Quality Improvement Organization Manual

Chapter 2 - Eligibility

TABLE OF CONTENTS (Rev. 1, 05-23-03)

2000 - Background - (Rev. 1, 05-23-03)

Every organization performing medical review and conducting quality improvement activities as a Quality Improvement Organization (QIO) must either be sponsored by a significant number of physicians actively practicing in the QIO area, or must have available to it the services of a sufficient number of area physicians to assure adequate peer review.

Any organization submitting a bid to perform QIO review in a QIO area is required to demonstrate that it meets the requirements of physician-access or physician-sponsorship in order to be eligible to compete for the bid.

2010 - Eligibility - (Rev. 1, 05-23-03)

A. Physician-sponsored -- To be eligible as a physician-sponsored organization, the organization must meet the following requirements:

- Be composed (have physicians as owners or members) of at least 20 percent of the licensed doctors of medicine and osteopathy practicing medicine or surgery in the State (e.g., at least 20 percent of the practicing physicians in the State are owners of the QIO, or the QIO is owned by an entity which includes at least 20 percent of the practicing physicians in the State as members); or

- Be composed (have physicians as owners or members) of at least 10 percent of the licensed doctors of medicine and osteopathy practicing medicine or surgery in the State, and demonstrate through means (e.g., letters of support from physicians or physician organizations) acceptable to CMS that the organization is representative of an additional 10 percent of the practicing physicians in the State; and

- Not be a health care facility, health care facility association, or health care facility affiliate.

B. Physician-access -- To be eligible as a physician-access organization, the organization must meet the following requirements:

- Have arrangements with doctors of medicine or osteopathy, licensed and practicing in the State, to conduct review for the organization;

- Have available at least one physician, licensed in the State, from every generally recognized specialty and subspecialty who is in active practice in your review area; and

- Not be a health care facility, health care facility association, or health care facility affiliate.

2020 - Competing for a QIO Contract - (Rev. 1, 05-23-03)

To be eligible to compete for a QIO contract, you must demonstrate in your proposal that your organizational structure meets the definition of either a physician-access or a physician-sponsored organization. The Request for Proposal (RFP) issued by CMS defines the terms of an offeror's bid to compete as a QIO, and states the obligations of the offeror to provide documentation supporting its status as a physician-access or physician-sponsored organization.

A. Competing as a Physician-sponsored Organization -- The RFP stipulates the requirements of an organization claiming eligibility as a physician-sponsored organization. The requirements include:

- Submitting written certifications or a statement of the number of actively practicing physicians in your area who support you as a QIO; and

- Having documentation on file that substantiates the support of individual physicians in your area.

B. Competing as a Physician-access Organization -- The RFP stipulates the requirements of an organization claiming eligibility as a physician-access organization. The requirements include:

- Submitting written certification or a statement that you have available, by arrangement or otherwise, the services of a sufficient number of physicians practicing in your review area to assure adequate peer review of services provided by the various medical specialties and subspecialties in your area.

NOTE: All certificates and statements of physician support are subject to audit by CMS and other government agencies. False certifications or statements are grounds for not awarding or terminating the contract.

C. Priority Status of Competing Physician-sponsored Organizations -- Priority in awarding contracts under a competitive procurement is given to physician-sponsored organizations. Physician-sponsored organizations receive additional points during the proposal evaluation process.

2030 - Additional Requirements for a Physician-access or Physician-sponsored Organization - (Rev. 1, 05-23-03)

An organization proposing to perform review on the basis that it is a physician-sponsored or physician-access organization must include written certification that it is not a health care facility in the QIO area, that it is not an association of health care facilities in the QIO area, or that it is not a health care facility affiliate.

- A "health care facility" is defined as 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 Social Security Act. For example, a health care facility may be a hospital, skilled nursing facility, home health agency, freestanding ambulatory surgical center, or any other entity that provides or supplies direct care to Medicare beneficiaries.

- A "health care facility affiliate" is defined as an organization that has a board on which more than 20 percent of the members are also either a governing board 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.

NOTE: These requirements do not apply to a payer organization if CMS determines that there is no other eligible organization available to perform QIO review.

2200 - Responsibilities of the Board - (Rev. 1, 05-23-03)

Each Quality Improvement Organization (QIO) must have a governing board that performs certain duties to assure the efficient and effective management of the organization. Outline these duties in the proposal to perform review, which you submit to CMS prior to the award of the contract. The duties detailed in your contract must conform to the minimal standards established by CMS in the Request for Proposal (RFP) and this manual.

CMS does not mandate a specific process for selecting board members (e.g., endorsement from community organizations). Thus, you have the flexibility to establish your own methodology for determining who will serve (except as provided below in §2220), how long they will serve, and what services they will perform as a member of your board.

2210 - Health Care Affiliate Limitations - (Rev. 1, 05-23-03)

Federal regulations require that QIO boards cannot be composed of a significant number of individuals with health care facility affiliations. Regulations at 42 CFR 475.105 require that you not have more than 20 percent of the members of your governing body affiliated with a health care facility or association of health care facilities located in the area in any of the following capacities:

- A governing member;
- An officer;
- A partner;
- An owner of five percent or more; or
- A managing employee.

NOTE: The prohibition does not apply to a payer organization if CMS determines that no other eligible organization is available.

2220 - Consumer Representative - (Rev. 1, 05-23-03)

With regard to all new consumer representatives appointed or reappointed to the QIO board as required under §2220 below, appointees shall meet the following appointment criteria in addition to all other requirements as set forth in §2220:

- Understand, or be willing to learn, the specific responsibilities of the QIO;

- Understand, or be willing to learn, the specific requirements of the Statement of Work (SOW) in effect at the time of the appointment; and

- Be willing to persevere in an ongoing process of learning about and developing contacts with major religious, community service, civic, union, consumer, public service, and other organizations in their state that have an interest in health care delivery and health care policy, including organizations that represent disadvantaged communities, rural, and non-English speaking populations.

In addition, appointees shall meet at least four (4) of the following five (5) criteria in order to be eligible for appointment as a consumer representative:

- Have a track record of advocacy in behalf of furthering consumer interests, especially in the area of health care;

- Be knowledgeable about the organizations representing or advocating for seniors in the state;

- Be knowledgeable about the needs and concerns of the diverse groups of Medicare beneficiaries and their caregivers in their state;

- Have a basic understanding of the Medicare program; and

- Have previous experience serving on the governing board of a business, religious organization, union, consumer organization, community service organization, community hospital, school board, or other type of service organization; or have previous experience serving on a governmental or non-governmental policy level commission or advisory council; or have held a governmental or non-governmental management position that involved working with boards or advisory committees or commissions.

In addition, the board must be composed of a diverse group of members so as to reflect, in terms of gender, race, ethnicity, rural/urban, and socio-economic status, the Medicare population of the state. If the current governing board does not meet this criterion, then the QIO must develop a written plan to reconstitute the board within three years to meet the requirements set forth in the previous sentence.

§9353(b) of the Omnibus Budget Reconciliation Act of 1986 amended §1152 of the Social Security Act (the Act) to require you to have at least one consumer representative on your governing board. As a member of the QIO governing board, the consumer representative must live in a State represented by the board. Therefore, if the board is a single State board, the consumer representative must live in the State. If, however, the

board is a joint board of two or more States (in the case of multi-State QIO contracts), the consumer representative may live in any State represented by the board.

QIOs must have a minimum of one consumer representative on each QIO governing board (regardless of the number of QIO areas governed by the board). Therefore, a joint board of two or more States is required to have a minimum of one consumer representative on the joint board. The consumer representative must meet the requirements listed below:

- The consumer representative must be a Medicare beneficiary (fee-for-service or managed care); and

- The consumer representative must not be: (1) a practicing or retired physician or (2) a governing board member, officer, partner, owner of more than five percent interest in a health care facility, or managing employee of a health care facility or association of health care facilities.

A nurse or other non-physician health care practitioner may serve as the consumer representative if he/she meets the other requirements.

QIOs that have a fee-for-service and managed care contract must ensure that each Medicare beneficiary population is adequately represented in QIO matters. Therefore, these QIOs must have a minimum of one consumer representative from the beneficiary population that is not included on the board as a permanent member of at least one appropriate committee/group. In the case of a joint board, there must be a managed care Medicare consumer representative from each QIO area (on the board or on a committee/group) because managed care plans differ from State to State.

Afford the consumer representative the same responsibilities as other non-physician board members. For example, if other non-physician board members participate in the sanction process and vote on sanction actions, then the consumer representative must be allowed to participate in the sanction process and to vote as well. You must assure that Medicare beneficiaries have a voice in the Health Care Quality Improvement Program. Representation on the board is one approach.

Create other positions on your board such as a health care ombudsman or a provider representative, as appropriate.

2230 - Prohibition Against Sanctioned Board Members - (Rev. 1, 05-23-03)

Organizations, which have sanctioned individuals on their boards, are excluded in almost all cases from obtaining contracts as QIOs. §1128 of the Act permits the Secretary to exclude sanctioned entities or entities controlled by sanctioned individuals when the person has direct or indirect ownership interest or controls a five percent or more interest

in the entity. §1128, when read in conjunction with §1124(a)(3) of the Act, excludes those entities having a sanctioned individual:

- As an officer or director, if the entity is organized as a corporation; or
- As a partner in the entity, if the entity is organized as a partnership.

Sanctioned entities or individuals include the following:

- Those who, under the Medicare program or under a State health care program, have been:
    - Convicted of a criminal offense related to the delivery of a health care item or service;
    - Excluded from participation; or
    - Assessed a civil monetary penalty in regard to the abuse of the rules and procedures under §1128A.
- Those convicted under Federal or State law:
    - Of a criminal offense relating to neglect or abuse of patients in connection with the delivery of a health care item or service;
    - Of a criminal offense relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct in connection with the delivery of a health care item or service or with respect to any act of omission in a program operated by or financed in whole or in part by any Federal, State, or local Government agency; or
    - In connection with the interference with or obstruction of any investigation into any criminal offense described above.
- Those convicted under Federal or State law of a criminal offense relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance.

2300 - Background - (Rev. 1, 05-23-03)

§1153(i)(3) of the Social Security Act (the Act) defines an in-State organization as an organization that has its primary place of business in the State in which review will be conducted or that is owned by a parent corporation the headquarters of which is located in that State. A geographic contract region comprising a territory or other area not defined by the boundaries of a State (e.g., the District of Columbia) is considered to be

the equivalent of a State for the purpose of applying the in-State provision of §1153 of the Act to QIO contracts.

Primary place of business is determined as follows:

- If you are designated in only one geographic contract region, then the location of your corporate headquarters, Board of Directors, day-to-day management of your contracts, and place of performance for all contracts determines your primary place of business.

- If, as a single corporate entity, you are designated in more than one geographic contract region, then the location of your corporate headquarters determines your primary place of business.

- If you are a corporate entity subsidiary to another corporate entity, you may qualify as an in-State organization in the State in which you have your primary place of business, regardless of your parent corporation's headquarters location, and regardless of whether the parent may also be designated in-State in the geographic contract region where it maintains its primary place of business. Subsidiary corporate entity's primary place of business is determined according to the criteria set forth above for an organization designated in only one geographic contract region, provided the subsidiary corporation (not the parent corporation) is the entity that holds, and has bound itself to perform, the contract.

2310 - Renewal - (Rev. 1, 05-23-03)

A. Statutory Restriction -- §1153(i) of the Act prohibits renewal of any QIO contract not held by an in-State organization, requiring CMS to provide to potential in-State bidders notice and opportunity to compete for such QIO contracts.

B. Notification Procedures -- Before CMS can renew a QIO that does not meet the requirements to be considered "in-State," CMS must:

- Publish an advance notice in the Federal Register announcing when the QIO's contract will expire and requesting a statement of interest from any in-State organizations interested in competing for the contract. The Federal Register notice must:

    - Be published no later than six months before the date the current QIO contract expires; and

    - Specify the period of time during which an in-State organization may submit a statement of interest for the contract.

NOTE: For purposes of this notice, your status in terms of being considered in-State or out-of-State is assumed to be the same as it was when your current contract was awarded, unless you submit acceptable evidence that you have changed your status (e.g., you are now an in-State organization). Send such evidence to the Contract Officer (CO) and the Project Officer (PO) no later than one year before the date of expiration of your contract to provide sufficient review time.

- Give in-State organizations 21 days from the date of publication of the Federal Register notice to submit a statement of interest to the CO (Office of Acquisitions & Grants) in order to compete for the contract.

NOTE: An interested organization must demonstrate that it meets the definition of an in-State organization at the time it responds to the notice and that it is otherwise an eligible organization in accordance with §§1152 and 1153 of the Act.

- Once an in-State organization expresses an interest in a given QIO contract, CMS must provide for competitive procurement for that contract, and any organization (in-State or out-of-State) may respond to the Request for Proposal.

2320 - Determination - (Rev. 1, 05-23-03)

The CO and the Director of the Office of Clinical Standards and Quality will make a formal decision as to whether the organization:

- Meets the definition of an in-State organization;

- Has submitted an adequate statement of interest within the 21-day timeframe; and

Has demonstrated that it meets, or will meet, the requirements as a physician-sponsored organization or physician-access organization by the date the contract is signed, as specified in 42 CFR 475.102 and 42 CFR 475.103.