

any time, if the reconsidered determination, review, or decision was obtained through fraud or a similar abusive practice that does not support a formal finding of fraud.

[50 FR 15372, Apr. 17, 1985, as amended at 61 FR 32349, June 24, 1996; 62 FR 25855, May 12, 1997]

PART 476—ACQUISITION, PROTECTION, AND DISCLOSURE OF PEER REVIEW INFORMATION

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A [Reserved]

Subpart B—Utilization and Quality Control Peer Review Organizations (PROs)

SOURCE: 50 FR 15359, Apr. 17, 1985, unless otherwise noted.

GENERAL PROVISIONS

§ 476.101 Scope and definitions.

(a) *Scope.* This subpart sets forth the policies and procedures governing—

(1) Disclosure of information collected, acquired or generated by a Utilization and Quality Control Peer Review Organization (PRO) (or the review component of a PRO subcontractor) in performance of its responsibilities under the Act and these regulations; and

(2) Acquisition and maintenance of information by a PRO to comply with its responsibilities under the Act.

(b) *Definitions.* As used in this part:

Abuse means any unlawful conduct relating to items or services for which payment is sought under Title XVIII of the Act.

Aggregate statistical data means any utilization, admission, discharge or diagnostic related group (DRG) data arrayed on a geographic, institutional

or other basis in which the volume and frequency of services are shown without identifying any individual.

Confidential information means any of the following:

(1) Information that explicitly or implicitly identifies an individual patient, practitioner or reviewer.

(2) Sanction reports and recommendations.

(3) Quality review studies which identify patients, practitioners or institutions.

(4) PRO deliberations.

Health care facility or *facility* means an organization involved in the delivery of health care services or items for which reimbursement may be made in whole or in part under Title XVIII of the Act.

Implicitly identify(ies) means data so unique or numbers so small so that identification of an individual patient, practitioner or reviewer would be obvious.

Non-facility organization means a corporate entity that: (1) Is not a health care facility; (2) is not a 5 percent or more owner of a facility; and (3) is not owned by one or more health care facilities in the PRO area.

Patient representative means—(1) an individual designated by the patient, in writing, as authorized to request and receive PRO information that would otherwise be disclosable to that patient; or (2) an individual identified by the PRO in accordance with § 476.132(c)(3) when the beneficiary is mentally, physically or legally unable to designate a representative.

Practitioner means an individual credentialed within a recognized health care discipline and involved in providing the services of that discipline to patients.

PRO deliberations means discussions or communications (within a PRO or between a PRO and a PRO subcontractor) including, but not limited to, review notes, minutes of meetings and any other records of discussions and judgments involving review matters regarding PRO review responsibilities and appeals from PRO determinations, in which the opinions of, or judgment about, a particular individual or institution can be discerned.

PRO information means any data or information collected, acquired or generated by a PRO in the exercise of its duties and functions under Title XI Part B or Title XVIII of the Act.

PRO interpretations and generalizations on the quality of health care means an assessment of the quality of care furnished by an individual provider or group of providers based on the PRO's knowledge of the area gained from its medical review experience (e.g., quality review studies) and any other information obtained through the PRO's review activities.

PRO review system means the PRO and those organizations and individuals who either assist the PRO or are directly responsible for providing medical care or for making determinations with respect to the medical necessity, appropriate level and quality of health care services that may be reimbursed under the Act. The system includes—

(1) The PRO and its officers, members and employees;

(2) PRO subcontractors;

(3) Health care institutions and practitioners whose services are reviewed;

(4) PRO reviewers and supporting staff; and

(5) Data support organizations.

Public information means information which has been disclosed to the public.

Quality review study means an assessment, conducted by or for a PRO, of a patient care problem for the purpose of improving patient care through peer analysis, intervention, resolution of the problem and follow-up.

Quality review study information means all documentation related to the quality review study process.

Reviewer means review coordinator, physician, or other person authorized to perform PRO review functions.

Sanction report means a report filed pursuant to section 1156 of the Act and part 474 of this chapter documenting the PRO's determination that a practitioner or institution has failed to meet obligations imposed by section 1156 of the Act.

Shared health data system means an agency or other entity authorized by Federal or State law that is used by the PRO review system to provide information or to conduct or arrange for

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the collection, processing, and dissemination of information on health care services.

Subcontractor means a facility or a non-facility organization under contract with a PRO to perform PRO review functions.

[50 FR 15359, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985]

§ 476.102 Statutory bases for acquisition and maintenance of information.

(a) Section 1154(a)(7)(C) of the Act requires PROs to the extent necessary and appropriate to examine the pertinent records of any practitioner or provider of health care services for which payment may be made under Title XVIII of the Act.

(b) Section 1154(a)(9) of the Act requires PROs to collect and maintain information necessary to carry out their responsibilities under the Act.

(c) Section 1156(a)(3) of the Act requires health care practitioners and providers to maintain evidence of the medical necessity and quality of health care services they provide to Medicare patients as required by PROs.

§ 476.103 Statutory bases for disclosure of information.

(a) Section 1154(a)(10) of the Act requires PROs to exchange information with intermediaries and carriers with contracts under sections 1816 and 1842 of the Act, other PROs, and other public or private review organizations as appropriate.

(b) Section 1160 of the Act provides that PRO information must be held in confidence and not be disclosed except where—

(1) Necessary to carry out the purpose of Title XI Part B of the Act;

(2) Specifically permitted or required under this subpart;

(3) Necessary, and in the manner prescribed under this subpart, to assist Federal and State agencies recognized by the Secretary as having responsibility for identifying and investigating cases or patterns of fraud or abuse;

(4) Necessary, and in the manner prescribed under the subpart to assist Federal or State agencies recognized by the Secretary as having responsibility

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for identifying cases or patterns involving risks to the public health;

(5) Necessary, and in the manner prescribed under this subpart, to assist appropriate State agencies having responsibility for licensing or certification of providers or practitioners; or

(6) Necessary, and in the manner prescribed under this subpart to assist Federal or State health planning agencies by furnishing them aggregate statistical data on a geographical, institutional or other basis.

[50 FR 15359, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985]

§ 476.104 Procedures for disclosure by a PRO.

(a) *Notice to accompany disclosure.*

(1) Any disclosure of information under the authority of this subpart is subject to the requirements in § 476.105 relating to the providing of a notice of the disclosure.

(2) Disclosure of confidential information made under the authority of this subpart, except as provided in § 476.106, must be accompanied by a written statement informing the recipient that the information may not be redisclosed except as provided under § 476.107 that limits redisclosure.

(b) *PRO interpretations.* A PRO may provide a statement of comment, analysis, or interpretation to guide the recipient in using information disclosed under this subpart.

(c) *Fees.* A PRO may charge a fee to cover the cost of providing information authorized under this subpart. These fees may not exceed the amount necessary to recover the cost to the PRO for providing the information.

(d) *Format for disclosure of public information.* A PRO is required to disclose public information (§ 476.120(a)(6)) only in the form in which it is acquired by the PRO or in the form in which it is maintained for PRO use.

(e) *Medicare provider number.* A PRO must include the provider identification number assigned by the Medicare program on information that HCFA requests.