

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 PRO must disclose information regarding PRO deliberations only as specified in § 476.139(a).

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

(c) *Manner of disclosure.* (1) The PRO 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 PRO 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 PRO must disclose the information to a person whom the PRO determines is responsible for the patient.

The PRO 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 PRO may rely on the attending practitioner for the information. If the practitioner is unable to provide a name, then the PRO 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 PRO.

(1) *Disclosure to the identified individual or institution.* A PRO 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 PRO must disclose to an institution, upon request, information on a practitioner

to 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 PRO 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 PRO 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 PRO 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 PRO must disclose information regarding PRO deliberations only as specified in § 476.139(a).

(3) A PRO 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 PRO information.

(a) A PRO 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 PRO.

(b) If the PRO agrees with the request for amendment, the PRO must