedural and diagnostic information that result in a change of DRG assignment, within 30 days of the PRO's decision.

(c) *Content of the notice.* The notice must be understandable and written in plain English and must contain—

(1) The reason for the initial denial determination or change as a result of the DRG validation;

(2) For day outliers in hospitals, the date on which the stay or services in the facility will not be approved as being reasonable and medically necessary or appropriate to the patients' health care needs;

(3) A statement informing each party or his or her representative of the right to request in accordance with the provisions of part 473, subpart B of this chapter—

(i) Review of a change resulting from DRG validation; or

(ii) Reconsideration of the initial denial determination;

(4) The locations for filing a request for reconsideration or review and the time period within which a request must be filed;

(5) A statement about who is liable for payment of the denied services under section 1879 of the Act; and

(6) A statement concerning the duties and functions of the PRO under the Act.

(d) *Notice to payers.* The PRO must provide prompt written notice of an initial denial determination or changes as a result of a DRG validation to the Medicare fiscal intermediary or carrier within the same time periods as the notices to the other parties.

(e) *Record of initial denial determination and changes as a result of a DRG validation.* (1) The PRO must document and preserve a record of all initial denial determinations and changes as a result of DRG validations for six years from the date the services in question were provided.

(2) The documentary record must include—

(i) The detailed basis for the initial denial determination or changes as a result of a DRG validation; and

(ii) A copy of the determination or change in DRG notices sent to all parties and identification of each party and the date on which the notice was mailed or delivered.

§ 466.96 Review period and reopening of initial denial determinations and changes as a result of DRG validations.

(a) *General timeframe.* A PRO or its subcontractor—

(1) Within one year of the date of the claim containing the service in question, may review and deny payment; and

(2) Within one year of the date of its decision, may reopen an initial denial determination or a change as a result of a DRG validation.

(b) *Extended timeframes.* (1) An initial denial determination or change as a result of a DRG validation may be made after one year but within four years of the date of the claim containing the service in question, if HCFA approves.

(2) A reopening of an initial denial determination or change as a result of a DRG validation may be made after one year but within four years of the date of the PRO's decision if—

(i) Additional information is received on the patient's condition;

(ii) Reviewer error occurred in interpretation or application of Medicare coverage policy or review criteria;

(iii) There is an error apparent on the face of the evidence upon which the initial denial or DRG validation was based; or

(iv) There is a clerical error in the statement of the initial denial determination or change as a result of a DRG validation.

(c) *Fraud and abuse.* (1) A PRO or its subcontractor may review and deny payment anytime there is a finding that the claim for service involves fraud or a similar abusive practice that does not support a finding of fraud.

(2) An initial denial determination or change as a result of a DRG validation may be reopened and revised anytime there is a finding that it was obtained through fraud or a similar abusive practice that does not support a finding of fraud.

§ 466.98 Reviewer qualifications and participation.

(a) *Peer review by physician.* (1) Except as provided in paragraph (a)(2) of this section, each person who makes an initial denial determination about services furnished or proposed to be furnished by a licensed doctor of medicine or osteopathy or by a doctor of dentistry must be respectively another licensed doctor of medicine or osteopathy or of dentistry with active staff privileges in one or more hospitals in the PRO area.

(2) If a PRO determines that peers are not available to make initial denial determinations, a doctor of medicine or osteopathy may make denial determinations for services ordered or performed by a doctor in any of the three specialties.

(3) For purposes of paragraph (a)(1) of this section, individuals authorized to practice medicine in American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands as ''medical officers'' may make determinations on care ordered or furnished by their peers but not on care ordered or furnished by licensed doctors of medicine or osteopathy.

(b) *Peer review by health care practitioners other than physicians.* Health care practitioners other than physicians may review services furnished by other practitioners in the same professional field.

(c) *DRG validation review.* Decisions about procedural and diagnostic information must be made by physicians. Technical coding issues must be reviewed by individuals with training and experience in ICD–9–CM coding.

(d) *Persons excluded from review.* (1) A person may not review health care services or make initial denial determinations or changes as a result of DRG validations if he or she, or a member of his or her family—

(i) Participated in developing or executing the beneficiary's treatment plan;

(ii) Is a member of the beneficiary's family; or

(iii) Is a governing body member, officer, partner, 5 percent or more owner, or managing employee in the health care facility where the services were or are to be furnished.

(2) A member of a reviewer's family is a spouse (other than a spouse who is legally separated under a decree of divorce or separate maintenance), child (including a legally adopted child), grandchild, parent, or grandparent.

§ 466.100 Use of norms and criteria.

(a) *Use of norms.* As specified in its contract, a PRO must use national, or where appropriate, regional norms in conducting review to achieve PRO contract objectives. However, with regard to determining the number of procedures selected for preadmission review, a PRO must use national admission norms.

(b) *Use of criteria.* In assessing the need for and appropriateness of an inpatient health care facility stay, a PRO must apply criteria to determine—

(1) The necessity for facility admission and continued stay (in cases of day outliers in hospitals under prospective payment);

(2) The necessity for surgery and other invasive diagnostic and therapeutic procedures; or

(3) The appropriateness of providing services at a particular health care facility or at a particular level of care. The PRO must determine whether the beneficiary requires the level of care received or whether a lower and less costly level of care would be equally effective.

(c) *Establishment of criteria and standards.* For the conduct of review a PRO must—

(1) Establish written criteria based upon typical patterns of practice in the PRO area, or use national criteria where appropriate; and

(2) Establish written criteria and standards to be used in conducting quality review studies.

(d) *Variant criteria and standards.* A PRO may establish specific criteria and standards to be applied to certain locations and facilities in the PRO area if the PRO determines that—

(1) The patterns of practice in those locations and facilities are substantially different from patterns in the remainder of the PRO area; and

(2) There is a reasonable basis for the difference which makes the variation appropriate.

§ 466.102 Involvement of health care practitioners other than physicians.

(a) *Basic requirement.* Except as provided in paragraph (b) of this section, a PRO must meet the following requirements:

(1) Consult with the peers of the practitioners who furnish the services under review if the PRO reviews care and services delivered by health care practitioners other than physicians.

(2) Assure that in determinations regarding medical necessity of services or the quality of the services they furnish, these practitioners are involved in—

(i) Developing PRO criteria and standards;

(ii) Selecting norms to be used; and

(iii) Developing review mechanisms for care furnished by their peers.

(3) Ensure that an initial denial determination or a change as a result of DRG validation of services provided by a health care practitioner other than a physician is made by a physician only after consultation with a peer of that practitioner. Initial denial determinations and changes as a result of DRG validations must be made only by a physician or dentist.

(b) *Exception.* The requirements of paragraph (a) of this section do not apply if—

(1) The PRO has been unable to obtain a roster of peer practitioners available to perform review; or

(2) The practitioners are precluded from performing review because they participated in the treatment of the patient, the patient is a relative, or the practitioners have a financial interest in the health care facility as described in § 466.98(d).

(c) *Peer involvement in quality review studies.* Practitioners must be involved in the design of quality review studies, development of criteria, and actual conduct of studies involving their peers.

(d) *Consultation with practitioners other than physicians.* To the extent practicable, a PRO must consult with nurses and other professional health care practitioners (other than physicians defined in 1861(r) (1) and (2) of the Act) and with representatives of institutional and noninstitutional providers and suppliers with respect to the PRO's responsibility for review.

[50 FR 15330, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985]

§ 466.104 Coordination of activities.

In order to achieve efficient and economical review, a PRO must coordinate its activities (including information exchanges) with the activities of—

(a) Medicare fiscal intermediaries and carriers;

(b) Other PROs; and

(c) Other public or private review organizations as may be appropriate.

PART 473—RECONSIDERATIONS AND APPEALS

Subpart A [Reserved]

Subpart B—Utilization and Quality Control Peer Review Organization (PRO) Reconsiderations and Appeals

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A [Reserved]

Subpart B—Utilization and Quality Control Peer Review Organization (PRO) Reconsiderations and Appeals

SOURCE: 50 FR 15372, Apr. 17, 1985, unless otherwise noted.

§ 473.10 Scope.

This subpart establishes the requirements and procedures for—

(a) Reconsiderations conducted by a Utilization and Quality Control Peer Review Organization (PRO) or its subcontractor of initial denial determinations concerning services furnished or proposed to be furnished under Medicare;

(b) Hearings and judicial review of reconsidered determinations; and

(c) PRO review of a change in diagnostic and procedural coding information.

[50 FR 15372, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985]

§ 473.12 Statutory basis.

(a) Under section 1154 of the Act, a PRO may make an initial determination that services furnished or proposed to be furnished are not reasonable, necessary, or delivered in the most appropriate setting.

(b) Under section 1155 of the Act, the following rules apply:

(1) A Medicare beneficiary, a provider, or an attending practitioner who is dissatisfied with an initial denial determination under paragraph (a) of this section is entitled to a reconsideration by the PRO that made that determination.

(2) The beneficiary is also entitled to the following:

(i) A hearing by an administrative law judge if $200 or more is still in controversy after a reconsidered determination.

(ii) Judicial review if $2000 or more is still in controversy after a final determination by the Department.

(c) Under section 1866(a)(1)(F) of the Act, a hospital that is reimbursed by the Medicare program must maintain an agreement with a PRO under which