

§ 21.44

or discussion in such other individual's presence.

(c) The Food and Drug Administration will make every reasonable effort to assure that records made available under this section can be understood by the individual, such as by providing an oral or written explanation of the records.

[42 FR 15626, Mar. 22, 1977, as amended at 46 FR 8458, Jan. 27, 1981]

§ 21.44 Verification of identity.

(a) An individual seeking access to records in a Privacy Act Record System may be required to comply with reasonable requirements to enable the Food and Drug Administration to determine his identity. The identification required shall be suitable considering the nature of the records sought. No identification shall be required to receive access to information that is required to be disclosed to any member of the public under part 20 of this chapter (the public information regulations).

(b) An individual who appears in person for access to records about himself shall be required to provide at least one document to identify himself, e.g., driver's license, passport, or alien or voter registration card to verify his identity. If an individual does not have any such document or requests access to records about himself without appearing in person under circumstances in which his identity cannot be verified from the request itself, he shall be required to certify in writing that he is the individual he claims to be and that he understands that the knowing and willful request for or acquisition of a record pertaining to an individual under false pretenses is a criminal offense subject to a \$5,000 fine.

(c) In making requests under § 21.75, a parent of a minor child or legal guardian of an incompetent individual may be required to verify his relationship to the minor child or the incompetent individual, in addition to verifying his own identity, by providing a copy of the minor's birth certificate, a court order, or other evidence of guardianship.

(d) Where an individual seeks access to particularly sensitive records, such as medical records, the individual may

21 CFR Ch. I (4-1-01 Edition)

be required to provide additional information beyond that specified in paragraph (b) or (c) of this section, such as the individual's years of attendance at a particular educational institution, rank attained in the uniformed services, date or place of birth, names of parents, an occupation, or the specific times the individual received medical treatment.

§ 21.45 Fees.

(a) Where applicable, fees for copying records shall be charged in accordance with the schedule set forth in this section. Fees may only be charged where an individual has requested that a copy be made of a record to which he is granted access. No fee may be charged for making a search of a Privacy Act Record System whether the search is manual, mechanical, or electronic. Where a copy of the record must be made to provide access to the record, e.g., computer printout where no screen reading is available, the copy shall be made available to the individual without cost. Where a medical record is made available to a representative designated by the individual under § 21.33, no fee will be charged.

(b) The fee schedule is as follows:

(1) Copying of records susceptible to photocopying—\$.10 per page.

(2) Copying of records not susceptible to photocopying, e.g., punch cards or magnetic tapes—at actual cost to the determined on a case-by-case basis.

(3) No charge will be made if the total amount of copying for an individual does not exceed \$25.

(c) When a fee is to be assessed, the individual shall be notified prior to the processing of the copies, and be given an opportunity to amend his request. Payment shall be made by check or money order made payable to the "Food and Drug Administration," and shall be sent to the Accounting Branch (HFA-120), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Advance deposit shall be required where the total amount exceeds \$50.

[42 FR 15626, Mar. 22, 1977, as amended at 54 FR 9038, Mar. 3, 1989]