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regarding the appropriateness of direct disclosure to the patient; and

(ii) Must provide only the information used to support that determination in accordance with the procedures for disclosure of information relating to determinations under § 473.24.

(2) A QIO must disclose information regarding QIO deliberations only as specified in § 476.139(a).

(3) A QIO must disclose quality review study information only as specified in § 476.140.

(c) *Manner of disclosure.* (1) The QIO must disclose the patient information directly to the patient unless knowledge of the information could harm the patient.

(2) If knowledge of the information could harm the patient, the QIO must disclose the information to the patient's designated representative.

(3) If the patient is mentally, physically or legally unable to designate a representative, the QIO must disclose the information to a person whom the QIO determines is responsible for the patient.

The QIO must first attempt to make that determination based on the medical record. If the responsible person is not named in the medical record, then the QIO may rely on the attending practitioner for the information. If the practitioner is unable to provide a name, then the QIO must make a determination based on other reliable information.

[50 FR 15359, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999]

§ 480.133 Disclosure of information about practitioners, reviewers and institutions.

(a) *General requirements for disclosure.* Except as specified in paragraph (b) of this section, the following provisions are required of the QIO.

(1) *Disclosure to the identified individual or institution.* A QIO must disclose, to particular practitioners, reviewers and institutions, information about themselves, upon request, and may disclose it to them without a request.

(2) *Disclosure to others.* (i) A QIO must disclose to an institution, upon request, information on a practitioner to

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the extent that the information displays practice or performance patterns of the practitioner in that institution.

(ii) In accordance with section 1160 of the Act, a QIO must disclose information that displays practice or performance patterns of a practitioner or institution in accordance with the procedures for disclosures specified in §§ 476.137 and 476.138 to—

(A) Federal and State agencies that are responsible for the investigation of fraud and abuse of the Medicare or Medicaid programs, and

(B) Federal and State agencies that are responsible for licensing and certification of practitioners and providers.

(iii) A QIO may disclose to any person, agency or organization, information on a particular practitioner or reviewer with the consent of that practitioner or reviewer provided that the information does not identify other individuals.

(b) *Exceptions.* (1) If the request is in connection with an initial denial determination or a change resulting from a diagnostic related group (DRG) coding validation under Part 466 of this subchapter, the QIO must provide only the information used to support that determination in accordance with the procedures for disclosure of information relating to determinations under § 473.24.

(2) A QIO must disclose information regarding QIO deliberations only as specified in § 476.139(a).

(3) A QIO must disclose quality review study information only as specified in § 476.140.

[50 FR 15359, Apr. 17, 1985, as amended at 52 FR 37458, Oct. 7, 1987; 52 FR 47004, Dec. 11, 1987. Redesignated at 64 FR 66279, Nov. 24, 1999]

§ 480.134 Verification and amendment of QIO information.

(a) A QIO must verify the accuracy of its information concerning patients, practitioners, reviewers, and institutions and must permit the individual or institution to request an amendment of pertinent information that is in the possession of the QIO.

(b) If the QIO agrees with the request for amendment, the QIO must correct the information in its possession. If the information being amended has already

been disclosed, the QIO must forward the amended information to the requester where it may affect decisions about a particular provider, practitioner or case under review.

(c) If the QIO disagrees with the request for amendment, a notation of the request, reasons for the request, and the reasons for refusal must be included with the information and attached to any disclosure of the information.

[50 FR 15358, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999]

§ 480.135 Disclosure necessary to perform review responsibilities.

(a) *Disclosure to conduct review.* The QIO must disclose or arrange for disclosure of information to individuals and institutions within the QIO review system as necessary to fulfill their particular duties and functions under Title XI Part B of the Act.

(b) *Disclosure to consultants and subcontractors.* The QIO must disclose to consultants or subcontractors the information they need to provide specified services to the QIO.

(c) *Disclosure to other QIO and medical review boards.* The QIO must disclose—

(1) To another QIO, information on patients and practitioners who are subject to review by the other QIO; and

(2) To medical review boards established under section 1881 of the Act, confidential information on patients, practitioners and institutions receiving or furnishing end stage renal disease services.

§ 480.136 Disclosure to intermediaries and carriers.

(a) *Required disclosure.* Except as specified in §§ 476.139(a) and 476.140 relating to disclosure of QIO deliberations and quality review study information, a QIO must disclose to intermediaries and carriers QIO information that relates to, or is necessary for, payment of claims for Medicare as follows:

(1) Review determinations and claims forms for health care services, furnished in the manner and form agreed to by the QIO and the intermediary or carrier.

(2) Upon request, copies of medical records acquired from practitioners or institutions for review purposes.

(3) QIO information about a particular patient or practitioner if the QIO and the intermediary or carrier (or CMS if the QIO and the intermediary or carrier cannot agree) determine that the information is necessary for the administration of the Medicare program.

(b) *Optional disclosure.* The QIO may disclose the information specified in paragraph (a) of this section to intermediaries and carriers without a request.

§ 480.137 Disclosure to Federal and State enforcement agencies responsible for the investigation or identification of fraud or abuse of the Medicare or Medicaid programs.

(a) *Required disclosure.* Except as specified in §§ 476.139(a) and 476.140 relating to disclosure of QIO deliberations and quality review study information, the QIO must disclose confidential information relevant to an investigation of fraud or abuse of the Medicare or Medicaid programs, including QIO medical necessity determinations and other information that includes patterns of the practice or performance of a practitioner or institution, when a written request is received from a State or Federal enforcement agency responsible for the investigation or identification of fraud or abuse of the Medicare or Medicaid programs that—

(1) Identifies the name and title of the individual initiating the request,

(2) Identifies the physician or institution about which information is requested, and

(3) States affirmatively that the institution or practitioner is currently under investigation for fraud or abuse of the Medicare or Medicaid programs and that the information is needed in furtherance of that investigation.

(b) *Optional disclosure.* The QIO may provide the information specified in paragraph (a) of this section to Federal or State fraud and abuse enforcement agencies responsible for the investigation or identification of fraud or abuse