SUBCHAPTER F—QUALITY IMPROVEMENT ORGANIZATIONS

PART 475—QUALITY IMPROVEMENT ORGANIZATIONS

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

Subpart A—General Provisions

§ 475.1 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 QIO 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 QIO is located;

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

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

§ 475.100 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 QIOs and establishes certain limitations and priorities regarding QIO contracting.

§ 475.101 Eligibility requirements for QIO contracts.

In order to be eligible for a QIO 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.

§ 475.102 Eligibility of physician-sponsored organizations.

(a) In order to be eligible for designation as a physician-sponsored QIO, 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.

§ 475.103 Eligibility of physician-access organizations.

(a) In order to be eligible for designation as a physician-access QIO, 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) In order to meet 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.

[49 FR 7207, Feb. 27, 1984. Redesignated and amended at 50 FR 15327, 15328, Apr. 17, 1985, and further redesignated at 64 FR 66279, Nov. 24, 1999]
§ 475.104 Requirements for demonstrating ability to perform review.

(a) A physician-sponsored or physician-access organization will be found capable of conducting review if CMS 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) CMS 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) CMS 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 CMS that it will act with complete independence and objectivity.

§ 475.105 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 QIO contracts:

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

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

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

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

[50 FR 15328, Apr. 17, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999]

§ 475.106 Prohibition against contracting with payor organizations.

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

[50 FR 15328, Apr. 17, 1985]

§ 475.107 QIO contract award.

CMS, in awarding QIO contracts, will take the following actions—

(a) Identify from among all proposals submitted in response to an RFP for a given QIO area all proposals submitted by organizations that meet the requirements of §§462.102 and 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 QIO area to the selected organization for a period of two years.

[49 FR 7207, Feb. 27, 1984. Redesignated and amended at 50 FR 15327, 15328, Apr. 17, 1985, and further redesignated at 64 FR 66279, Nov. 24, 1999]
Subpart A—General Provisions

§ 476.1 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 QIO of the medical necessity and appropriateness of a patient’s admission to a specific facility.

Continued stay review means QIO 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 QIO 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.
Centers for Medicare & Medicaid Services, HHS § 476.1

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

(a) Has an ownership interest of 5 percent or more;
(b) Has an indirect ownership interest equal to 5 percent or more;
(c) Has a combination of direct and indirect ownership interests (the possession of equity in the capital, the stock, or the profits of an entity) equal to five percent or more; or
(d) Is the owner of an interest of five percent or more in any obligation secured by an entity, if the interest equals at least five percent of the value of the property or assets of the entity.

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

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

Hospital means a health care institution or distinct part of a health care institution, as defined in Section 1861(e)-(g) of the Act, other than a religious nonmedical institution as defined in §440.170(b) of this chapter.

Initial denial determination means an initial negative decision by a QIO, 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 QIO 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.

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

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 QIO of a patient care problem for the purpose of improving patient care through peer analysis, intervention, resolution of the problem and follow-up.
§ 476.70 Statutory bases and applicability.

(a) Statutory basis. Sections 1154, 1866(a)(1)(F) and 1886(f)(2) of the Act require that a QIO 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 QIOs, or, in certain circumstances, non-QIO 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 QIO 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-QIO 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.

§ 476.71 QIO review requirements.

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

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

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

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

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

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

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

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

(ii) Unnecessary multiple admissions of an individual; or

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

(b) Payment determinations. On the basis of the review specified under paragraphs (a)(1), (3), (6), (7), and (8) of this section, the QIO must determine whether payment may be made for these services. A QIO 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 QIO 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 CMS, the QIO must review changes in DRG and LTC-DRG assignments made by the intermediary under the provisions of §§ 412.60(d) and 412.513(c) of this chapter that result in the assignment of a higher-weighted DRG or a different LTC-DRG. The QIO’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 QIO 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.

§ 476.72 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 QIO must determine whether the quality of services (including both inpatient and outpatient services) provided by an HMO or CMP meets professionally recognized standards of health care, including whether appropriate health care services have not been provided or have been provided in inappropriate settings.

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

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

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

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

§ 476.73 Notification of QIO designation and implementation of review.

(a) Notice of CMS's decision. CMS sends written notification of a QIO contract award to the State survey agency and Medicare fiscal intermediaries and carriers. The notification includes the effective dates of the QIO contract and specifies the area and types of health care facilities to be reviewed by the QIO. The QIO 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 CMS, the QIO 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 QIO 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 QIO area, a notice that states the date the QIO will assume review responsibilities and lists each area health care facility to be under review. The QIO must indicate that its plan for the review of health care services as approved in its contract with CMS is available for public inspection in the QIO's business office and give the address, telephone number and usual hours of business.

§ 476.74 General requirements for the assumption of review.

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

(b) A QIO 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 QIO 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 QIO's method for implementing review; and

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

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

(e) If required by CMS, a QIO 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 CMS, QIOs 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 QIO must make its responsibilities under its contract with CMS, primary to all other interests and activities that the QIO undertakes.

§ 476.76 Cooperation with health care facilities.

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

§ 476.78 Responsibilities of health care facilities.

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

(b) Cooperation with QIOs. Health care providers that submit Medicare claims must cooperate in the assumption and conduct of QIO review. Providers must—
(1) Allocate adequate space to the QIO for its conduct of review at the times the QIO is conducting review.

(2) Provide patient care data and other pertinent data to the QIO at the time the QIO is collecting review information that is required for the QIO to make its determinations. The provider must photocopy and deliver to the QIO all required information within 30 days of a request. QIOs pay providers paid under the prospective payment system for the costs of photocopying records requested by the QIO 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 QIO. When the QIO does postadmission, 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 QIO 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 QIO within 3 working days.

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

(6)(i) Agree to accept financial liability for any admission subject to preadmission review that was not reviewed by the QIO 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 QIO, makes a timely request for preadmission review and the QIO 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 QIO.

(c) Photocopying reimbursement methodology for prospective payment system providers. Providers subject to the prospective payment system are paid for the photocopying costs that are directly attributable to the providers' responsibility to the QIOs to provide photocopies of requested provider 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 CMS as follows:

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

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

(4) CMS will periodically review the photocopy reimbursement rate to ensure that it still accurately reflects provider costs. CMS will publish any changes to the rate in a FEDERAL REGISTER notice.

(d) Appeals. Reimbursement for the costs of photocopying and mailing records for QIO review is an additional payment to providers under the prospective payment system, as specified in § 412.115, § 413.355, and § 494.265 of this chapter. Thus, appeals concerning these costs are subject to the review
§ 476.80 Coordination with Medicare fiscal intermediaries and carriers.

(a) Procedures for agreements. The Medicare fiscal intermediary or carrier must have a written agreement with the QIO. The QIO 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 QIO and the fiscal intermediary or carrier must negotiate in good faith in an effort to reach written agreement. If they cannot reach agreement, CMS will assist them in resolving matters in dispute.

(2) The QIO must incorporate its administrative procedures into an agreement with the fiscal intermediary or carrier and obtain approval from CMS, before it makes conclusive determinations for the Medicare program, unless CMS 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 CMS; and

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

(c) Action by CMS. (1) Within the time specified in its contract, the QIO must submit to CMS for approval its agreement with the Medicare fiscal intermediaries and carriers, or if an agreement has not been established, the QIO’s proposed administrative procedures, including any comments by the Medicare fiscal intermediaries and carriers.

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

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

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

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

(d) Modification of agreements. Agreements or procedures may be modified, with CMS’s approval—

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

(2) In the case of procedures, by the QIO, 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 QIO, until it receives notice that the QIO has approved the admission after preadmission or retrospective review.

(2) A QIO’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.

§ 476.82 Continuation of functions not assumed by QIOs.

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

QIO REVIEW FUNCTIONS

§ 476.83 Initial denial determinations.
A determination by a QIO that the health care services furnished or proposed to be furnished to a patient are not medically necessary, are not reasonable, or are not at the appropriate level of care, is an initial denial determination and is appealable under part 473 of this chapter.

§ 476.84 Changes as a result of DRG validation.
A provider or practitioner may obtain a review by a QIO 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 QIO validation activities.

§ 476.85 Conclusive effect of QIO initial denial determinations and changes as a result of DRG validations.
A QIO initial denial determination or change as a result of DRG validation is final and binding unless, in accordance with the procedures in part 473—
(a) The initial denial determination is reconsidered and revised; or
(b) The change as a result of DRG validation is reviewed and revised.

§ 476.86 Correlation of Title XI functions with Title XVIII functions.
(a) Payment determinations. (1) QIO 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) QIOs make determinations as to the appropriateness of the location in which procedures are performed. A procedure may be medically necessary but denied if the QIO 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) QIO 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. QIO 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 §§405.1033, 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 CMS 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 QIO, 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 QIO to make a determination on those issues if a QIO is conducting review in the area and must abide by the QIO’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. QIO review and monitoring activities fulfill the requirements for compliance and assistance activities of State survey agencies under section 1861(a) with respect to sections 1861(e)(6), 1861(j)(8), 1861(j)(12), and 1861(k) of the Act, and activities required of intermediaries and carriers under §§421.100(d) and 421.200(f) of this chapter.

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

§476.88 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 QIO or its subcontractor to examine its operation and records (including information on charges) that are pertinent to health care services furnished to Medicare beneficiaries and are necessary for the QIO 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 QIO norms and criteria, or standards; and

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

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

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

(2) The QIO 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 QIO 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.

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

(a) If a health care facility or practitioner refuses to allow a QIO to enter and perform the duties and functions required under its contract with CMS, the QIO 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 QIO 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 QIO will deny the claim.

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

Before a QIO 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 QIO 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.

§ 476.94 Notice of QIO initial denial determination and changes as a result of a DRG validation.

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

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

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

(iii) The facility; and

(iv) The fiscal intermediary or carrier.

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

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

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

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

(iv) For preadmission review, before admission;

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

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

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

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

(b) Notice of changes as a result of a DRG validation. The QIO 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 QIO’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 QIO under the Act.

(d) Notice to payers. The QIO must provide prompt written notice of an initial denial determination or changes as a result of a DRG validation to the
§ 476.96 Review period and reopening of initial denial determinations and changes as a result of DRG validations.

(a) General timeframe. A QIO 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 CMS 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 QIO’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 QIO or its subcontractor may review and deny payment anytime there is a finding that the claim for service involves fraud or a similar abusive practice that does not support a finding of fraud.

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

§ 476.98 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 QIO area.

(2) If a QIO 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 their peers but not on care ordered or furnished by licensed doctors of medicine or osteopathy.

(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.

§ 476.102 Involvement of health care practitioners other than physicians.

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

(1) Consult with the peers of the practitioners who furnish the services under review if the QIO 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 QIO 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 QIO 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.
(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 QIO 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 QIO’s responsibility for review.

§ 476.104 Coordination of activities.

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

(a) Medicare fiscal intermediaries and carriers;

(b) Other QIOs; and

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

PART 478—RECONSIDERATIONS AND APPEALS

Subpart A [Reserved]

Subpart B—Utilization and Quality Control Quality Improvement Organization (QIO) Reconsiderations and Appeals

§ 478.10 Scope.

This subpart establishes the requirements and procedures for—

(a) Reconsiderations conducted by a Utilization and Quality Control Quality Improvement Organization (QIO) 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) QIO review of a change in diagnostic and procedural coding information.

§ 478.12 Statutory basis.

(a) Under section 1154 of the Act, a QIO 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 1153 of the Act, the following rules apply:
(1) A Medicare beneficiary, a provider, or an attending practitioner who is dissatisfied with an initial denial determination under paragraph (a) of this section is entitled to a reconsideration by the QIO that made that determination.

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

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

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

(c) Under section 1866(a)(1)(F) of the Act, a hospital that is reimbursed by the Medicare program must maintain an agreement with a QIO under which the QIO reviews the validity of diagnostic information furnished by the hospital.


§ 478.14 Applicability.

(a) Basic provision. This subpart applies to reconsiderations and hearings of a QIO initial denial determination involving the following issues:

(1) Reasonableness of services.

(2) Medical necessity of services.

(3) Appropriateness of the inpatient setting in which services were furnished or are proposed to be furnished.

(b) Concurrent appeal. A reconsideration or hearing provided under this subpart fulfills the requirements of any other review, hearing, or appeal under the Act to which a party may be entitled with respect to the same issues.

(c) Nonapplicability of rules to related determinations. (1) A QIO may not reconsider its decision whether to grant grace days.

(2) Limitation of liability determinations on excluded coverage of certain services are made under section 1879 of the Act. Initial determinations under section 1879 and further appeals are governed by the reconsideration and appeal procedures in part 405, subpart G of this chapter for determinations under Medicare Part A, and part 405, subpart H of this chapter for determinations under Medicare Part B. References in those subparts to initial and reconsidered determinations made by an intermediary, carrier or CMS should be read to mean initial and reconsidered determinations made by a QIO.


§ 478.18 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...
obtain a reconsideration must submit a written request to one of the following:

(1) The QIO or the QIO subcontractor that made the initial determination.
(2) An SSA District Office.
(3) A Railroad Retirement Board Office, if the beneficiary is a railroad retiree.
(b) Others. A provider, physician or other practitioner that wishes to obtain reconsideration must submit a written request to the QIO or QIO subcontractor that made the initial determination.
(c) Expedited reconsideration. A request for an expedited reconsideration of a preadmission denial determination must be submitted directly to the QIO.

§ 478.20 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 an 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.
(3) A request is considered filed on the date it is postmarked.
(b) Late filing of request. A QIO will accept a request filed after 60 days after receipt of the notice of the initial determination if the QIO 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 under § 473.18(c) must be submitted within three days after receipt of the notice of the initial denial determination.

§ 478.22 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 QIO 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 QIO 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 the time limit, and requested reconsideration within 60 days of receiving the explanation (or within 30 days for a Departmental Appeals Board hearing).
(6) The QIO 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.

§ 478.24 Opportunity for a party to obtain and submit information.

(a) Subject to the rules concerning disclosure of QIO information in section 1160 of the Act, at the request of a provider, practitioner or beneficiary,
the QIO must provide an opportunity for examination of the material upon which the initial denial determination was based. The QIO may not furnish a provider, practitioner or beneficiary with—
(1) A record of the QIO deliberation; or
(2) The identity of the QIO review coordinators, physician advisors, or consultants who assisted in the initial denial determination without their consent.
(b) The QIO may require the requester to pay a reasonable fee for the reproduction of the material requested.
(c) The QIO must provide a party with an opportunity to submit new evidence before the reconsidered determination is made.

§478.26 Delegation of the reconsideration function.
A QIO may delegate the authority to reconsider an initial determination to a nonfacility subcontractor, including the organization that made the initial determination as a QIO subcontractor.

§478.28 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 QIO review.

§478.30 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.

§478.32 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 QIO must complete its reconsidered determination and send written notice to the beneficiary within the following time limits—
(i) Within three working days after the QIO receives the request for reconsideration if—
(ii) The beneficiary is still an inpatient in a hospital for the stay in question when the QIO receives the request for reconsideration;
(iii) 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.
(b) Providers or practitioners. If the provider or practitioner files a request for reconsideration of an initial determination, the QIO must complete its reconsidered determination and send written notice to the provider or practitioner within 30 working days.

§478.34 Notice of a reconsidered determination.
(a) Notice to parties. A written notice of a QIO reconsidered determination must contain the following:
(i) The basis for the reconsidered determination.
(ii) A detailed rationale for the reconsidered determination.
(iii) A statement explaining the Medicare payment consequences of the reconsidered determination.
(4) A statement informing the parties of their appeal rights, including the information concerning what must be included in the request for hearing, the amount in controversy, locations for submitting a request for an administrative hearing and the time period for filing a request.

(b) Notice to payers. (1) A QIO must provide written notice of its reconsidered determination to the appropriate Medicare intermediary or carrier within 30 days if the initial determination is modified or reversed.

(2) This notice must contain adequate information to allow the intermediary or carrier to locate the claim file. This must include the name of the beneficiary, the Health Insurance Claim Number, the name of the provider, date of admission, and dates or services for which Medicare payment will not be made.

§ 478.36 Record of reconsideration.

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

(1) Four years after the date on the notice of the QIO’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 QIO reconsideration is subject to prohibitions against disclosure of information as specified in section 1160 of the Act.

§ 478.38 Effect of a reconsidered determination.

A QIO reconsidered determination is 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.

§ 478.40 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 QIO 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 CMS should be read to mean initial and reconsidered determinations made by a QIO.

§ 478.42 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 QIO or QIO subcontractor that made the initial determination.
§ 478.48 Reopening and revision of a reconsidered determination or a hearing decision.

(a) QIO reopenings—(1) General rule. A QIO or QIO subcontractor that made a reconsidered determination, or conducted a review of a DRG change as described in §473.15, that is otherwise binding, 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 QIO or QIO subcontractor may reopen and revise its reconsidered determination, or its review of a DRG change as described in §473.15, that is otherwise binding, after one year but within four years of the date of the determination or review if—

(i) The QIO receives new material evidence;

(ii) The QIO 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, whichever made the 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.


PART 480—ACQUISITION, PROTECTION, AND DISCLOSURE OF QUALITY IMPROVEMENT ORGANIZATION REVIEW INFORMATION

Subpart A [Reserved]

Subpart B—Utilization and Quality Control
Quality Improvement Organizations (QIOs)

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AUTHORITY: Secs. 1102 and 1371 of the Social Security Act (42 U.S.C. 1395hh).

Subpart A [Reserved]

Subpart B—Utilization and Quality Control
Quality Improvement Organizations (QIOs)

SOURCE: 50 FR 15359, Apr. 17, 1985, unless otherwise noted. Redesignated at 64 FR 66279, Nov. 24, 1999.

GENERAL PROVISIONS

§ 480.101 Scope and definitions.

(a) Scope. This subpart sets forth the policies and procedures governing—
(1) Disclosure of information collected, acquired or generated by a Utilization and Quality Control Quality Improvement Organization (QIO) (or the review component of a QIO subcontractor) in performance of its responsibilities under the Act and these regulations; and
(2) Acquisition and maintenance of information by a QIO 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) QIO 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 QIO area.
Patient representative means—(1) an individual designated by the patient, in writing, as authorized to request and receive QIO information that would otherwise be disclosable to that patient; or (2) an individual identified by the QIO in accordance with § 480.132(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.
QIO deliberations means discussions or communications (within a QIO or between a QIO and a QIO subcontractor) including, but not limited to, review notes, minutes of meetings and any other records of discussions and judgments involving review matters regarding QIO review responsibilities and appeals from QIO determinations, in which the opinions of, or judgment about, a particular individual or institution can be discerned.
QIO information means any data or information collected, acquired or generated by a QIO in the exercise of its duties and functions under Title XI Part B or Title XVIII of the Act.
QIO 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 QIO’s knowledge of the area gained from its medical review experience (e.g., quality review studies) and any other information obtained through the QIO’s review activities.
QIO review system means the QIO and those organizations and individuals who either assist the QIO 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 QIO and its officers, members and employees;
(2) QIO subcontractors;
(3) Health care institutions and practitioners whose services are reviewed;
(4) QIO 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 QIO, of a patient care problem for the purpose of improving patient care through peer analysis, intervention, resolution of the problem and follow-up.
§ 480.102 Statutory bases for acquisition and maintenance of information.

(a) Section 1154(a)(7)(C) of the Act requires QIOs 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 QIOs 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 QIOs.

§ 480.103 Statutory bases for disclosure of information.

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

(b) Section 1156 of the Act provides that QIO 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 the 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.

§ 480.104 Procedures for disclosure by a QIO.

(a) Notice to accompany disclosure. (1) Any disclosure of information under the authority of this subpart is subject to the requirements in § 480.105 relating to the providing of a notice of the disclosure.

(2) Disclosure of confidential information made under the authority of this subpart, except as provided in § 480.106, must be accompanied by a written statement informing the recipient that the information may not be disclosed except as provided under § 480.107 that limits redisclosure.

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

(c) Fees. A QIO may charge a fee to cover the cost of providing information authorized under this subpart. These
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§ 480.107  Limitations on redisclosure.

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

(a) As directed by the QIO to carry out a disclosure permitted or required under a particular provision of this part;
§ 480.108 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.

§ 480.109 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 QIO information.


§ 480.111 QIO access to records and information of institutions and practitioners.

(a) A QIO is authorized to have access to and obtain records and information pertinent to the health care services furnished to Medicare patients, held by any institution or practitioner in the QIO area. The QIO may require the institution or practitioner to provide copies of such records or information to the QIO.

(b) A QIO may obtain non-Medicare patient records relating to review performed under a non-Medicare QIO contract if authorized by those patients in accordance with State law.

(c) In accordance with its quality review responsibilities under the Act, a QIO may have access to and obtain information from, the records of non-Medicare patients if authorized by the institution or practitioner.

(d) A QIO may reimburse for requested information at the rate of $.10 per page for photocopying plus first class postage. The photocopying amount includes the cost of labor, supplies, equipment, and overhead.

§ 480.113 QIO access to information collected for QIO purposes.

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

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

§ 480.114 Limitation on data collection.

A QIO 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.

§ 480.115 Requirements for maintaining confidentiality.

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

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

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

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

(1) Has completed a training program in the handling of QIO 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 QIO 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 CMS that those identifiers are no longer necessary.

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

§ 480.116 Notice to individuals and institutions under review.

The QIO 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 QIO information;

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

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

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


**DISCLOSURE OF NONCONFIDENTIAL INFORMATION**

§ 480.120 Information subject to disclosure.

Subject to the procedures for disclosure and notice of disclosure specified in §§ 480.104 and 480.105, the QIO 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) Copies of documents describing administrative procedures, agreed to between the QIO and institutions or between a QIO and the Medicare intermediary or Medicare carrier;

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

(5) Summaries of the proceedings of QIO regular and other meetings of the governing body and general membership except for those portions of the summaries involving QIO deliberations, which are confidential information and subject to the provisions of § 480.139;

(6) Public information in its possession;

(7) Aggregate statistical information that does not implicitly or explicitly identify individual patients, practitioners or reviewers;

(b) Quality review study information including summaries and conclusions from which the identification of patients, practitioners and institutions has been deleted; and

(9) Information describing the characteristics of a quality review study, including a study design and methodology.

(b) Aggregate statistical information that does not implicitly or explicitly identify individual patients, practitioners or reviewers, to Federal or State health planning agencies (including Health Systems Agencies and State Health Planning and Development Agencies) in carrying out their health care planning and related activities.

A QIO may, on its own initiative, subject to the notification requirements in § 480.105, furnish the information available under § 480.120 to any person, agency, or organization.

**DISCLOSURE OF CONFIDENTIAL INFORMATION**

§ 480.130 Disclosure to the Department.

Except as limited by §§ 480.139(a) and 480.140 of this subpart, QIOs must disclose all information requested by the Department to it in the manner and form required.

§ 480.131 Access to medical records for the monitoring of QIOs.

CMS or any person, organization or agency authorized by the Department or Federal statute to monitor a QIO will have access to medical records maintained by institutions or health care practitioners on Medicare patients. The monitor can require copies of the records.

§ 480.132 Disclosure of information about patients.

(a) General requirements for disclosure. Except as specified in paragraph (b) of this section, a QIO must—

(1) Disclose patient identified information in its possession to the identified patient or the patient’s representative if—

(i) The patient or the patient’s representative requests the information in writing;

(ii) The request by a patient’s representative includes the designation, by the patient, of the representative; and
(iii) All other patient and practitioner identifiers have been removed.

(2) Seek the advice of the attending practitioner that treated the patient regarding the appropriateness of direct disclosure to the patient 15 days before the QIO provides the requested information. If the attending practitioner states that the released information could harm the patient, the QIO must act in accordance with paragraph (c)(2) of this section. The QIO must make disclosure to the patient or patient’s representative within 30 calendar days of receipt of the request.

(b) Exceptions. (1) If the request is in connection with an initial denial determination under section 1154(a)(3) of the Act, the QIO—

(i) Need not seek the advice of the practitioner that treated the patient regarding the appropriateness of direct disclosure to the patient; and

(ii) 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 QIO must disclose information regarding QIO deliberations only as specified in §480.139(a).

(3) A QIO must disclose quality review study information only as specified in §480.140.

(c) Manner of disclosure. (1) The QIO must disclose the patient information directly to the patient unless knowledge of the information could harm the patient.

(2) If knowledge of the information could harm the patient, the QIO must disclose the information to the patient’s designated representative.

(3) If the patient is mentally, physically or legally unable to designate a representative, the QIO must disclose the information to a person whom the QIO determines is responsible for the patient.

The QIO must first attempt to make that determination based on the medical record. If the responsible person is not named in the medical record, then the QIO may rely on the attending practitioner for the information. If the practitioner is unable to provide a name, then the QIO must make a determination based on other reliable information.

§ 480.133 Disclosure of information about practitioners, reviewers and institutions.

(a) General requirements for disclosure. Except as specified in paragraph (b) of this section, the following provisions are required of the QIO.

(1) Disclosure to the identified individual or institution. A QIO must disclose, to particular practitioners, reviewers and institutions, information about themselves, upon request, and may disclose it to them without a request.

(2) Disclosure to others. (i) A QIO must disclose to an institution, upon request, information on a practitioner to the extent that the information displays practice or performance patterns of the practitioner in that institution.

(ii) In accordance with section 1160 of the Act, a QIO must disclose information that displays practice or performance patterns of a practitioner or institution in accordance with the procedures for disclosures specified in §§480.137 and 480.138 to—

(A) Federal and State agencies that are responsible for the investigation of fraud and abuse of the Medicare or Medicaid programs, and

(B) Federal and State agencies that are responsible for licensing and certification of practitioners and providers.

(iii) A QIO may disclose to any person, agency, or organization information on a particular practitioner or reviewer at the written request of or with the written consent of that practitioner or reviewer. The recipient of the information has the same redisclosure rights and responsibilities as the requesting or consenting practitioner or reviewer as provided under this Subpart B.

(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 QIO must provide only the
§ 480.134 Verification and amendment of QIO information.

(a) A QIO must verify the accuracy of its information concerning patients, practitioners, reviewers, and institutions and must permit the individual or institution to request an amendment of pertinent information that is in the possession of the QIO.

(b) If the QIO agrees with the request for amendment, the QIO must correct the information in its possession. If the information being amended has already been disclosed, the QIO must forward the amended information to the requester where it may affect decisions about a particular provider, practitioner or case under review.

(c) If the QIO disagrees with the request for amendment, a notation of the request, reasons for the request, and the reasons for refusal must be included with the information and attached to any disclosure of the information.

§ 480.135 Disclosure necessary to perform review responsibilities.

(a) Disclosure to conduct review. The QIO must disclose or arrange for disclosure of information to individuals and institutions within the QIO review 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 QIO must disclose to consultants or subcontractors the information they need to provide specified services to the QIO.

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

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

§ 480.136 Disclosure to intermediaries and carriers.

(a) Required disclosure. Except as specified in §§ 480.139(a) and 480.140 relating to disclosure of QIO deliberations and quality review study information, a QIO must disclose to intermediaries and carriers QIO 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 QIO and the intermediary or carrier.

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

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

(b) Optional disclosure. The QIO may disclose the information specified in paragraph (a) of this section to intermediaries and carriers without a request.

§ 480.137 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 §§ 480.139(a) and 480.140 relating to disclosure of QIO deliberations and quality review study information, the QIO must disclose confidential information relevant to an investigation of fraud or abuse of the
Medicare or medicaid programs, including QIO 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 QIO 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.

§ 480.138 Disclosure for other specified purposes.

(a) General requirements for disclosure. Except as specified in paragraph (b) of this section, the following provisions are required of the QIO.

(1) Disclosure to licensing and certification bodies. (i) A QIO must disclose confidential information upon request, to State or Federal licensing bodies responsible for the professional licensure of a practitioner or a particular institution. Confidential information, including QIO medical necessity determinations that display the practice or performance patterns of that practitioner, must be disclosed by the QIO but only to the extent that it is required by the agency to carry out a function within the jurisdiction of the agency under Federal or State law.

(ii) A QIO may provide the information specified in paragraph (a)(1)(i) of this section to the State or Federal licensing body without request.

(b) Exceptions. (1) The restriction set forth in paragraph (a)(3) of this section does not apply to HHS, including Inspector General, administrative subpoenas issued in the course of audits and investigations of Department programs, in the course of administrative hearings held under the Social Security Act or to disclosures to the General Accounting Office as necessary to carry out its statutory responsibilities.

(2) A QIO must disclose information regarding QIO deliberations and quality review study information only as specified in §§ 480.139(a) and 480.140.

§ 480.139 Disclosure of QIO deliberations and decisions.

(a) QIO deliberations. (1) A QIO must not disclose its deliberations except to—

(i) CMS, at the QIO office or at a subcontracted organization;

(ii) CMS, to the extent that the deliberations are incorporated in sanction and appeals reports; or

(iii) The Office of the Inspector General, and the General Accounting Office as necessary to carry out statutory responsibilities.

(2) QIO deliberations are not disclosable, either in written form or through oral testimony, in connection with the administrative hearing or review of a beneficiary’s claim.

(b) Reasons for QIO decisions. (1) A QIO may disclose to those who have access to QIO information under other provisions of this subpart, the reasons...
§ 480.140 Disclosure of quality review study information.

(a) A QIO 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; CMS; 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 QIO 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 QIO may disclose information onsite 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.

(d) A QIO may disclose quality review study information with identifiers of particular practitioners or institutions, or both, at the written request of, or with the written consent of, the identified practitioner(s) or institution(s).

(1) The consent or request must specify the information that is to be disclosed and the intended recipient of the information.

(2) The recipient of the information has the same redisclosure rights and responsibilities as the requesting or consenting practitioner or institution as provided under this Subpart B.

(e) An institution or group of practitioners may redisclose quality review study information, if the information is limited to health care services they provided.

(f) Quality review study information with patient identifiers is not subject to subpoena or discovery in a civil action, including an administrative, judicial or arbitration proceeding. This restriction does not apply to HHS, including Inspector General, administrative subpoenas issued in the course of audits and investigations of Department programs, in the course of administrative hearings held under the Social Security Act, or to disclosures to the General Accounting Office as necessary to carry out its statutory responsibilities.


§ 480.141 Disclosure of QIO interpretations on the quality of health care.

Subject to the procedures for disclosure and notice of disclosure specified in §§ 480.104 and 480.105, a QIO may disclose to the public QIO interpretations and generalizations on the quality of health care that identify a particular institution.


§ 480.142 Disclosure of sanction reports.

(a) The QIO must disclose sanction reports directly to the Office of the Inspector General and, if requested, to CMS.
(b) The QIO 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 §480.137.

(c) CMS will disclose sanction determinations in accordance with part 474 of this chapter.


§ 480.143 QIO involvement in shared health data systems.

(a) Information collected by a QIO. Except as prohibited in paragraph (b) of this section, information collected by a QIO 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) QIO participation. A QIO 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 QIO from complying with the rules of this part.

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

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

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

PART 481 [RESERVED]