

receiver of the information is authorized under its own authorities to acquire the information directly from the source, the receiver may disclose the information in accordance with the source's redisclosure rules;

(f) As necessary for the General Accounting Office to carry out its statutory responsibilities;

(g) Information pertaining to a patient or practitioner may be disclosed by that individual provided it does not identify any other patient or practitioner;

(h) An institution may disclose information pertaining to itself provided it does not identify an individual patient or practitioner;

(i) Governmental fraud or abuse agencies and State licensing or certification agencies recognized by CMS may disclose information as necessary in a judicial, administrative or other formal legal proceeding resulting from an investigation conducted by the agency;

(j) State and local public health officials to carry out their responsibilities, as necessary, to protect against a substantial risk to the public health; or

(k) As necessary for the Office of the Inspector General to carry out its statutory responsibilities.

[50 FR 15359, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999]

**§ 480.108 Penalties for unauthorized disclosure.**

A person who discloses information not authorized under Title XI Part B of the Act or the regulations of this part will, upon conviction, be fined no more than \$1,000, or be imprisoned for no more than six months, or both, and will pay the costs of prosecution.

**§ 480.109 Applicability of other statutes and regulations.**

The provisions of 42 U.S.C. 290dd-3 and 290ee-3 governing confidentiality of alcohol and drug abuse patients' records, and the implementing regulations at 42 CFR part 2, are applicable to QIO information.

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

QIO ACCESS TO INFORMATION

**§ 480.111 QIO access to records and information of institutions and practitioners.**

(a) A QIO is authorized to have access to and obtain records and information pertinent to the health care services furnished to Medicare patients, held by any institution or practitioner in the QIO area. The QIO may require the institution or practitioner to provide copies of such records or information to the QIO.

(b) A QIO may obtain non-Medicare patient records relating to review performed under a non-Medicare QIO contract if authorized by those patients in accordance with State law.

(c) In accordance with its quality review responsibilities under the Act, a QIO may have access to and obtain information from, the records of non-Medicare patients if authorized by the institution or practitioner.

(d) A QIO may reimburse for requested information at the rate of \$.10 per page for photocopying plus first class postage. The photocopying amount includes the cost of labor, supplies, equipment, and overhead.

[50 FR 15359, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999, as amended at 65 FR 83154, Dec. 29, 2000]

**§ 480.112 QIO access to records and information of intermediaries and carriers.**

A QIO is authorized to have access to and require copies of Medicare records or information held by intermediaries or carriers if the QIO determines that the records or information are necessary to carry out QIO review responsibilities.

**§ 480.113 QIO access to information collected for QIO purposes.**

(a) Institutions and other entities must disclose to the QIO information collected by them for QIO purposes.

(b) Information collected or generated by institutions or practitioners to carry out quality review studies must be disclosed to the QIO.

**§ 480.114 Limitation on data collection.**

A QIO or any agent, organization, or institution acting on its behalf, that is

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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

DISCLOSURE OF NONCONFIDENTIAL INFORMATION

(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