

§ 480.138

42 CFR Ch. IV (10–1–04 Edition)

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 of the Medicare or Medicaid programs, without a request.

[50 FR 15358, Apr. 17, 1985, as amended at 52 FR 37458, Oct. 7, 1987. Redesignated at 64 FR 66279, Nov. 24, 1999, as amended at 69 FR 49267, Aug. 11, 2004]

§ 480.138 Disclosure for other specified purposes.

(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 licensing and certification bodies.* (i) A QIO must disclose confidential information upon request, to State or Federal licensing bodies responsible for the professional licensure of a practitioner or a particular institution. Confidential information, including QIO medical necessity determinations that display the practice or performance patterns of that practitioner, must be disclosed by the QIO but only to the extent that it is required by the agency to carry out a function within the jurisdiction of the agency under Federal or State law.

(ii) A QIO may provide the information specified in paragraph (a)(1)(i) of

this section to the State or Federal licensing body without request.

(2) *Disclosure to State and local public health officials.* A QIO must disclose QIO information to State and local public health officials whenever the QIO determines that the disclosure of the information is necessary to protect against a substantial risk to the public health.

(3) *Disclosure to the courts.* Patient identified records in the possession of a QIO are not subject to subpoena or discovery in a civil action, including an administrative, judicial or arbitration proceeding.

(b) *Exceptions.* (1) The restriction set forth in paragraph (a)(3) of this section does not apply to HHS, including Inspector General, administrative subpoenas issued in the course of audits and investigations of Department programs, in the course of administrative hearings held under the Social Security Act or to disclosures to the General Accounting Office as necessary to carry out its statutory responsibilities.

(2) A QIO must disclose information regarding QIO deliberations and quality review study information only as specified in §§ 480.139(a) and 480.140.

[50 FR 15359, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999, as amended at 69 FR 49267, Aug. 11, 2004]

§ 480.139 Disclosure of QIO deliberations and decisions.

(a) *QIO deliberations.* (1) A QIO must not disclose its deliberations except to—

- (i) CMS, at the QIO office or at a sub-contracted organization;
- (ii) CMS, to the extent that the deliberations are incorporated in sanction and appeals reports; or
- (iii) The Office of the Inspector General, and the General Accounting Office as necessary to carry out statutory responsibilities.

(2) QIO deliberations are not disclosable, either in written form or through oral testimony, in connection with the administrative hearing or review of a beneficiary's claim.

(b) *Reasons for QIO decisions.* (1) A QIO may disclose to those who have access to QIO information under other provisions of this subpart, the reasons

for QIO decisions pertaining to that information provided that the opinions or judgements of a particular individual or practitioner cannot be identified.

(2) A QIO must disclose, if requested in connection with the administrative hearing or review of a beneficiary's claim, the reasons for QIO decisions. The QIO must include the detailed facts, findings and conclusions supporting the QIO's determination. The QIO must insure that the opinions or judgements of a particular individual or practitioner cannot be identified through the materials that are disclosed.

§ 480.140 Disclosure of quality review study information.

(a) A QIO must disclose, onsite, quality review study information with identifiers of patients, practitioners or institutions to—

(1) Representatives of authorized licensure, accreditation or certification agencies as is required by the agencies in carrying out functions which are within the jurisdiction of such agencies under state law; to federal and state agencies responsible for identifying risks to the public health when there is substantial risk to the public health; CMS; or to Federal and State fraud and abuse enforcement agencies;

(2) An institution or practitioner, if the information is limited to health care services furnished by the institution or practitioner; and

(3) A medical review board established under section 1881 of the Act pertaining to end-stage renal disease facilities, if the information is limited to health care services subject to its review.

(b) A QIO must disclose quality review study information with identifiers of patients, practitioners or institutions to the Office of the Inspector General and the General Accounting Office as necessary to carry out statutory responsibilities.

(c) A QIO may disclose information offsite from a particular quality review study to any institution or practitioner involved in that study, provided the disclosed information is limited to that institution or practitioner.

(d) A QIO may disclose quality review study information with identifiers of particular practitioners or institutions, or both, at the written request of, or with the written consent of, the identified practitioner(s) or institution(s).

(1) The consent or request must specify the information that is to be disclosed and the intended recipient of the information.

(2) The recipient of the information has the same redisclosure rights and responsibilities as the requesting or consenting practitioner or institution as provided under this Subpart B.

(e) An institution or group of practitioners may redisclose quality review study information, if the information is limited to health care services they provided.

(f) Quality review study information with patient identifiers is not subject to subpoena or discovery in a civil action, including an administrative, judicial or arbitration proceeding. This restriction does not apply to HHS, including Inspector General, administrative subpoenas issued in the course of audits and investigations of Department programs, in the course of administrative hearings held under the Social Security Act, or to disclosures to the General Accounting Office as necessary to carry out its statutory responsibilities.

[50 FR 15359, Apr. 17, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999, as amended at 69 FR 49266, Aug. 11, 2004]

§ 480.141 Disclosure of QIO interpretations on the quality of health care.

Subject to the procedures for disclosure and notice of disclosure specified in §§ 480.104 and 480.105, a QIO may disclose to the public QIO interpretations and generalizations on the quality of health care that identify a particular institution.

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

§ 480.142 Disclosure of sanction reports.

(a) The QIO must disclose sanction reports directly to the Office of the Inspector General and, if requested, to CMS.