

§ 475.100

(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 has the same meaning as provided in § 476.1 of this chapter.

QIO area means the defined geographic area, such as the State(s), region(s), or community(ies), in which the CMS contract directs the QIO to perform.

Quality improvement initiative has the same meaning as provided in § 476.1 of this chapter.

[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, as amended at 78 FR 75198, Dec. 10, 2013]

Subpart B [Reserved]

Subpart C—Quality Improvement Organizations

SOURCE: 78 FR 75198, Dec. 10, 2013, unless otherwise noted.

§ 475.100 Scope and applicability.

This subpart implements sections 1152 and 1153(b) and (c) of the Social Security Act as amended by section 261 of the Trade Adjustment Assistance Extension Act of 2011. This subpart defines the types of organizations that are eligible to become Quality Improvement Organizations (QIOs) and describes certain steps CMS will take in selecting QIOs.

§ 475.101 Eligibility requirements for QIO contracts.

In order to be eligible for a QIO contract, an organization must meet the following requirements:

(a) Have a governing body that includes at least one individual who is a representative of health care providers and at least one individual who is a representative of consumers.

(b) Demonstrate the ability to perform the functions of a QIO, including—

(1) The ability to meet the eligibility requirements and perform activities as set forth in the QIO Request for Proposal; and

42 CFR Ch. IV (10–1–24 Edition)

(2) The ability to—

(i) Perform case reviews as described in § 475.102; and/or

(ii) Perform quality improvement initiatives as set forth in § 475.103.

(c) Demonstrate the ability to actively engage beneficiaries, families, and consumers, as applicable, in case reviews as set forth in § 475.102, and/or quality improvement initiatives as set forth in § 475.103.

(d) Demonstrate the ability to perform the functions of a QIO with objectivity and impartiality and in a fair and neutral manner.

§ 475.102 Requirements for performing case reviews.

(a) In determining whether or not an organization has demonstrated the ability to perform case review, CMS will take into consideration factors such as:

(1) The organization's proposed processes, capabilities, quantitative, and/or qualitative performance objectives and methodology to perform case reviews;

(2) The organization's proposed involvement of and access to physicians and practitioners in the QIO area with the appropriate expertise and specialization in the areas of health care related to case reviews;

(3) The organization's ability to take into consideration urban versus rural, local, and regional characteristics in the health care setting where the care under review was provided;

(4) The organization's ability to take into consideration evidence-based national clinical guidelines and professionally recognized standards of care; and

(5) The organization's access to qualified information technology (IT) expertise.

(b) In making determinations under this section, CMS may consider characteristics such as the organization's geographic location and size. CMS may also consider prior experience in health care quality improvement that CMS considers relevant to performing case reviews; such prior experience may include prior similar case review experience.

(c) A State government that administers a Medicaid program will be considered incapable of performing case

review in an effective manner, unless the State demonstrates to the satisfaction of CMS that the State agency performing the case review will act with complete objectivity and independence from the Medicaid program.

§ 475.103 Requirements for performing quality improvement initiatives.

(a) In determining whether or not an organization has demonstrated the ability to perform quality improvement initiatives, CMS will take into consideration factors such as:

(1) The organization's proposed processes, capabilities, quantitative, and/or qualitative performance objectives, and methodology to perform quality improvement initiatives;

(2) The organization's proposed involvement of and access to physicians and practitioners in the QIO area with the appropriate expertise and specialization in the areas of health care concerning the quality improvement initiatives;

(3) The organization's access to professionals with appropriate knowledge of quality improvement methodologies and practices; and

(4) The organization's access to qualified information technology (IT) expertise.

(b) In making determinations under this section, CMS may consider characteristics such as the organization's geographic location and size. CMS may also consider prior experience in health care quality improvement that CMS considers relevant to performing quality improvement initiatives; such prior experience may include prior similar quality improvement initiative experience and whether it achieved successful results.

(c) A State government that administers a Medicaid program will be considered incapable of performing quality improvement initiative functions in an effective manner, unless the State demonstrates to the satisfaction of CMS that the State agency performing the quality improvement initiatives will act with complete objectivity and independence from the Medicaid program.

§ 475.104 [Reserved]

§ 475.105 Prohibition against contracting with health care facilities, affiliates, and payor organizations.

(a) *Basic rule.* Except as permitted under paragraph (a)(3) of this section, the following are not eligible for QIO contracts:

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

(2) 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 in the QIO area.

(3) A payor organization, unless the Secretary determines that—

(i) There is no other entity available for an area with which the Secretary can enter into a contract under this part; or

(ii) A payor organization is a more qualified entity to perform one or more of the functions of a QIO described in § 475.101(b), meets all other requirements and standards of this part, and demonstrates to the satisfaction of CMS that, in performing QIO activities, the payor organization will act with complete objectivity and independence from its payor program.

(b) [Reserved]

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

§ 475.106 [Reserved]

§ 475.107 QIO contract awards.

Subject to the provisions of § 475.105, CMS will—

(a) Ensure that all awardees meet the requirements of §§ 475.101 through 475.103, as applicable; and

(b) Award the contract to the selected organization for a specific QIO area for a period of 5 years.