Health Care Financing Administration, HHS § 462.1

SUBCHAPTER D—PEER REVIEW ORGANIZATIONS

PART 462—PEER REVIEW ORGANIZATIONS

Subpart A—General Provisions

Sec. 462.1 Definitions.

For purposes of this part:

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 5 percent or more; or

(d) Is the owner of an interest of 5 percent or more in any obligation secured by an entity, if the interest equals at least 5 percent of the value of the property or assets of the entity.

Health care facility means an institution that directly provides or supplies health care services for which payment may be made in whole or in part under Title XVIII of the Act. A health care facility may be a hospital, skilled nursing facility, home health agency, free-standing ambulatory surgical center, or outpatient facility or any other entity which provides or supplies direct care to Medicare beneficiaries.

Managing employee means a general manager, business manager, administrator, director or other individual who exercises operational or managerial control over the entity or organization, or who, directly or indirectly, conducts the day-to-day operations of the entity or organization.

Payor organization means any organization, other than a self-insured employer, which makes payments directly or indirectly to health care practitioners or providers whose health care services are reviewed by the organization or would be reviewed by the organization if it entered into a PRO contract. “Payor organization” also means any organization which is affiliated with any entity which makes payments as described above, by virtue of the organization having two or more governing body members who are also either governing body members, officers, partners, 5 percent or more owners or managing employees in a health maintenance organization or competitive medical plan.

Physician means:

(1) A doctor of medicine or osteopathy licensed under State law to practice medicine, surgery, or osteopathy in the State in which the PRO is located;

(2) An intern, resident, or Federal Government employee authorized under State or Federal law to practice medicine, surgery, or osteopathy in the PRO area; and

(3) An individual licensed to practice medicine in American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands.

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

Subpart A—General Provisions

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Physician means:

(1) A doctor of medicine or osteopathy licensed under State law to practice medicine, surgery, or osteopathy in the State in which the PRO is located;

(2) An intern, resident, or Federal Government employee authorized under State or Federal law to practice medicine, surgery, or osteopathy in the PRO area; and

(3) An individual licensed to practice medicine in American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands.


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Subpart B—[Reserved]

Subpart C—Utilization and Quality Control Peer Review Organizations

SOURCE: 49 FR 7207, Feb. 27, 1984, unless otherwise noted. Redesignated at 50 FR 15327, Apr. 17, 1985.

§ 462.100 Scope and applicability.

This subpart implements sections 1152 and 1153(b) of the Social Security Act as amended by the Peer Review Improvement Act of 1982 (Pub. L. 97-248). It defines the types of organizations eligible to become PROs and establishes certain limitations and priorities regarding PRO contracting.

§ 462.101 Eligibility requirements for PRO contracts.

In order to be eligible for a PRO contract, an organization must—

(a) Be either a physician-sponsored organization as described in §462.102; or a physician-access organization as described in §462.103; and

(b) Demonstrate its ability to perform review as set forth in §462.104.

§ 462.102 Eligibility of physician-sponsored organizations.

(a) In order to be eligible for designation as a physician-sponsored PRO, an organization must meet the following conditions:

(1) Be composed of a substantial number of the licensed doctors of medicine and osteopathy practicing medicine or surgery in the review area and who are representative of the physicians practicing in the area.

(2) Not be a health care facility, health care facility association, or health care facility affiliate, as specified in §462.105.

(b) In order to meet the requirements of paragraph (a)(1) of this section, an organization must state and have documentation in its files showing that it is composed of at least 20 percent of the licensed doctors of medicine and osteopathy practicing medicine or surgery in the review area; or

(2) If the organization is not composed of at least 20 percent of the licensed doctors of medicine and osteopathy practicing medicine or surgery in the review area, then the organization must demonstrate in its contract proposal, through letters of support from physicians or physician organizations, or through other means, that it is representative of the area physicians.

(d) Organizations that meet the requirements in paragraph (a) of this section will receive, during the contract evaluation process, a set number of bonus points.


§ 462.103 Eligibility of physician-access organizations.

(a) In order to be eligible for designation as a physician-access PRO, an organization must meet the following conditions:

(1) Have available to it, by arrangement or otherwise, the services of a sufficient number of licensed doctors of medicine or osteopathy practicing medicine or surgery in the review area to assure adequate peer review of the services provided by the various medical specialties and subspecialties.

(2) Not be a health care facility, health care facility association, or health care facility affiliate, as specified in §462.105.

(b) An organization meets the requirements of paragraph (a)(1) of this section if it demonstrates—

(1) That it has available to it at least one physician in every generally recognized specialty; and

(2) The existence of an arrangement or arrangements with physicians under which the physicians would conduct review for the organization.

[50 FR 15328, Apr. 17, 1985]

§ 462.104 Requirements for demonstrating ability to perform review.

(a) A physician-sponsored or physician-access organization will be found capable of conducting review if HCFA...
determines that the organization is able to set quantifiable performance 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.

§ 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.

§ 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.

PART 466—UTILIZATION AND QUALITY CONTROL REVIEW

Subpart A—General Provisions

Sec. 466.1 Definitions.
Subpart B—[Reserved]

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

GENERAL PROVISIONS

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466.71 PRO review requirements.
466.72 Review of the quality of care of risk-basis health maintenance organizations and competitive medical plans.
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466.90 Lack of cooperation by a health care facility or practitioner.
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466.96 Review period and reopening of initial denial determinations and changes as a result of DRG validations.
466.98 Reviewer qualifications and participation.
466.100 Use of norms and criteria.
466.102 Involvement of health care practitioners other than physicians.
466.104 Coordination of activities.

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 a 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
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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 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
§ 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
§ 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.

(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.

§ 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.

§ 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 requires 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 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.

(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
§ 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]
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 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(l)(8), 1861(l)(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.

§ 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
§ 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 patient’s 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.
§ 466.96 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.

§ 466.98 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.

§ 466.102 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) 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.
(b) Exception. The requirements of paragraph (a) of this section do not apply if—
(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 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—

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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.


§ 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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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]

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

SOURCE: 50 F.R. 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.


§ 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:
§ 473.18 Location for submitting requests for reconsideration.

(a) Beneficiaries. Except as provided in paragraph (c) of this section concerning requests for expedited reconsideration, a beneficiary who wishes to

an intermediary, carrier or HCFA should be read to mean initial and reconsidered determinations made by a PRO.

[50 FR 15372, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985]
§ 473.20 Time limits for requesting reconsideration.

(a) Basic rules. (1) Except for a request for expedited reconsideration as provided in paragraph (c) of this section, or a late request with good cause under §473.22, a dissatisfied party must file a request for reconsideration within 60 days after receipt of the notice of the initial determination.

(2) The date of receipt of the notice of the initial determination is presumed to be five days after the date on the notice, unless there is a reasonable showing to the contrary.

(b) Late filing of request. A PRO will accept a request filed after 60 days after receipt of the notice of the initial determination if the PRO finds under the criteria set forth in §473.22 that there was good cause for the party’s failure to file a timely request.

(c) Request for expedited reconsideration. A request for an expedited reconsideration of a preadmission denial determination must be submitted directly to the PRO.

§ 473.22 Good cause for late filing of a request for a reconsideration or hearing.

(a) General Rule. In determining whether a party has good cause for not filing a request for reconsideration or hearing timely, the PRO or ALJ, respectively, must consider the following:

(1) What circumstances kept the party from making the request on time.

(2) Whether an action by the PRO misled the party.

(3) Whether the party understood the requirements of the Act as affected by amendments to the Act, other legislation, or court decisions.

(b) Examples. Examples of circumstances in which good cause may exist include, but are not limited to, the following:

(1) A party was seriously ill and was prevented from requesting a reconsideration in person, through another person, or in writing.

(2) There was a death or serious illness in a party’s immediate family.

(3) Important records were accidentally destroyed or damaged by fire or other cause.

(4) A party made a diligent effort but could not find or obtain necessary relevant information within the appropriate time period.

(5) A party requested additional information to further explain the determination within 60 days of receiving the explanation (or within 30 days for a Departmental Appeals Board hearing).

(6) The PRO gave the party incorrect or incomplete information about when and how to request a reconsideration or hearing.

(7) A party sent the request to another Government agency in good faith within the time limit, but the request did not reach an office authorized to receive the request until after the time period had expired.

(8) Other unusual or unavoidable circumstances exist that—

(i) Show that a party could not have known of the need to file timely; or

(ii) Prevented a party from filing timely.

[50 FR 15372, Apr. 17, 1985, as amended at 61 FR 32349, June 24, 1996]
§ 473.34 Notice of a reconsidered determination.

(a) Notice to parties. A written notice of a PRO reconsidered determination must contain the following:

(1) The basis for the reconsidered determination.

(2) A detailed rationale for the reconsidered determination.

(b) Notice to beneficiary. The notice to the beneficiary must include:

(1) The basis for the reconsidered determination.

(2) A detailed rationale for the reconsidered determination.

§ 473.33 Time limits for issuance of the reconsidered determination.

(a) Beneficiaries. If a beneficiary files a timely request for reconsideration of an initial denial determination, the PRO must complete its reconsidered determination and send written notice to the beneficiary within the following time limits:

(1) Within three working days after the PRO receives the request for reconsideration if—

(i) The beneficiary is still an inpatient in a hospital for the stay in question when the PRO receives the request for reconsideration; or

(ii) The initial determination relates to institutional services for which admission to the institution is sought, the initial determination was made before the patient was admitted to the institution; and a request was submitted timely for an expedited reconsideration.

(2) Within 10 working days after the PRO receives the request for reconsideration if the beneficiary is still an inpatient in a SNF for the stay in question when the PRO receives the request for reconsideration.

(3) Within 30 working days after the PRO receives the request for reconsideration if—

(i) The initial determination concerns ambulatory or noninstitutional services;

(ii) The beneficiary is no longer an inpatient in a hospital or SNF for the stay in question; or

(iii) The beneficiary does not submit a request for expedited reconsideration timely.

(b) Providers or practitioners. If the provider or practitioner files a request for reconsideration of an initial determination, the PRO must complete its reconsidered determination and send written notice to the provider or practitioner within 30 working days.

§ 473.28 Qualifications of a reconsideration reviewer.

A reconsideration reviewer must be someone who is:

(a) Qualified under § 466.98 of this chapter to make an initial determination.

(b) Not the individual who made the initial denial determination.

(c) A specialist in the type of services under review, except where meeting this requirement would compromise the effectiveness or efficiency of PRO review.

§ 473.30 Evidence to be considered by the reconsideration reviewer.

A reconsidered determination must be based on:

(a) The information that led to the initial determination;

(b) New information found in the medical records; or

(c) Additional evidence submitted by a party.

§ 473.26 Delegation of the reconsideration function.

A PRO may delegate the authority to reconsider an initial determination to a nonfacility subcontractor, including the organization that made the initial determination as a PRO subcontractor.

#### Notes

- Under § 473.34, a written notice to the beneficiary must include:
  - The basis for the reconsidered determination;
  - A detailed rationale for the reconsidered determination.

- Under § 473.33, time limits for reconsideration of initial determinations are as follows:
  - Beneficiaries:
    - Within 3 working days for certain conditions.
    - Within 10 working days for other conditions.
    - Within 30 working days for additional conditions.
  - Providers or practitioners:
    - Within 30 working days.

- The reconsideration reviewer must be qualified under § 466.98 or otherwise meet specific criteria to ensure the effectiveness and efficiency of the review process.

- Additional evidence can be submitted by a party, and new information found in medical records must be considered.

- Reconsidered determinations must be based on the information leading to the initial determination or new evidence submitted.

- The notice to the provider or practitioner must be sent within 30 working days.

- The reconsideration process is designed to provide a structured and timely evaluation of initial determinations.
§ 473.36 Record of reconsideration.

(a) PRO requirements. A PRO must maintain the record of its reconsideration until the later of the following:

(1) Four years after the date on the notice of the PRO's reconsidered determination.

(2) Completion of litigation and the passage of the time period for filing all appeals.

(b) Contents of the record. The record of the reconsideration must include:

(1) The initial determination.

(2) The basis for the initial determination.

(3) Documentation of the date of the receipt of the request for reconsideration.

(4) The detailed basis for the reconsidered determination.

(5) Evidence submitted by the parties.

(6) A copy of the notice of the reconsidered determination that was provided to the parties.

(7) Documentation of the delivery or mailing and, if appropriate, the receipt of the notice of the reconsidered determination by the parties.

(c) Confidentiality. The record of a PRO reconsideration is subject to prohibitions against disclosure of information as specified in section 1160 of the Act.

§ 473.38 Finality of a reconsidered determination.

A PRO reconsidered determination is final and binding upon all parties to the reconsideration unless—

(a) A hearing is requested in accordance with §473.40 and a final decision rendered; or

(b) The reconsidered determination is later reopened and revised in accordance with §473.48.

§ 473.40 Beneficiary's right to a hearing.

(a) Amount in controversy. If the amount in controversy is at least $200, a beneficiary (but not a provider or practitioner) who is dissatisfied with a PRO reconsidered determination may obtain a hearing by an administrative law judge (ALJ) of the Office of Hearings and Appeals of the SSA.

(b) Subject matter. A beneficiary has a right to a hearing on the following issues:

(1) Reasonableness of the services.

(2) Medical necessity of the services.

(3) Appropriateness of the setting in which the services were furnished.

(c) Governing provisions. The provisions of subpart G, Reconsiderations and Appeals under the Hospital Insurance Program, of part 405 of this chapter apply to hearings and appeals under this subpart unless they are inconsistent with specific provisions in this subpart. References in subpart G to initial and reconsidered determinations made by an intermediary, carrier, or HCFA should be read to mean initial and reconsidered determinations made by a PRO.

§ 473.42 Submitting a request for a hearing.

(a) Where to submit the written request. A beneficiary who wants to obtain a hearing under §473.40 must submit a written request to one of the following:

(1) The office of the PRO or PRO subcontractor that made the initial determination.
§ 473.48 Reopening and revision of a reconsidered determination or a hearing decision.

(a) PRO reopenings—(1) General rule. A PRO or PRO subcontractor that made a reconsidered determination, or conducted a review of a DRG change as described in §473.15, that is otherwise final, may reopen and revise the reconsidered determination or review, either on its own motion or at the request of a party, within one year from the date of the reconsidered determination or review.

(2) Extension of time limit. A PRO or PRO subcontractor may reopen and revise its reconsidered determination, or its review of a DRG change as described in §473.15, that is otherwise final, after one year but within four years of the date of the determination or review if—

(i) The PRO receives new material evidence;

(ii) The PRO erred in interpretation or application of Medicare coverage policy;

(iii) There is an error apparent on the face of the evidence upon which the reconsidered determination was based; or

(iv) There is a clerical error in the statement of the reconsidered determination.

(b) ALJ and Departmental Appeals Board Reopening—Applicable procedures. The ALJ or the Departmental Appeals Board may reopen and revise the reconsidered determination or review if—

(i) The ALJ or the Departmental Appeals Board receives new material evidence;

(ii) The ALJ or the Departmental Appeals Board erred in interpretation or application of Medicare coverage policy;

(iii) There is an error apparent on the face of the evidence upon which the reconsidered determination was based; or

(iv) There is a clerical error in the statement of the reconsidered determination.

[50 FR 32349, June 24, 1996; 51 FR 42386, Aug. 15, 1996]
Board, whichever made the final decision, may reopen and revise the decision in accordance with the procedures set forth in §405.750(b) of this chapter, which concerns reopenings and revisions under subpart G of part 405 of this chapter.

(c) Fraud or similar abusive practice. A reconsidered determination, a review of a DRG change, or a decision of an ALJ or the Departmental Appeals Board may be reopened and revised at any time, if the reconsidered determination, review, or decision was obtained through fraud or a similar abusive practice that does not support a formal finding of fraud.

[50 FR 15372, Apr. 17, 1985, as amended at 61 FR 32349, June 24, 1996]
(2) Acquisition and maintenance of information by a PRO to comply with its responsibilities under the Act.

(b) Definitions. As used in this part:

Abuse means any unlawful conduct relating to items or services for which payment is sought under Title XVIII of the Act.

Aggregate statistical data means any utilization, admission, discharge or diagnostic related group (DRG) data arrayed on a geographic, institutional or other basis in which the volume and frequency of services are shown without identifying any individual.

Confidential information means any of the following:

(1) Information that explicitly or implicitly identifies an individual patient, practitioner or reviewer.

(2) Sanction reports and recommendations.

(3) Quality review studies which identify patients, practitioners or institutions.

(4) PRO deliberations.

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

Implicitly identify(ies) means data so unique or numbers so small so that identification of an individual patient, practitioners or reviewer would be obvious.

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 in the PRO area.

Patient representative means—(1) an individual designated by the patient, in writing, as authorized to request and receive PRO information that would otherwise be disclosable to that patient; or (2) an individual identified by the PRO in accordance with §476.132(c)(3) when the beneficiary is mentally, physically or legally unable to designate a representative.

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

PRO deliberations means discussions or communications (within a PRO or between a PRO and a PRO subcontractor) including, but not limited to, review notes, minutes of meetings and any other records of discussions and judgments involving review matters regarding PRO review responsibilities and appeals from PRO determinations, in which the opinions of, or judgment about, a particular individual or institution can be discerned.

PRO information means any data or information collected, acquired or generated by a PRO in the exercise of its duties and functions under Title XI Part B or Title XVIII of the Act.

PRO interpretations and generalizations on the quality of health care means an assessment of the quality of care furnished by an individual provider or group of providers based on the PRO’s knowledge of the area gained from its medical review experience (e.g., quality review studies) and any other information obtained through the PRO’s review activities.

PRO review system means the PRO and those organizations and individuals who either assist the PRO or are directly responsible for providing medical care or for making determinations with respect to the medical necessity, appropriate level and quality of health care services that may be reimbursed under the Act. The system includes—

(1) The PRO and its officers, members and employees;

(2) PRO subcontractors;

(3) Health care institutions and practitioners whose services are reviewed;

(4) PRO reviewers and supporting staff; and

(5) Data support organizations.

Public information means information which has been disclosed to the public.

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.

Quality review study information means all documentation related to the quality review study process.

Reviewer means review coordinator, physician, or other person authorized to perform PRO review functions.
§ 476.102 Statutory bases for acquisition and maintenance of information.

(a) Section 1154(a)(7)(C) of the Act requires PROs to the extent necessary and appropriate to examine the pertinent records of any practitioner or provider of health care services for which payment may be made under Title XVIII of the Act.

(b) Section 1154(a)(9) of the Act requires PROs to collect and maintain information necessary to carry out their responsibilities under the Act.

(c) Section 1156(a)(3) of the Act requires health care practitioners and providers to maintain evidence of the medical necessity and quality of health care services they provide to Medicare patients as required by PROs.

§ 476.103 Statutory bases for disclosure of information.

(a) Section 1154(a)(10) of the Act requires PROs to exchange information with intermediaries and carriers with contracts under sections 1816 and 1842 of the Act, other PROs, and other public or private review organizations as appropriate.

(b) Section 1160 of the Act provides that PRO information must be held in confidence and not be disclosed except where—

(1) Necessary to carry out the purpose of Title XI Part B of the Act;

(2) Specifically permitted or required under this subpart;

(3) Necessary, and in the manner prescribed under this subpart, to assist Federal and State agencies recognized by the Secretary as having responsibility for identifying and investigating cases or patterns of fraud or abuse;

(4) Necessary, and in the manner prescribed under this subpart to assist Federal or State agencies recognized by the Secretary as having responsibility for identifying cases or patterns involving risks to the public health;

(5) Necessary, and in the manner prescribed under this subpart to assist appropriate State agencies having responsibility for licensing or certification of providers or practitioners; or

(6) Necessary, and in the manner prescribed under this subpart to assist Federal or State health planning agencies by furnishing them aggregate statistical data on a geographical, institutional or other basis.

§ 476.104 Procedures for disclosure by a PRO.

(a) Notice to accompany disclosure. Any disclosure of information under the authority of this subpart is subject to the requirements in §476.105 relating to the providing of a notice of the disclosure.

(b) Disclosure of confidential information made under the authority of this subpart, except as provided in §476.106, must be accompanied by a written statement informing the recipient that the information may not be redisclosed except as provided under §476.107 that limits redisclosure.

(b) PRO interpretations. A PRO may provide a statement of comment, analysis, or interpretation to guide the recipient in using information disclosed under this subpart.

(c) Fees. A PRO may charge a fee to cover the cost of providing information authorized under this subpart. These fees may not exceed the amount necessary to recover the cost to the PRO for providing the information.

(d) Format for disclosure of public information. A PRO is required to disclose public information (§476.120(a)(6)) only in the form in which it is acquired by
§ 476.105 Notice of disclosures made by a PRO.

(a) Notification of the disclosure of non-confidential information. Except as permitted under §476.106, at least 30 calendar days before disclosure of nonconfidential information, the PRO must notify an identified institution of its intent to disclose information about the institution (other than reports routinely submitted to HCFA or Medicare fiscal intermediaries, or to or from PRO subcontractors, or to or from the institution) and provide the institution with a copy of the information. The institution may submit comments to the PRO that must be attached to the information disclosed if received before disclosure, or forwarded separately if received after disclosure.

(b) Notification of the disclosure of confidential information. (1) A PRO must notify the practitioner who has treated a patient, of a request for disclosure to the patient or patient representative in accordance with the requirements and exceptions to the requirements for disclosure specified under §476.132.

(2) A PRO must notify a practitioner or institution of the PRO’s intent to disclose information on the practitioner or institution to an investigative or licensing agency (§§476.137 and 476.138) except for cases specified in §476.106 involving fraud or abuse or imminent danger to individuals or the public health. The practitioner or institution must be notified and provided a copy of the information to be disclosed at least 30 calendar days before the PRO discloses the identifying information. The PRO must forward with the information any comments submitted by the practitioner or institution in response to the PRO notice if received before disclosure, or forwarded separately if received after disclosure.

§ 476.106 Exceptions to PRO notice requirements.

(a) Imminent danger to individuals or public health. When the PRO determines that requested information is necessary to protect against an imminent danger to individuals or the public health, the notification required in §476.105 may be sent simultaneously with the disclosure.

(b) Fraud or Abuse. The notification requirement in §476.105 does not apply if—

(1) The disclosure is made in an investigation of fraud or abuse by the Office of the Inspector General or the General Accounting Office; or

(2) The disclosure is made in an investigation of fraud or abuse by any other Federal or State fraud or abuse agency and the investigative agency specifies in writing that the information is related to a potentially prosecutable criminal offense.

§ 476.107 Limitations on redisclosure.

Persons or organizations that obtain confidential PRO information must not further disclose the information to any other person or organization except—

(a) As directed by the PRO to carry out a disclosure permitted or required under a particular provision of this part;

(b) As directed by HCFA to carry out specific responsibilities of the Secretary under the Act;

(c) As necessary for HCFA to carry out its responsibilities for appeals under section 1155 of the Act or for HCFA to process sanctions under section 1156 of the Act;

(d) If the health care services furnished to an individual patient are reimbursed from more than one source, these sources of reimbursement may exchange confidential information as necessary for the payment of claims;

(e) If the information is acquired by the PRO from another source and the receiver of the information is authorized under its own authorities to acquire the information directly from the source, the receiver may disclose the information in accordance with the source’s redisclosure rules;

(f) As necessary for the General Accounting Office to carry out its statutory responsibilities.
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(g) Information pertaining to a patient or practitioner may be disclosed by that individual provided it does not identify any other patient or practitioner;

(h) An institution may disclose information pertaining to itself provided it does not identify an individual patient or practitioner;

(i) Governmental fraud or abuse agencies and State licensing or certification agencies recognized by HCFA may disclose information as necessary in a judicial, administrative or other formal legal proceeding resulting from an investigation conducted by the agency;

(j) State and local public health officials to carry out their responsibilities, as necessary, to protect against a substantial risk to the public health; or

(k) As necessary for the Office of the Inspector General to carry out its statutory responsibilities.

[50 FR 15359, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985]

§ 476.109 Penalties for unauthorized disclosure.

A person who discloses information not authorized under Title XI Part B of the Act or the regulations of this part will, upon conviction, be fined no more than $1,000, or be imprisoned for no more than six months, or both, and will pay the costs of prosecution.

§ 476.109 Applicability of other statutes and regulations.

The provisions of 42 U.S.C. 290dd-3 and 290ee-3 governing confidentiality of alcohol and drug abuse patients' records, and the implementing regulations at 42 CFR part 2, are applicable to PRO information.

[50 FR 15359, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985]

§ 476.111 PRO access to information collected for PRO purposes.

(a) Institutions and other entities must disclose to the PRO information collected by them for PRO purposes.

(b) Information collected or generated by institutions or practitioners to carry out quality review studies must be disclosed to the PRO.

§ 476.114 Limitation on data collection.

A PRO or any agent, organization, or institution acting on its behalf, that is collecting information under authority of this part, must collect only that information which is necessary to accomplish the purposes of Title XI Part B of the Act in accordance with 44 U.S.C. Chapter 35, Coordination of Federal Reporting Services Information Policy.

PRO RESPONSIBILITIES

§ 476.115 Requirements for maintaining confidentiality.

(a) Responsibilities of PRO officers and employees. The PRO must provide reasonable physical security measures to prevent unauthorized access to PRO information and to ensure the integrity of the information, including those
measures needed to secure computer files. Each PRO must instruct its officers and employees and health care institution employees participating in PRO activities of their responsibility to maintain the confidentiality of information and of the legal penalties that may be imposed for unauthorized disclosure of PRO information.

(b) Responsible individuals within the PRO. The PRO must assign a single individual the responsibility for maintaining the system for assuring the confidentiality of information within the PRO review system. That individual must notify HCFA of any violations of these regulations.

(c) Training requirements. The PRO must train participants of the PRO review system in the proper handling of confidential information.

(d) Authorized access. An individual participating in the PRO review system on a routine or ongoing basis must not have authorized access to confidential PRO information unless that individual—

(1) Has completed a training program in the handling of PRO information in accordance with paragraph (c) of this section or has received comparable training from another source; and

(2) Has signed a statement indicating that he or she is aware of the legal penalties for unauthorized disclosure.

(e) Purging of personal identifiers. (1) The PRO must purge or arrange for purging computerized information, patient records and other noncomputerized files of all personal identifiers as soon as it is determined by HCFA that those identifiers are no longer necessary.

(2) The PRO must destroy or return to the facility from which it was collected confidential information generated from computerized information, patient records and other noncomputerized files when the PRO determines that the maintenance of hard copy is no longer necessary to serve the specific purpose for which it was obtained or generated.

(f) Data system procedures. The PRO must assure that organizations and consultants providing data services to the PRO have established procedures for maintaining the confidentiality of PRO information in accordance with requirements defined by the PRO and consistent with procedures established under this part.

§476.116 Notice to individuals and institutions under review.

The PRO must establish and implement procedures to provide patients, practitioners, and institutions under review with the following information—

(a) The title and address of the person responsible for maintenance of PRO information;

(b) The types of information that will be collected and maintained;

(c) The general rules governing disclosure of PRO information; and

(d) The procedures whereby patients, practitioners, and institutions may obtain access to information about themselves.

DISCLOSURE OF NONCONFIDENTIAL INFORMATION

§476.120 Information subject to disclosure.

Subject to the procedures for disclosure and notice of disclosure specified in §§476.104 and 476.105, the PRO must disclose—

(a) Nonconfidential information to any person upon request, including—

(1) The norms, criteria, and standards it uses for initial screening of cases, and for other review activities;

(2) Winning technical proposals for contracts from the Department, and winning technical proposals for subcontracts under those contracts (except for proprietary or business information);

(3) Routine reports submitted by the PRO to HCFA to the extent that they do not contain confidential information.

(4) Routine reports submitted by the PRO to HCFA to the extent that they do not contain confidential information.

(5) Summaries of the proceedings of PRO regular and other meetings of the governing body and general membership except for those portions of the summaries involving PRO deliberations, which are confidential information and subject to the provisions of §476.139;
§ 476.121 Optional disclosure of non-confidential information.

A PRO may, on its own initiative, subject to the notification requirements in §476.105, furnish the information available under §476.120 to any person, agency, or organization.

DISCLOSURE OF CONFIDENTIAL INFORMATION

§ 476.130 Disclosure to the Department.

Except as limited by §§476.139(a) and 476.140 of this subpart, PROs must disclose all information requested by the Department to it in the manner and form required.

§ 476.131 Access to medical records for the monitoring of PROs.

HCFA or any person, organization or agency authorized by the Department or Federal statute to monitor a PRO will have access to medical records maintained by institutions or health care practitioners on Medicare patients. The monitor can require copies of the records.
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§ 476.135 Disclosure necessary to perform review responsibilities.

(a) Disclosure to conduct review. The PRO must disclose or arrange for disclosure of information to individuals and institutions within the PRO review

(b) Exceptions. (1) If the request is in connection with an initial denial determination or a change resulting from a diagnostic related group (DRG) coding validation under Part 466 of this subchapter, the PRO must provide only the information used to support that determination in accordance with the procedures for disclosure of information relating to determinations under §473.24.

(2) A PRO must disclose information regarding PRO deliberations only as specified in §476.139(a).

(3) A PRO must disclose quality review study information only as specified in §476.140.

system as necessary to fulfill their particular duties and functions under Title XI Part B of the Act.

(b) Disclosure to consultants and subcontractors. The PRO must disclose to consultants or subcontractors the information they need to provide specified services to the PRO.

(c) Disclosure to other PRO and medical review boards. The PRO must disclose—

(1) To another PRO, information on patients and practitioners who are subject to review by the other PRO; and

(2) To medical review boards established under section 1881 of the Act, confidential information on patients, practitioners and institutions receiving or furnishing end stage renal disease services.

§ 476.136 Disclosure to intermediaries and carriers.

(a) Required disclosure. Except as specified in §§ 476.139(a) and 476.140 relating to disclosure of PRO deliberations and quality review study information, a PRO must disclose to intermediaries and carriers PRO information that relates to, or is necessary for, payment of claims for Medicare as follows:

(1) Review determinations and claims forms for health care services furnished in the manner and form agreed to by the PRO and the intermediary or carrier.

(2) Upon request, copies of medical records acquired from practitioners or institutions for review purposes.

(3) PRO information about a particular patient or practitioner if the PRO and the intermediary or carrier (or HCFA if the PRO and the intermediary or carrier cannot agree) determine that the information is necessary for the administration of the Medicare program.

(b) Optional disclosure. The PRO may disclose the information specified in paragraph (a) of this section to Federal or State fraud and abuse enforcement agencies responsible for the investigation or identification of fraud or abuse of the Medicare or Medicaid programs, without a request.


§ 476.137 Disclosure to Federal and State enforcement agencies responsible for the investigation or identification of fraud or abuse of the Medicare or Medicaid programs.

(a) Required disclosure. Except as specified in §§ 476.139(a) and 476.140 relating to disclosure of PRO deliberations and quality review study information, the PRO must disclose confidential information relevant to an investigation of fraud or abuse of the Medicare or Medicaid programs, including PRO medical necessity determinations and other information that includes patterns of the practice or performance of a practitioner or institution, when a written request is received from a State or Federal enforcement agency responsible for the investigation or identification of fraud or abuse of the Medicare or Medicaid programs that—

(1) Identifies the name and title of the individual initiating the request,

(2) Identifies the physician or institution about which information is requested, and

(3) States affirmatively that the institution or practitioner is currently under investigation for fraud or abuse of the Medicare or Medicaid programs and that the information is needed in furtherance of that investigation.

(b) Optional disclosure. The PRO may provide the information specified in paragraph (a) of this section to Federal or State fraud and abuse enforcement agencies responsible for the investigation or identification of fraud or abuse of the Medicare or Medicaid programs, without a request.

§ 476.140 Disclosure of quality review study information.

(a) A PRO must disclose, onsite, quality review study information with identifiers of patients, practitioners or institutions to—

(1) Representatives of authorized licensure, accreditation or certification agencies as is required by the agencies in carrying out functions which are within the jurisdiction of such agencies under state law; to federal and state agencies responsible for identifying risks to the public health when there is substantial risk to the public health; HCFA; or to Federal and State fraud and abuse enforcement agencies;

(2) An institution or practitioner, if the information is limited to health care services furnished by the institution or practitioner; and

(3) A medical review board established under section 1881 of the Act pertaining to end-stage renal disease facilities, if the information is limited to health care services subject to its review.

(b) A PRO must disclose quality review study information with identifiers of patients, practitioners or institutions to the Office of the Inspector General and the General Accounting Office as necessary to carry out statutory responsibilities.

(c) A PRO may disclose information offsite from a particular quality review study to any institution or practitioner involved in that study, provided the disclosed information is limited to that institution or practitioner.
§ 476.141 Disclosure of PRO interpretations on the quality of health care.

Subject to the procedures for disclosure and notice of disclosure specified in §§476.104 and 476.105, a PRO may disclose to the public PRO interpretations and generalizations on the quality of health care that identify a particular institution.

§ 476.142 Disclosure of sanction reports.

(a) The PRO must disclose sanction reports directly to the Office of the Inspector General and, if requested, to HCFA.

(b) The PRO must, upon request, and may without a request, disclose sanction reports to State and Federal agencies responsible for the identification, investigation or prosecution of cases of fraud or abuse in accordance with §476.137.

§ 476.143 PRO involvement in shared health data systems.

(a) Information collected by a PRO. Except as prohibited in paragraph (b) of this section, information collected by a PRO may be processed and stored by a cooperative health statistics system established under the Public Health Service Act (42 U.S.C. 242k) or other State or Federally authorized shared data system.

(b) PRO participation. A PRO may not participate in a cooperative health statistics system or other shared health data system if the disclosure rules of the system would prevent the PRO from complying with the rules of this part.

(c) Disclosure of PRO information obtained by a shared health data system. PRO information must not be disclosed by the shared health data system unless—

(1) The source from which the PRO acquired the information consents to or requests disclosure; or

(2) The PRO requests the disclosure of the information to carry out a disclosure permitted under a provision of this part.