duties and functions under Title XI Part B or Title XVIII of the Act.

*QIO interpretations and generalizations on the quality of health care* means an assessment of the quality of care furnished by an individual provider or group of providers based on the QIO's knowledge of the area gained from its medical review experience (e.g., quality review studies) and any other information obtained through the QIO's review activities.

*QIO review system* means the QIO and those organizations and individuals who either assist the QIO or are directly responsible for providing medical care or for making determinations with respect to the medical necessity, appropriate level and quality of health care services that may be reimbursed under the Act. The system includes—

(1) The QIO and its officers, members and employees;

(2) QIO subcontractors;

(3) Health care institutions and practitioners whose services are reviewed;

(4) QIO reviewers and supporting staff;

(5) Data support organizations; and

(6) CMS.

*Quality review study* means an assessment, conducted by or for a QIO, of a patient care problem for the purpose of improving patient care through peer analysis, intervention, resolution of the problem and follow-up.

*Quality review study information* means all documentation related to the quality review study process.

*Reviewer* means review coordinator, physician, or other person authorized to perform QIO review functions.

*Sanction report* means a report filed pursuant to section 1156 of the Act and part 474 of this chapter documenting the QIO's determination that a practitioner or institution has failed to meet obligations imposed by section 1156 of the Act.

*Shared health data system* means an agency or other entity authorized by Federal or State law that is used by the QIO review system to provide information or to conduct or arrange for the collection, processing, and dissemination of information on health care services.

*Subcontractor* means a facility or a non-facility organization under contract with a QIO to perform QIO review functions.

[50 FR 15359, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999; 69 FR 49267, Aug. 11, 2004; 76 FR 26546, May 6, 2011]

### § 480.102 Statutory bases for acquisition and maintenance of information.

(a) Section 1154(a)(7)(C) of the Act requires QIOs to the extent necessary and appropriate to examine the pertinent records of any practitioner or provider of health care services for which payment may be made under Title XVIII of the Act.

(b) Section 1154(a)(9) of the Act requires QIOs to collect and maintain information necessary to carry out their responsibilities under the Act.

(c) Section 1156(a)(3) of the Act requires health care practitioners and providers to maintain evidence of the medical necessity and quality of health care services they provide to Medicare patients as required by QIOs.

### § 480.103 Statutory bases for disclosure of information.

(a) Section 1154(a)(10) of the Act requires QIOs to exchange information with intermediaries and carriers with contracts under sections 1816 and 1842 of the Act, other QIOs, and other public or private review organizations as appropriate.

(b) Section 1160 of the Act provides that QIO information must be held in confidence and not be disclosed except where—

(1) Necessary to carry out the purpose of Title XI Part B of the Act;

(2) Specifically permitted or required under this subpart;

(3) Necessary, and in the manner prescribed under this subpart, to assist Federal and State agencies recognized by the Secretary as having responsibility for identifying and investigating cases or patterns of fraud or abuse;

(4) Necessary, and in the manner prescribed under the subpart to assist Federal or State agencies recognized by the Secretary as having responsibility for identifying cases or patterns involving risks to the public health;

(5) Necessary, and in the manner prescribed under this subpart, to assist appropriate State agencies having responsibility for licensing or certification of providers or practitioners; or

(6) Necessary, and in the manner prescribed under this subpart to assist Federal or State health planning agencies by furnishing them aggregate statistical data on a geographical, institutional or other basis.

[50 FR 15359, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999]

### § 480.104 Procedures for disclosure by a QIO.

(a) *Notice to accompany disclosure.* (1) Any disclosure of information under the authority of this subpart is subject to the requirements in § 480.105 relating to the providing of a notice of the disclosure.

(2) Disclosure of confidential information made under the authority of this subpart, except as provided in § 480.106, must be accompanied by a written statement informing the beneficiary that the information may not be redisclosed except as provided under § 480.107 that limits redisclosure.

(b) *QIO interpretations.* A QIO may provide a statement of comment, analysis, or interpretation to guide the beneficiary in using information disclosed under this subpart.

(c) *Fees.* A QIO may charge a fee to cover the cost of providing information authorized under this subpart. These fees may not exceed the amount necessary to recover the cost to the QIO for providing the information.

(d) *Format for disclosure of public information.* A QIO is required to disclose public information (§ 480.120(a)(6)) only in the form in which it is acquired by the QIO or in the form in which it is maintained for QIO use.

(e) *Medicare provider number.* A QIO must include the provider identification number assigned by the Medicare program on information that CMS requests.

[50 FR 15359, Apr. 17, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999, as amended at 69 FR 49267, Aug. 11, 2004]

### § 480.105 Notice of disclosures made by a QIO.

(a) *Notification of the disclosure of nonconfidential information.* Except as permitted under § 480.106, at least 30 calendar days before disclosure of nonconfidential information, the QIO must notify an identified institution of its intent to disclose information about the institution (other than reports routinely submitted to CMS or Medicare fiscal intermediaries, or to or from QIO subcontractors, or to or from the institution) and provide the institution with a copy of the information. The institution may submit comments to the QIO that must be attached to the information disclosed if received before disclosure, or forwarded separately if received after disclosure.

(b) *Notification of the disclosure of confidential information.* (1) A QIO must notify the practitioner who has treated a patient, of a request for disclosure to the patient or patient representative in accordance with the requirements and exceptions to the requirements for disclosure specified under § 480.132.

(2) A QIO must notify a practitioner or institution of the QIO's intent to disclose information on the practitioner or institution to an investigative or licensing agency (§§ 480.137 and 480.138) except for cases specified in § 480.106 involving fraud or abuse or imminent danger to individuals or the public health. The practitioner or institution must be notified and provided a copy of the information to be disclosed at least 30 calendar days before the QIO discloses the identifying information. The QIO must forward with the information any comments submitted by the practitioner or institution in response to the QIO notice if received before disclosure, or forwarded separately if received after disclosure.

[50 FR 15359, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999, as amended at 69 FR 49267, Aug. 11, 2004]

### § 480.106 Exceptions to QIO notice requirements.

(a) *Imminent danger to individuals or public health.* When the QIO determines that requested information is necessary to protect against an imminent danger to individuals or the public health, the notification required in