

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.

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.

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]

Subpart B [Reserved]

Subpart C—Review Responsibilities of Utilization and Quality Control 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 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.

[52 FR 37457, Oct. 7, 1987. Redesignated at 64 FR 66279, Nov. 24, 1999]

§ 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;

§ 476.72

42 CFR Ch. IV (10–1–04 Edition)

(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.

(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.

[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]

§ 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.

[52 FR 37457, Oct. 7, 1987. Redesignated at 64 FR 66279, Nov. 24, 1999]