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FINAL RULE - EXCERPT
FDA SORNS 09-10-0010, 09-10-0002, 09-10-0013

FEDERAL REGISTER

Rules and Regulations

Title 45--Public Welfare

SUBTITLE A—DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, GENERAL
ADMINISTRATION

PART 5b—PRIVACY ACT REGULATION

DATE: October 8, 1975

SUMMARY: A notice of proposed rulemaking to implement Section 3 of the Privacy Act of 1974, 5 U.S.C. 552a (hereinafter referred to as the Act) was published in the FEDERAL REGISTER on August 14, 1975 (40 FR 34129). The notice proposed procedures whereby individuals could avail themselves of the provisions of the Act which, among other things (1) permit an individual to determine what records pertaining to him are maintained in a system of records by the Department; (2) permit an individual to gain access to records pertaining to him in such systems of records and to have copies made of any or all such records; and, (3) permit an individual to correct or amend a record pertaining to him in a system of records.

The notice also proposed procedures under which the Department would operate to comply with the provisions of the Act mentioned above as well as other provisions of the Act which impose requirements on federal agencies with respect to the manner in which they collect, use, disseminate and otherwise maintain records which pertain to specific individuals.

Pursuant to the provisions of subsections (j)(2) and (k)(4) of the Act, exemptions from certain provisions of the Act were proposed for four systems of records maintained by the Department.

On September 5, 1975 an additional notice of proposed rulemaking was published in the FEDERAL REGISTER (40 FR 41140) which proposed exemptions pursuant to subsections (j)(2), (k)(2), (k)(4), and (k)(5) for 10 other systems of records.

Five comments were received on the August 14, 1975 proposal. These comments are from an intermediary and a carrier which perform functions under contracts and agreements entered into under §§ 1816 and 1842 of the Social Security Act, 42 U.S.C. 1395h and 1395u, a medical specialty association representing general and family practitioners, a public interest group, and a health statistics consultant. The comments address the proposed inclusion of intermediaries and carriers as a part of the Department, the proposed special procedures for medical records, the prohibition on blanket consents, and the scope of the proposed exemption of systems of records required by statute to be maintained and used solely as statistical records.

No comments were received on those additional exemptions proposed on September 5, 1975.

The comments and recommendations, and the Secretary's conclusion in light of them, are detailed below.

INTERACTION BETWEEN THE FREEDOM OF INFORMATION ACT AND THE PRIVACY ACT
[text omitted]

GENERAL POLICY AND FORMAT
[text omitted]

DEFINITIONS
[text omitted]

MAINTENANCE OF RECORDS
[text omitted]

NOTIFICATION OF OR ACCESS TO RECORDS
[text omitted]

SPECIAL PROCEDURES FOR MEDICAL RECORDS
[text omitted]

CORRECTION OR AMENDMENT OF RECORDS
[text omitted]

DISCLOSURE OF RECORDS
[text omitted]

EXEMPT SYSTEMS

The four exemptions which were proposed in section 5b.9 of the proposed regulation published in the FEDERAL REGISTER on August 14, 1975 and the ten other exemptions which were proposed in a notice published in the FEDERAL REGISTER on September 5, 1975 are included as final exemptions in section 5b.11 of this regulation. As was noted in the preambles of these two proposals, the exemptions are necessary to assure: continued and uninterrupted activity in the area of health services statistical research and the continued cooperation of the sources of such statistical information; the orderly and unbiased conduct of law enforcement investigations, and that efforts by the Department to obtain accurate and objective information relating to an individual's suitability and eligibility for Department employment will not be prejudiced (40 FR 34130-34131, 40 FR 41141).

Two substantive changes have been made. As proposed the fourteen systems of records were exempted from all of those requirements of the Act authorized by subsections (j) and (k). The Department has determined, however, that it is necessary to exempt these systems of records only from the notification and access and correction and amendment provisions of the Act and this regulation. It was also determined that criminal law enforcement systems of records exempt under subsection (j)(2) of the Act need only be additionally exempted from subsection (e)(3) of the Act (requiring agencies to inform individuals whom it asks to provide a record, including the authority for providing the record, whether providing the record is mandatory or voluntary, the principal purpose for maintaining the record, etc.) to the extent that subsection (e)(3) requirements would prejudice the conduct of a criminal investigation.

A provision was also added in the final regulation to...[text omitted]

It is also noted that the Food and Drug Administration system of records, "employee, consultant, contractor security and investigative records," proposed to be exempted in the September 5 notice is divided into two separate systems of records in section 5b.11 of this regulation. These systems are entitled: the "Employee Conduct Investigative Records, HEW/FDA," and the "Service Contractor Employee Investigative Records, HEW/FDA," and are divided to indicate more clearly the specific types of records included in systems of records maintained by the Food and Drug Administration.

APPENDIX A
[text omitted]

Effective date. This regulation is effective immediately on October 3, 1975.

Dated: September 30, 1975.
DAVID MATHEWS,
Secretary.

Sec.

5b.1 Definitions.

5b.2 Purpose and Scope.

5b.3 Policy.

5b.4 Maintenance of records.

5b.5 Notification of or access to records.

5b.6 Special procedures for notification of or access to medical records.

5b.7 Procedures for correction and amendment of records.

5b.8 Appeals of refusals to correct or amend records.

5b.9 Disclosure of records.

5b.10 Parents and Guardians

5b.11 Exempt systems.

5b.12 Contractors.

5b.13 Fees.

Appendix A Employee standards of conduct.

Appendix B Routine uses for multiple systems of records.

Appendix C Delegations of Authority.

AUTHORITY: (5 U.S.C. 301, 5 U.S.C. 552a)

[text omitted]

§ 5b.11 Exempt systems.

(a) *General policy.* The Act permits certain types of specific systems of records to be exempt from some of its requirements. It is the policy of the Department to exercise authority to exempt systems of records only in compelling cases.

(b) *Specific systems of records exempted.* (1) Those systems of records listed in paragraph (b)(2) of this section are exempt from the following provisions of the Act and this Part:

(i) 5 U.S.C. 552a(c)(3) and paragraph (c)(2) of § 5b.9 of this part which require a subject individual to be granted access to an accounting of disclosures of a record.

(ii) 5 U.S.C. 552a(d)(1) through (4) and (f) and §§ 5b.6, 5b.7, and 5b.8 of this part relating to notification of or access to records and correction or amendment of records.

(iii) 5 U.S.C. 552a(e)(4)(G) and (H) which require inclusion of information about Department procedures for notification, access, and correction or amendment of records in the notice for the system of records.

(iv) 5 U.S.C. 552a(e)(3) and paragraph (a)(3) of § 5b.4 of this Part which require that an individual asked to provide a record to the Department be informed of the authority for providing the record (including whether the providing of the record is mandatory or voluntary, the principal purposes for maintaining the record, the routine uses for the record, and what effect his refusal to provide the record may have on him), and if the record is not required by statute or Executive Order to be provided by the individual, he agrees to provide the record. This exemption applies only to an investigatory record compiled by the Department for criminal law enforcement purposes in a system of records exempt under subsection (j)(2) of the Act to the extent that these requirements would prejudice the conduct of the investigation.

(2) The following systems of records are exempt from those provisions of the Act and this part listed in paragraph (b)(1) of this section.

(i) Pursuant to subsection (j)(2) of the Act: [text omitted]

(ii) Pursuant to subsection (k)(2) of the Act: [text omitted]

(iii) Pursuant to subsection (k)(4) of the Act: [text omitted]

(iv) Pursuant to subsection (k)(5) of the Act: [text omitted]

(v) Pursuant to subsections (j)(2), (k)(2), and (k)(5) of the Act:

(A) the Clinical Investigatory Records, HEW/FDA;

(B) the Regulated Industry Employee Enforcement Records, HEW/FDA;

(C) the Employee Conduct Investigative Records, HEW/FDA; and,

(D) text omitted].

(c) *Notification of or access...*[text omitted]

(d) *Discretionary actions...*[text omitted]

§ 5b.12 Contractors.

[text omitted]

§ 5b.13 Fees.

[text omitted]

APPENDIX A

EMPLOYEE STANDARDS OF CONDUCT

[text omitted]

APPENDIX B

ROUTINE USES APPLICABLE TO MORE THAN ONE SYSTEM OF RECORDS MAINTAINED BY HEW

[text omitted]

APPENDIX C

DELEGATIONS OF AUTHORITY [RESERVED]

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