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

(i) CMS; or

(ii) The Office of the Inspector General, and the Government Accountability 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.

[50 FR 15359, Apr. 17, 1985,, as amended at 76 FR 26547, May 6, 2011; 77 FR 68564, Nov. 15, 2012]

§ 480.140 Disclosure of quality review study information.

(a) A QIO must disclose 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; 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 beneficiary of the information.

(2) The beneficiary 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.

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

(1) For purposes of quality improvement. Activities include, but are not limited to, data validation, measurement, reporting, and evaluation.

(2) As requested by CMS when CMS deems it necessary for purposes of overseeing and planning QIO program activities.

[50 FR 15359, Apr. 17, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999, as amended at 69 FR 49266, Aug. 11, 2004; 75 FR 19826, Apr. 15, 2010; 76 FR 26547, May 6, 2011]

§ 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.

(b) The QIO must upon request, and may without a request, disclose sanction reports to State and Federal agencies responsible for the identification, investigation or prosecution of cases of fraud or abuse in accordance with § 480.137.

(c) CMS will disclose sanction determinations in accordance with part 474 of this chapter.

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

§ 480.143 QIO involvement in shared health data systems.

(a) *Information collected by a QIO.* Except as prohibited in paragraph (b) of this section, information collected by a QIO may be processed and stored by a cooperative health statistics system established under the Public Health Service Act (42 U.S.C. 242k) or other State or Federally authorized shared data system.

(b) *QIO participation.* A QIO may not participate in a cooperative health statistics system or other shared health data system if the disclosure rules of the system would prevent the QIO from complying with the rules of this part.

(c) *Disclosure of QIO information obtained by a shared health data system.* QIO information must not be disclosed by the shared health data system unless—

(1) The source from which the QIO acquired the information consents to or requests disclosure; or

(2) The QIO requests the disclosure of the information to carry out a disclosure permitted under a provision of this part.

§ 480.144 Access to QIO data and information.

CMS may approve the requests of researchers for access to QIO confidential information not already authorized by other provisions in 42 CFR part 480.

[76 FR 26547, May 6, 2011]

§ 480.145 Beneficiary authorization of use of confidential information.

(a) Except as otherwise provided under this Part, a QIO may not use or disclose a beneficiary's confidential information without an authorization from the beneficiary. The QIO's use or disclosure must be consistent with the authorization.

(b) A valid authorization is a document that contains the following:

(1) A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion.

(2) The name or other specific identification of the QIO(s) and QIO point(s) of contact making the request to use or disclose the information.

(3) The name or other specific identification of the person(s), or class of