

§ 476.105 Notice of disclosures made by a PRO.

(a) *Notification of the disclosure of non-confidential information.* Except as permitted under § 476.106, at least 30 calendar days before disclosure of nonconfidential information, the PRO must notify an identified institution of its intent to disclose information about the institution (other than reports routinely submitted to HCFA or Medicare fiscal intermediaries, or to or from PRO subcontractors, or to or from the institution) and provide the institution with a copy of the information. The institution may submit comments to the PRO that must be attached to the information disclosed if received before disclosure, or forwarded separately if received after disclosure.

(b) *Notification of the disclosure of confidential information.* (1) A PRO must notify the practitioner who has treated a patient, of a request for disclosure to the patient or patient representative in accordance with the requirements and exceptions to the requirements for disclosure specified under § 476.132.

(2) A PRO must notify a practitioner or institution of the PRO's intent to disclose information on the practitioner or institution to an investigative or licensing agency (§§ 476.137 and 476.138) except for cases specified in § 476.106 involving fraud or abuse or imminent danger to individuals or the public health. The practitioner or institution must be notified and provided a copy of the information to be disclosed at least 30 calendar days before the PRO discloses the identifying information. The PRO must forward with the information any comments submitted by the practitioner or institution in response to the PRO notice if received before disclosure, or forwarded separately if received after disclosure.

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

§ 476.106 Exceptions to PRO notice requirements.

(a) *Imminent danger to individuals or public health.* When the PRO determines that requested information is necessary to protect against an imminent danger to individuals or the public health, the notification required in

§ 476.105 may be sent simultaneously with the disclosure.

(b) *Fraud or Abuse.* The notification requirement in § 476.105 does not apply if—

(1) The disclosure is made in an investigation of fraud or abuse by the Office of the Inspector General or the General Accounting Office; or

(2) The disclosure is made in an investigation of fraud or abuse by any other Federal or State fraud or abuse agency and the investigative agency specifies in writing that the information is related to a potentially prosecutable criminal offense.

§ 476.107 Limitations on redisclosure.

Persons or organizations that obtain confidential PRO information must not further disclose the information to any other person or organization except—

(a) As directed by the PRO to carry out a disclosure permitted or required under a particular provision of this part;

(b) As directed by HCFA to carry out specific responsibilities of the Secretary under the Act;

(c) As necessary for HCFA to carry out its responsibilities for appeals under section 1155 of the Act or for HCFA to process sanctions under section 1156 of the Act;

(d) If the health care services furnished to an individual patient are reimbursed from more than one source, these sources of reimbursement may exchange confidential information as necessary for the payment of claims;

(e) If the information is acquired by the PRO from another source and the 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

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does not identify an individual patient or practitioner;

(i) Governmental fraud or abuse agencies and State licensing or certification agencies recognized by HCFA 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.

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§ 476.108 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.

§ 476.109 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 PRO information.

[50 FR 15359, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985]

PRO ACCESS TO INFORMATION

§ 476.111 PRO access to records and information of institutions and practitioners.

(a) A PRO 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 PRO area. The PRO may require the institution or practitioner to provide copies of such records or information to the PRO.

(b) A PRO may obtain non-Medicare patient records relating to review performed under a non-Medicare PRO con-

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tract if authorized by those patients in accordance with State law.

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

[50 FR 15359, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985]

§ 476.112 PRO access to records and information of intermediaries and carriers.

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

§ 476.113 PRO access to information collected for PRO purposes.

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

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

§ 476.114 Limitation on data collection.

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

PRO RESPONSIBILITIES

§ 476.115 Requirements for maintaining confidentiality.

(a) *Responsibilities of PRO officers and employees.* The PRO must provide reasonable physical security measures to prevent unauthorized access to PRO information and to ensure the integrity of the information, including those measures needed to secure computer files. Each PRO must instruct its officers and employees and health care institution employees participating in PRO activities of their responsibility