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Subpart A—General Provisions

§ 476.1 Definitions.

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

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.

Appointed representative means an individual appointed by a Medicare beneficiary to represent the beneficiary in the beneficiary complaint review process.

Authorized representative means an individual authorized, under State or other applicable law, to act on behalf of a Medicare beneficiary. An authorized representative has all of the rights and responsibilities of a Medicare beneficiary throughout the processing of a beneficiary complaint.

Beneficiary complaint means a complaint by a Medicare beneficiary or a Medicare beneficiary's representative alleging that the quality of Medicare covered services received by the beneficiary did not meet professionally recognized standards of care. A complaint may consist of one or more quality of care concerns.

Beneficiary complaint review means a review conducted by a QIO in response to the receipt of a written beneficiary complaint to determine whether the quality of Medicare covered services provided to the beneficiary was consistent with professionally recognized standards of health care.

Beneficiary representative means an individual identified as an authorized or appointed representative of a Medicare beneficiary.

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.

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

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

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

(3) 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

(4) 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.

General quality of care review means a review conducted by a QIO to determine whether the quality of Medicare covered services provided to a Medicare beneficiary was consistent with professionally recognized standards of health care. A general quality of care review may be carried out as a result of a referral to the QIO or a QIO's identification of a potential concern during the course of another review activity or through the analysis of data.

Gross and flagrant violation means a violation of an obligation resulting from inappropriate or unnecessary services, services that do not meet recognized professional standards of care, or services that are not supported by evidence of medical necessity or quality as required by the QIO. The violation must have occurred in one or more instances that present an imminent danger to the health, safety, or well-being of a program patient or places the program patient unnecessarily in high-risk situations.

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.

Immediate advocacy means an informal alternative dispute resolution process used to quickly resolve an oral complaint a Medicare beneficiary or his or her representation has regarding the quality of Medicare covered health care received. This process involves a QIO representative's direct contact with the provider and/or practitioner.

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:

(1) A doctor or medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatry, a doctor of optometry, or a chiropractor, as described in section 1861(r) of the Act;

(2) An intern, resident, or Federal Government employee authorized under State or Federal law to practice as a doctor as described in paragraph (1) of this definition; and

(3) An individual licensed to practice as a doctor as described in paragraph (1) of this definition in any Territory or Commonwealth of the United States of America.

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 or the Medicare administrative contractor, 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.

Provider means a health care facility, institution, or organization, including but not limited to a hospital, involved in the delivery of health care services for which payment may be made in whole or in part under Title XVIII of the Act.

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

Quality improvement initiative means any formal activity designed to serve as a catalyst and support for quality improvement that uses proven methodologies to achieve these improvements. The improvements may relate to safety, health care, health and value and involve providers, practitioners, beneficiaries, and/or communities.

Quality of care concern means a concern that care provided did not meet a professionally recognized standard of health care. A general quality of care review or a beneficiary complaint review may cover a single or multiple concerns.

Quality of care review means a review conducted by a QIO to determine whether the quality of Medicare covered services provided to beneficiaries was consistent with professionally recognized standards of health care. A quality of care review can either be a beneficiary complaint review or a general quality of care review.

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.

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

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

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

Significant quality of care concern means a determination by the QIO that the quality of care provided to a Medicare beneficiary did not meet the standard of care and, while not a gross and flagrant or substantial violation of the standard, represents a noticeable departure from the standard that could reasonably be expected to have a negative impact on the health of a beneficiary.

Skilled nursing facility (SNF) means a health care institution or distinct part of an institution that (a) is primarily engaged in providing skilled nursing care or rehabilitative services to injured, disabled, or sick persons, and (b) has an agreement to participate in Medicare or Medicaid or both, and (c) is not a religious nonmedical institution as defined in §440.170(b) of this chapter

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

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

Substantial violation in a substantial number of cases means a pattern of providing care that is inappropriate, unnecessary, or does not meet recognized professional standards of care, or is not supported by the necessary documentation of care as required by the QIO.

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

[44 FR 32081, June 4, 1979, as amended at 45 FR 67545, Oct. 10, 1980; 46 FR 48569, Oct. 1, 1981. Redesignated and amended at 50 FR 15328, 15329, Apr. 17, 1985; 51 FR 43197, Dec. 1, 1986. Redesignated at 64 FR 66279, Nov. 24, 1999, as amended at 64 FR 67052, Nov. 30, 1999; 77 FR 53682, Aug. 31, 2012; 77 FR 68559, Nov. 15, 2012; 78 FR 75199, Dec. 10, 2013]

Subpart B [Reserved]

Subpart C—Review Responsibilities of Quality Improvement Organizations (QIOs)

SOURCE: 50 FR 15330, Apr. 17, 1985, unless otherwise noted. Redesignated at 64 FR 66279, Nov. 24, 1999.

GENERAL PROVISIONS

§ 476.70 Statutory bases and applicability.

(a) *Statutory bases.* 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.

(b) *Applicability.* The regulations in this subpart apply to review conducted by a QIO and its subcontractors.

[77 FR 68560, Nov. 15, 2012]

§ 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 the palliation and management of terminal illness;

(2) Whether the quality of the services meets professionally recognized standards of health care, as determined through the resolution of oral beneficiary complaints as specified in §476.110, written beneficiary complaints as specified in §476.120, or the completion of general quality of care reviews as specified in §476.160.

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

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

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

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

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

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

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

(ii) Unnecessary multiple admissions of an individual; or

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

(9) Hospital reclassification of a beneficiary's inpatient admission status to that of an outpatient receiving observation services when a beneficiary meets the eligibility criteria at §§ 405.1210 through 405.1212 of this chapter. Appeals of determinations are available as specified in § 405.1212 of this chapter.

(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 administrative contractor, 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.

[52 FR 37457, Oct. 7, 1987; 52 FR 47003, Dec. 11, 1987, as amended at 59 FR 45402, Sept. 1, 1994. Redesignated at 64 FR 66279, Nov. 24, 1999; 67 FR 56056, Aug. 30, 2002; 77 FR 68560, Nov. 15, 2012; 89 FR 83294, Oct. 15, 2024]

§ 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 administrative contractors, 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 § 476.78(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.

[50 FR 15330, Apr. 17, 1985. Redesignated at 52 FR 37457, Oct. 7, 1987, and further redesignated at 64 FR 66279, Nov. 24, 1999; 77 FR 68560, Nov. 15, 2012]

§ 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 administrative contractor, 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 administrative contractors, 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 § 411.402 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.

[50 FR 15330, Apr. 17, 1985, as amended at 77 FR 68560, Nov. 15, 2012]

§ 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 providers and practitioners.

(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 § 476.71.

(b) *Cooperation with QIOs.* Health care providers that submit Medicare claims must cooperate in the assumption and conduct of QIO review.

(1) Providers must allocate adequate space to the QIO for its conduct of review at the times the QIO is conducting review.

(2) Providers and practitioners must 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. When the QIO does postadmission, preprocedure review, the provider must provide the necessary information before the procedure is performed, unless it must be performed on an emergency basis. Providers and practitioners must—

(i) Except as provided under §§ 476.130(b) and 476.160(b), relating to beneficiary complaint reviews and general quality of care reviews, deliver to the QIO all required information within 14 calendar days of a request. A QIO

is authorized to require the receipt of the medical information earlier than the 14-day timeframe if the QIO makes a preliminary determination that the review involves a potential gross and flagrant or substantial violation as specified in part 1004 of this title and circumstances warrant earlier receipt of the medical information. A practitioner's or provider's failure to comply with the request for medical information within the established timeframe may result in the QIO taking action in accordance with § 476.90.

(ii) Except if granted a waiver as described in paragraph (d) of this section, send secure transmission of an electronic version of each requested patient record to the QIO.

(A) Providers and practitioners must deliver electronic versions of patient records within 14 calendar days of the request.

(B) A QIO is authorized to require the receipt of the patient records earlier than the 14-day timeframe if the QIO makes a preliminary determination that the review involves a potential gross and flagrant or substantial violation as specified in part 1004 of this title and circumstances warrant earlier receipt of the patient records.

(C) A practitioner's or provider's failure to comply with the request for patient records within the established timeframe may result in the QIO taking action in accordance with § 476.90.

(3) Providers must 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 § 411.402(a) of this chapter, that can support a finding that the beneficiary knew the services were not covered.

(4) When the provider 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) Providers must assure, in accordance with the provisions of their agreements 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) Providers must 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 provider, 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) Hospitals must 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) *Submission of patient records in electronic format.* Except as specified in paragraph (d) of this section, a provider or practitioner must deliver patient records requested by a QIO for the purpose of fulfilling one or more QIO functions, in an electronic format, using the mechanism specified by the QIO. In the absence of any mechanism specified by the requesting QIO, the requested patient records must be submitted using any CMS-approved mechanism.

(d) *Waiver from the requirement to submit patient records in an electronic format.* (1) A provider or practitioner that lacks the capability to submit requested patient records to the requesting QIO in an electronic format may request a waiver from the requirements in paragraph (c) of this section.

(i) For providers that are required to execute a written agreement with the QIO, a request for a waiver must be made during execution of the written agreement with the QIO.

(ii) Providers that are required to execute a written agreement with the QIO must request a waiver by notifying the QIO that they lack the capability to submit patient records in electronic format, if their lack of capability

arises after the written agreement is executed.

(iii) Upon approval of the waiver, the waiver becomes part of the written agreement with the QIO.

(iv) A provider with an approved waiver may submit patient records by facsimile or by photocopying and mailing to the QIO.

(v) A provider with an approved waiver may be reimbursed by the QIO for patient records submitted by facsimile or by photocopying and mailing in accordance with paragraph (e)(2) of this section.

(vi) A QIO may not reimburse for any patient record submitted to the QIO by facsimile or by photocopying and mailing if the provider does not have an approved waiver.

(2) Providers and practitioners that are not required to execute a written agreement with the QIO may request a waiver to be exempted from submitting patient records in an electronic format.

(i) Such providers and practitioners may request a waiver by notifying the QIO that they lack the capability to submit patient records in electronic format.

(ii) Upon approval of the waiver, a provider or practitioner may submit patient records by facsimile or by photocopying and mailing to the QIO.

(iii) Providers and practitioners with approved waivers may be reimbursed by the QIO for patient records submitted by facsimile or by photocopying and mailing in accordance with paragraph (e)(2) of this section.

(iv) A QIO may not reimburse for any patient records submitted to the QIO by facsimile or by photocopying and mailing, if the provider or practitioner does not have an approved waiver.

(e) *Reimbursement for submitting patient records to the QIO.* (1) For purposes of this paragraph (e), a *patient record* means all patient care data and other pertinent data or information relating to care or services provided to an individual patient in the possession of the provider or practitioner, as requested by a QIO for the purpose of performing one or more QIO functions.

(2) A QIO may reimburse a provider or practitioner for requested patient records submitted in an electronic format, at the rate of $3.00 per patient record.

(3) For a provider or practitioner that has an approved waiver under paragraph (d) of this section, a QIO may reimburse the provider or practitioner for requested records submitted by—

(i) Facsimile at the rate of $0.15 per page; or

(ii) Photocopying and mailing at the rate of $0.15 per page, plus the cost of first class postage.

(4) A QIO may only reimburse a provider or practitioner once for each patient record submitted, per request, even if a patient record is submitted using multiple formats, in fragments, or more than once in response to a single request by the QIO.

(f) *Appeals.* Reimbursement for the costs of submitting requested patient records to the QIO in electronic format, by facsimile or by photocopying and mailing is an additional payment to providers under the prospective payment system, as specified in §§ 412.115, 413.355, and 484.265 of this chapter. Appeals concerning these costs are subject to the review process specified in part 405, subpart R, of this chapter.

(c) *Submission of patient records in electronic format.* Except as specified in paragraph (d) of this section, a provider or practitioner must deliver patient records requested by a QIO for the purpose of fulfilling one or more QIO functions, in an electronic format, using the mechanism specified by the QIO. In the absence of any mechanism specified by the requesting QIO, the requested patient records must be submitted using any CMS-approved mechanism.

(d) *Waiver from the requirement to submit patient records in an electronic format.* (1) A provider or practitioner that lacks the capability to submit requested patient records to the requesting QIO in an electronic format may request a waiver from the requirements in paragraph (c) of this section.

(i) For providers that are required to execute a written agreement with the QIO, a request for a waiver must be made during execution of the written agreement with the QIO.

(ii) Providers that are required to execute a written agreement with the

QIO must request a waiver by notifying the QIO that they lack the capability to submit patient records in electronic format, if their lack of capability arises after the written agreement is executed.

(iii) Upon approval of the waiver, the waiver becomes part of the written agreement with the QIO.

(iv) A provider with an approved waiver may submit patient records by facsimile or by photocopying and mailing to the QIO.

(v) A provider with an approved waiver may be reimbursed by the QIO for patient records submitted by facsimile or by photocopying and mailing in accordance with paragraph (e)(2) of this section.

(vi) A QIO may not reimburse for any patient record submitted to the QIO by facsimile or by photocopying and mailing if the provider does not have an approved waiver.

(2) Providers and practitioners that are not required to execute a written agreement with the QIO may request a waiver to be exempted from submitting patient records in an electronic format.

(i) Such providers and practitioners may request a waiver by notifying the QIO that they lack the capability to submit patient records in electronic format.

(ii) Upon approval of the waiver, a provider or practitioner may submit patient records by facsimile or by photocopying and mailing to the QIO.

(iii) Providers and practitioners with approved waivers may be reimbursed by the QIO for patient records submitted by facsimile or by photocopying and mailing in accordance with paragraph (e)(2) of this section.

(iv) A QIO may not reimburse for any patient records submitted to the QIO by facsimile or by photocopying and mailing, if the provider or practitioner does not have an approved waiver.

(e) *Reimbursement for submitting patient records to the QIO.* (1) For purposes of this paragraph (e), a *patient record* means all patient care data and other pertinent data or information relating to care or services provided to an individual patient in the possession of the provider or practitioner, as requested by a QIO for the purpose of performing one or more QIO functions.

(2) A QIO may reimburse a provider or practitioner for requested patient records submitted in an electronic format, at the rate of $3.00 per patient record.

(3) For a provider or practitioner that has an approved waiver under paragraph (d) of this section, a QIO may reimburse the provider or practitioner for requested records submitted by—

(i) Facsimile at the rate of $0.15 per page; or

(ii) Photocopying and mailing at the rate of $0.15 per page, plus the cost of first class postage.

(4) A QIO may only reimburse a provider or practitioner once for each patient record submitted, per request, even if a patient record is submitted using multiple formats, in fragments, or more than once in response to a single request by the QIO.

(f) *Appeals.* Reimbursement for the costs of submitting requested patient records to the QIO in electronic format, by facsimile or by photocopying and mailing is an additional payment to providers under the prospective payment system, as specified in §§ 412.115, 413.355, and 484.265 of this chapter. Appeals concerning these costs are subject to the review process specified in part 405, subpart R, of this chapter.

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§ 476.80 Coordination with Medicare administrative contractors, fiscal intermediaries, and carriers

(a) *Procedures for agreements.* Medicare administrative contractor, 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 Medicare administrative contractor, 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 Medicare administrative contractor, fiscal intermediary, or carrier and obtain approval from CMS, before it makes conclusive determinations for the Medicare program, unless CMS finds that the Medicare administrative contractor, 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 administrative contractors, 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 administrative contractors, fiscal intermediaries, and carriers, or if an agreement has not been established, the QIO's proposed administrative procedures, including any comments by the Medicare administrative contractors, 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 Medicare administrative contractor, 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 Medicare administrative contractor, fiscal intermediary, or carrier, or

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

(e) *Role of the Medicare administrative contractor or fiscal intermediary.* (1) The Medicare administrative contractor or 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 Medicare administrative contractor or fiscal intermediary. Medicare coverage requirements must also be applied.

[50 FR 15330, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999; 77 FR 68560, Nov. 15, 2012]

§ 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 § 411.15(g) or § 411.15(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 administrative contractors, fiscal intermediaries, and 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 §§ 405.1035, 405.1042, and 405.1137 of this chapter.

(c) *Coverage.* Nothing in paragraphs (a) (1) and (3) of this section will be construed as precluding CMS or a Medicare administrative contractor, 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 Medicare administrative contractor, 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 administrative contractors, 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 1864(a) with respect to sections 1861(e)(6), 1861(j)(8), 1861(j)(12), and 1861(k) of the Act, and activities required of Medicare administrative contractors, fiscal 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 478 of this chapter.

[50 FR 15330, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985, as amended at 53 FR 6648, Mar. 2, 1988. Redesignated at 64 FR 66279, Nov. 24, 1999; 77 FR 68561, Nov. 15, 2012]

§ 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 provider or practitioner.

(a) If a provider 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 provider or practitioner has failed to comply with the requirements of 42 CFR 1004.10(c) 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 provider or practitioner, and may report the matter to the HHS Inspector General.

(b) If a QIO gives a provider or practitioner sufficient notice and a reasonable amount of time to respond to a request for information about a claim, and if the provider or practitioner does not respond in a timely manner, the QIO will deny the claim. A provider or practitioner may request that the QIO reconsider its decision to deny the claim. No further appeal rights are available.

[77 FR 53683, Aug. 31, 2012]

§ 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 Medicare administrative contractor, 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 478, 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 Medicare administrative contractor, fiscal intermediary, or carrier within

the same time periods as the notices to the other parties.

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

(2) The documentary record must include—

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

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

[50 FR 15330, Apr. 17, 1985, as amended at 77 FR 68561, Nov. 15, 2012]

§ 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 date 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 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 other practitioners in the same professional field.

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

(d) *Persons excluded from review.* (1) A person may not review health care

services or make initial denial determinations or changes as a result of DRG validations if he or she, or a member of his or her family—

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

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

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

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

[50 FR 15330, Apr. 17, 1985, as amended at 77 FR 68561, Nov. 15, 2012]

§ 476.100 Use of norms and criteria.

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

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

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

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

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

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

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

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

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

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

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

§ 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

in the health care facility as described in § 466.98(d).

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

(d) *Consultation with practitioners other than physicians.* To the extent practicable, a 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.

[50 FR 15330, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999]

§ 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 administrative contractors, fiscal intermediaries, and carriers.

(b) Other QIOs; and

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

[50 FR 15330, Apr. 17, 1985, as amended at 77 FR 68561, Nov. 15, 2012]

§ 476.110 Use of immediate advocacy to resolve oral beneficiary complaints.

(a) *Immediate advocacy.* A QIO may offer the option of resolving an oral complaint through the use of immediate advocacy if:

(1) The complaint is received not later than 6 months from the date on which the care giving rise to the complaint occurred.

(2) After initial screening of the complaint, the QIO makes a preliminary determination that—

(i) The complaint is unrelated to the clinical quality of health care itself but relates to items or services that accompany or are incidental to the medical care and are provided by a practitioner and/or provider; or

(ii) The complaint, while related to the clinical quality of health care received by the beneficiary, does not rise to the level of being a gross and flagrant, substantial, or significant quality of care concern.

(3) The beneficiary agrees to the disclosure of his or her name to the involved provider and/or practitioner.

(4) All parties orally consent to the use of immediate advocacy.

(5) All parties agree to the limitations on redisclosure set forth in § 480.107 of this subchapter.

(b) *Discontinuation of immediate advocacy.* The QIO or either party may discontinue participation in immediate advocacy at any time.

(1) The QIO must inform the parties that immediate advocacy will be discontinued; and

(2) The beneficiary must be informed of his or her right to submit a written complaint in accordance with the procedures in § 476.120.

(c) *Confidentiality requirements.* All communications, written and oral, exchanged during the immediate advocacy process must not be redisclosed without the written consent of all parties.

(d) *Abandoned complaints.* If any party fails to participate or otherwise comply with the requirements of the immediate advocacy process, the QIO may determine that the complaint has been abandoned and—

(1) Inform the parties that immediate advocacy will be discontinued; and

(2) Inform the Medicare beneficiary of his or her right to submit a written complaint in accordance with the procedures in § 476.120.

[77 FR 68561, Nov. 15, 2012]

§ 476.120 Submission of written beneficiary complaints.

(a) *Timeframe for submission of written complaints.* A QIO shall be responsible for conducting a review of any written complaint received from a Medicare beneficiary or a Medicare beneficiary's representative about the quality of health care if the complaint is received not later than 3 years from the date on which the care giving rise to the complaint occurred.

(1) A written complaint includes a complaint submitted electronically to the QIO.

(2) In those instances where a Medicare beneficiary contacts the QIO regarding a complaint but declines to

submit the complaint in writing and immediate advocacy has not been offered, the QIO may complete a general quality of care review in accordance with § 476.160 if the QIO makes a preliminary determination that the complaint involves a potential gross and flagrant, substantial or significant quality of care concern.

(b) *New concerns raised by a Medicare beneficiary*. If a Medicare beneficiary raises new concerns relating to the same complaint after the completion of the interim initial determination in § 476.130(c), the concerns will be processed as a new complaint. The QIO may process new concerns raised after the receipt of the written complaint as part of the same complaint, provided they are received prior to the completion of the interim initial determination. Even if a concern is received before the interim initial determination, the QIO can address it as a separate complaint if the QIO determines that this is warranted by the circumstances.

[77 FR 68561, Nov. 15, 2012]

§ 476.130 Beneficiary complaint review procedures.

(a) *Scope of the QIO review*. In completing its review, the QIO shall consider any information and materials submitted by the Medicare beneficiary or his or her representative and any information submitted by the provider and/or practitioner. All information obtained by the QIO that fits within the definition of ''confidential information'' under § 480.101, will be held by the QIO as confidential.

(1) The QIO's review will focus on the episode of care from which the complaint arose and address the specific concerns identified by the beneficiary and any additional concerns identified by the QIO. The QIO may separate concerns into different complaints if the QIO determine that the concerns relate to different episodes of care.

(2) The QIO will use evidence-based standards of care to the maximum extent practicable. If no standard of care exists, the QIO will use available norms, best practices and established guidelines to establish the standard that will be used in completing the review. The QIO's determination regarding the standard used is not subject to appeal.

(b) *Medical information requests*. (1) Upon request by the QIO, a provider or practitioner must deliver all medical information requested in response to a Medicare beneficiary complaint within 14 calendar days of the request. A QIO is authorized to require the receipt of the medical information sooner if the QIO make a preliminary determination that the complaint involves a potential gross and flagrant or substantial quality of care concern as specified in part 1004 of this title and circumstances warrant earlier receipt of the medical information. A practitioner's or provider's failure to comply with the request for medical information within the established timeframe may result in the QIO taking action in accordance with § 476.90.

(2) In requesting medical information in response to a Medicare beneficiary complaint, the QIO must notify the practitioner and/or provider that the medical record is being requested in response to a beneficiary complaint, explain the practitioner's and/or provider's right to discuss the QIO's interim initial determination, and request the name of a contact person in order to ensure timely completion of the discussion.

(c) *Interim initial determination*. The QIO peer reviewer will complete the review and the practitioner and/or provider will be notified of the interim initial determination within 10 calendar days of the receipt of all medical information.

(1) A practitioner and provider will be notified by telephone of the opportunity to discuss the QIO's interim initial determination with the QIO in those situations where the peer reviewer determines that the quality of services does not meet professionally recognized standards of care for any concern in the complaint. The discussion must be held no later than 7 calendar days from the date of the initial offer.

(2) The interim initial determination becomes the final initial determination if the discussion is not completed timely as a result of the practitioner's and/or provider's failure to respond.

(3) Written statements in lieu of a discussion must be received no later than 7 calendar days from the date of the initial offer.

(4) In rare circumstances, the QIO may grant additional time to complete the discussion or submission of a written statement in lieu of a discussion.

(d) *Final initial determination.* The QIO must issue written notification of its final initial determination in those cases in which the QIO has determined that care met professionally recognized standards, as well as in those cases in which the QIO determined that standards were not met and the opportunity for discussion has been completed.

(1) No later than 3 business days after completion of its review, or for cases in which the standard was not met, no later than 3 business days after the discussion or receipt of the provider's and/or practitioner's written statement, the QIO will notify (by telephone) the beneficiary and the provider/practitioner of its final initial determination and of the right to request a reconsideration of the QIO's final initial determination.

(2) Written notice of the QIO's final initial determination will be forwarded to all parties within 5 calendar days after completion of its review, and must include:

(i) A statement for each concern that care did or did not meet the standard of care;

(ii) The standard identified by the QIO for each of the concerns; and

(iii) A summary of the specific facts that the QIO determines are pertinent to its findings, including references to medical information and, if held, the discussion with the involved practitioner and/or provider.

[77 FR 68561, Nov. 15, 2012]

§476.140 Beneficiary complaint reconsideration procedures.

(a) *Right to request a reconsideration.* Beginning with complaints filed after July 31, 2014, a Medicare beneficiary, a provider, or a practitioner who is dissatisfied with a QIO's final initial determination may request a reconsideration by the QIO.

(1) The reconsideration request must be received by the QIO, in writing or by telephone, no later than 3 calendar days following initial notification of the QIO's determination. If the QIO is unable to accept a request, the request must be submitted by noon of the next day the QIO is available to accept a request.

(2) The Medicare beneficiary, or his or her representative, and the practitioner and/or provider must be available to answer any questions or supply any information that the QIO requests in order to conduct its reconsideration.

(3) The QIO must offer the Medicare beneficiary and the practitioner and/or provider an opportunity to provide further information. A Medicare beneficiary, a practitioner, and a provider may, but are not required to, submit evidence to be considered by the QIO in making its reconsideration decision.

(b) *Issuance of the QIO's final decision.* No later than 5 calendar days after receipt of the request for a reconsideration, or, if later, 5 calendar days after receiving any medical or other records needed for such reconsideration, the QIO must complete the review and notify the beneficiary and the practitioner/provider of its decision.

(1) The QIO's initial notification may be done by telephone, followed by the mailing of a written notice by noon of the next calendar day that includes—

(i) A statement for each concern that care did or did not meet the standard of care;

(ii) The standard identified by the QIO for each of the concerns;

(iii) A summary of the specific facts that the QIO determines are pertinent to its findings; and

(iv) A statement that the letter represents the QIO's final determination and that there is no right to further appeal.

(2) The QIO may provide information to the beneficiary, practitioner, and provider regarding opportunities for improving the care given to patients based on the specific findings of its review and the development of quality improvement initiatives.

[77 FR 68561, Nov. 15, 2012]

§476.150 Abandoned complaints and reopening rights.

(a) *Abandoned complaints.* If a Medicare beneficiary fails to participate or

otherwise comply with the requirements of the beneficiary complaint review process and the QIO does not have sufficient information to complete its review, the QIO may determine that the complaint has been abandoned and—

(1) Inform the parties that its complaint review will be discontinued; and

(2) Inform the beneficiary of his or her right to resubmit a written complaint in accordance with the procedures in § 476.120.

(b) *Reopening complaint reviews.* A QIO may reopen a Medicare beneficiary complaint review using the same procedures that the QIO would use for reopening initial denial determinations and changes as a result of DRG validation, as described in § 476.96.

[77 FR 68561, Nov. 15, 2012]

§ 476.160 General quality of care review procedures.

(a) *Scope of the QIO review.* A QIO may conduct a general quality of care review in accordance with section 1154(a)(1)(B) of the Act.

(1) A QIO may conduct general quality of care reviews based on—

(i) Concerns identified during the course of other QIO review activities;

(ii) Referrals from other sources, including but not limited to individuals, contractors, other Federal or State agencies; or

(iii) Analysis of data.

(2) The QIO's review will focus on all concerns identified by the QIO and/or identified by those who have referred or reported the concerns, with consideration being given to the episode of care related to the concerns.

(3) The QIO will use evidence-based standards of care to the maximum extent practicable. If no standard of care exists, the QIO must use available norms, best practices, and established guidelines to establish the standard that will be used in completing the review. The QIO's determination regarding the standard used is not subject to appeal.

(b) *Medical information requests.* Upon request by the QIO, a provider or practitioner must deliver all medical information requested within 14 calendar days of the request. A QIO is authorized to require the receipt of the medical information sooner if the QIO makes a preliminary determination that the review involves a potential gross and flagrant or substantial quality of care concern and circumstances warrant earlier receipt of the medical information. A practitioner's or provider's failure to comply with the request for medical information within the established timeframe may result in the QIO taking action in accordance with § 476.90.

(c) *Initial determination.* The QIO peer reviewer will complete the review and the practitioner and/or provider will be notified of the initial determination in writing within 10 calendar days of the receipt of all medical information.

[77 FR 68561, Nov. 15, 2012]

§ 476.170 General quality of care reconsideration procedures.

(a) *Right to request a reconsideration.* Beginning with reviews initiated after July 31, 2014, a provider or practitioner who is dissatisfied with a QIO's initial determination may request a reconsideration by the QIO.

(1) The reconsideration request must be received by the QIO, in writing or by telephone, by no later than 3 calendar days following receipt of the QIO's initial determination. If the QIO is unable to accept the request, the request must be submitted by noon of the next day the QIO is available to accept a request.

(2) The practitioner or provider must be available to answer any questions or supply any information that the QIO requests in order to conduct its reconsideration.

(3) The QIO must offer the practitioner or provider an opportunity to provide further information. A practitioner or provider may, but is not required to, submit evidence to be considered by the QIO in making its reconsideration decision.

(b) *Issuance of the QIO's final decision.* No later than 5 calendar days after receipt of the request for a reconsideration, or, if later, 5 calendar days after receiving any medical or other records needed for such reconsideration, the QIO must complete the review and notify the practitioner or provider of its decision.

(1) The QIO's initial notification may be done by telephone, followed by the mailing of a written notice by noon the next calendar day that includes:

(i) A statement for each concern that care did or did not meet the standard of care;

(ii) The standard identified by the QIO for each of the concerns;

(iii) A summary of the specific facts that the QIO determines are pertinent to its findings; and

(iv) A statement that the letter represents the QIO's final determination and that there is no right to further appeal.

(2) The QIO may provide information regarding opportunities for improving the care given to patients based on the specific findings of its review.

[77 FR 68561, Nov. 15, 2012]

PART 478—RECONSIDERATIONS AND APPEALS

Subpart A [Reserved]

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

Subpart A [Reserved]

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

SOURCE: 50 FR 15372, Apr. 17, 1985, unless otherwise noted. Redesignated at 64 FR 66279, Nov. 24, 1999.

§ 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.

[50 FR 15372, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999]

§ 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 1155 of the Act, the following rules apply:

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

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