

## SUBCHAPTER F—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.

[43 FR 32085, July 24, 1978, as amended at 49 FR 7206, Feb. 27, 1984. Redesignated at 50 FR 15327, Apr. 17, 1985, and amended at 50 FR 15328, Apr. 17, 1985; 51 FR 43197, Dec. 1, 1986. Redesignated at 64 FR 66279, Nov. 24, 1999]

#### Subpart B [Reserved]

**Subpart C—Utilization and Quality Control Quality Improvement Organizations**

SOURCE: 49 FR 7207, Feb. 27, 1984, unless otherwise noted. Redesignated at 50 FR 15327, Apr. 17, 1985, and further redesignated at 64 FR 66279, Nov. 24, 1999.

**§ 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 10 percent of the licensed doctors of medicine and osteopathy practicing medicine or surgery in the review area.

(c) In order to meet the requirements of paragraph (a)(2) of this section, an organization must—

- (1) State and have documentation in its files demonstrating that it is com-

posed 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.

[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]

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

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

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

[50 FR 15328, Apr. 17, 1985. 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 or § 462.103;

(b) Identify from among all proposals identified in paragraph (a) of this section all proposals that set forth minimally acceptable plans in accordance with the requirements of § 462.104 and the RFPs;

(c) Assign bonus points not to exceed 10% of the total points available to all physician-sponsored organizations identified in paragraph (b) of this section, consistent with statute; and

(d) Subject to the limitations established by §§ 462.105 and 462.106, award the contract for the given 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]

## PART 476—UTILIZATION AND QUALITY CONTROL REVIEW

### Subpart A—General Provisions

Sec.

476.1 Definitions.

### Subpart B [Reserved]

### Subpart C—Review Responsibilities of Utilization and Quality Control Quality Improvement Organizations (QIOs)

#### GENERAL PROVISIONS

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- 476.104 Coordination of activities.

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

SOURCE: 44 FR 32081, June 4, 1979, unless otherwise noted. 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.