§ 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.

§ 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.
§ 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 operations 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.

(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 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.

(c) Fraud and abuse. (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.

(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

Sec.
473.10 Scope.
473.12 Statutory basis.
473.14 Applicability.
473.15 PRO review of changes resulting from DRG validation.
473.16 Right to reconsideration.
473.18 Location for submitting requests for reconsideration.
473.20 Time limits for requesting reconsideration.
473.22 Good cause for late filing of a request for a reconsideration or hearing.
473.24 Opportunity for a party to obtain and submit information.
473.26 Delegation of the reconsideration function.
473.28 Qualifications of a reconsideration reviewer.
473.30 Evidence to be considered by the reconsideration reviewer.
473.32 Time limits for issuance of the reconsidered determination.
473.34 Notice of a reconsidered determination.
473.36 Record of reconsideration.
473.38 Effect of a reconsidered determination.
473.40 Beneficiary’s right to a hearing.
473.42 Submitting a request for a hearing.
473.44 Determining the amount in controversy for a hearing.
473.46 Departmental Appeals Board and judicial review.
473.48 Reopening and revision of a reconsidered determination or a hearing decision.

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

Subpart A [Reserved]