

## § 476.100

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.

### § 476.100 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

## 42 CFR Ch. IV (10–1–04 Edition)

(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 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**

Sec.

- 478.10 Scope.
- 478.12 Statutory basis.
- 478.14 Applicability.
- 478.15 QIO review of changes resulting from DRG validation.
- 478.16 Right to reconsideration.
- 478.18 Location for submitting requests for reconsideration.
- 478.20 Time limits for requesting reconsideration.
- 478.22 Good cause for late filing of a request for a reconsideration or hearing.
- 478.24 Opportunity for a party to obtain and submit information.
- 478.26 Delegation of the reconsideration function.
- 478.28 Qualifications of a reconsideration reviewer.

478.30 Evidence to be considered by the reconsideration reviewer.

478.32 Time limits for issuance of the reconsidered determination.

478.34 Notice of a reconsidered determination.

478.36 Record of reconsideration.

478.38 Effect of a reconsidered determination.

478.40 Beneficiary's right to a hearing.

478.42 Submitting a request for a hearing.

478.44 Determining the amount in controversy for a hearing.

478.46 Departmental Appeals Board and judicial review.

478.48 Reopening and revision of a reconsidered determination or a hearing decision.

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

**Subpart A [Reserved]**

**Subpart B—Utilization and Quality Control 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: