AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO



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 to maintain the confidentiality of information and of the legal penalties that may be imposed for unauthorized disclosure of PRO information.

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

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

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

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

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

(e) *Purging of personal identifiers.* (1) The PRO 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 HCFA that those identifiers are no longer necessary.

(2) The PRO 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 PRO determines that the maintenance of hard copy is no longer necessary to serve the specific purpose for which it was obtained or generated.

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

**§ 476.116 Notice to individuals and institutions under review.**

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

(a) The title and address of the person responsible for maintenance of PRO information;

(b) The types of information that will be collected and maintained;

(c) The general rules governing disclosure of PRO information; and

(d) The procedures whereby patients, practitioners, and institutions may obtain access to information about themselves.

DISCLOSURE OF NONCONFIDENTIAL INFORMATION

**§ 476.120 Information subject to disclosure.**

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

(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 subcontracts under those contracts (except for proprietary or business information);

(3) Copies of documents describing administrative procedures, agreed to between the PRO and institutions or