

§ 480.115

42 CFR Ch. IV (10-1-03 Edition)

collecting information under authority of this part, must collect only that information which is necessary to accomplish the purposes of Title XI Part B of the Act in accordance with 44 U.S.C. Chapter 35, Coordination of Federal Reporting Services Information Policy.

those identifiers are no longer necessary.

QIO RESPONSIBILITIES

(2) The QIO must destroy or return to the facility from which it was collected confidential information generated from computerized information, patient records and other noncomputerized files when the QIO determines that the maintenance of hard copy is no longer necessary to serve the specific purpose for which it was obtained or generated.

§ 480.115 Requirements for maintaining confidentiality.

(a) Responsibilities of QIO officers and employees. The QIO must provide reasonable physical security measures to prevent unauthorized access to QIO information and to ensure the integrity of the information, including those measures needed to secure computer files. Each QIO must instruct its officers and employees and health care institution employees participating in QIO activities of their responsibility to maintain the confidentiality of information and of the legal penalties that may be imposed for unauthorized disclosure of QIO information.

(f) Data system procedures. The QIO must assure that organizations and consultants providing data services to the QIO have established procedures for maintaining the confidentiality of QIO information in accordance with requirements defined by the QIO and consistent with procedures established under this part.

(b) Responsible individuals within the QIO. The QIO must assign a single individual the responsibility for maintaining the system for assuring the confidentiality of information within the QIO review system. That individual must notify CMS of any violations of these regulations.

§ 480.116 Notice to individuals and institutions under review.

The QIO must establish and implement procedures to provide patients, practitioners, and institutions under review with the following information—

(c) Training requirements. The QIO must train participants of the QIO review system in the proper handling of confidential information.

(d) Authorized access. An individual participating in the QIO review system on a routine or ongoing basis must not have authorized access to confidential QIO information unless that individual—

- (a) The title and address of the person responsible for maintenance of QIO information;
- (b) The types of information that will be collected and maintained;
- (c) The general rules governing disclosure of QIO information; and
- (d) The procedures whereby patients, practitioners, and institutions may obtain access to information about themselves.

(1) Has completed a training program in the handling of QIO information in accordance with paragraph (c) of this section or has received comparable training from another source; and

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(2) Has signed a statement indicating that he or she is aware of the legal penalties for unauthorized disclosure.

§ 480.120 Information subject to disclosure.

Subject to the procedures for disclosure and notice of disclosure specified in §§ 476.104 and 476.105, the QIO must disclose—

(e) Purging of personal identifiers. (1) The QIO must purge or arrange for purging computerized information, patient records and other noncomputerized files of all personal identifiers as soon as it is determined by CMS that

- (a) Nonconfidential information to any person upon request, including—
  - (1) The norms, criteria, and standards it uses for initial screening of cases, and for other review activities;
  - (2) Winning technical proposals for contracts from the Department, and

winning technical proposals for sub-contracts under those contracts (except for proprietary or business information);

(3) Copies of documents describing administrative procedures, agreed to between the QIO and institutions or between a QIO and the Medicare intermediary or Medicare carrier;

(4) Routine reports submitted by the QIO to CMS to the extent that they do not contain confidential information.

(5) Summaries of the proceedings of QIO regular and other meetings of the governing body and general membership except for those portions of the summaries involving QIO deliberations, which are confidential information and subject to the provisions of § 476.139;

(6) Public information in its possession;

(7) Aggregate statistical information that does not implicitly or explicitly identify individual patients, practitioners or reviewers;

(8) Quality review study information including summaries and conclusions from which the identification of patients, practitioners and institutions has been deleted; and

(9) Information describing the characteristics of a quality review study, including a study design and methodology.

(b) Aggregate statistical information that does not implicitly or explicitly identify individual patients, practitioners or reviewers, to Federal or State health planning agencies (including Health Systems Agencies and State Health Planning and Development Agencies) in carrying out their health care planning and related activities.

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

**§ 480.121 Optional disclosure of non-confidential information.**

A QIO may, on its own initiative, subject to the notification requirements in § 476.105, furnish the information available under § 476.120 to any person, agency, or organization.

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**§ 480.130 Disclosure to the Department.**

Except as limited by §§ 476.139(a) and 476.140 of this subpart, QIOs must disclose all information requested by the Department to it in the manner and form required.

**§ 480.131 Access to medical records for the monitoring of QIOs.**

CMS or any person, organization or agency authorized by the Department or Federal statute to monitor a QIO will have access to medical records maintained by institutions or health care practitioners on Medicare patients. The monitor can require copies of the records.

**§ 480.132 Disclosure of information about patients.**

(a) *General requirements for disclosure.* Except as specified in paragraph (b) of this section, a QIO must—

(1) Disclose patient identified information in its possession to the identified patient or the patient's representative if—

(i) The patient or the patient's representative requests the information in writing;

(ii) The request by a patient's representative includes the designation, by the patient, of the representative; and

(iii) All other patient and practitioner identifiers have been removed.

(2) Seek the advice of the attending practitioner that treated the patient regarding the appropriateness of direct disclosure to the patient 15 days before the QIO provides the requested information. If the attending practitioner states that the released information could harm the patient, the QIO must act in accordance with paragraph (c)(2) of this section. The QIO must make disclosure to the patient or patient's representative within 30 calendar days of receipt of the request.

(b) *Exceptions.* (1) If the request is in connection with an initial denial determination under section 1154(a)(3) of the Act, the QIO—

(i) Need not seek the advice of the practitioner that treated the patient