

§5b.10

routine uses listed in appendix B. Appendix B will be published with any compendium of notices of systems of records.

(4) To the Bureau of the Census for purposes of planning or carrying out a census or survey or related activity pursuant to the provisions of Title 13 U.S.C.

(5) To a recipient who has provided the agency with advance written assurance that the record will be used solely as a statistical research or reporting record; *Provided*, That, the record is transferred in a form that does not identify the subject individual.

(6) To the National Archives of the United States as a record which has sufficient historical or other value to warrant its continued preservation by the United States Government, or for evaluation by the Administrator of General Services or his designee to determine whether the record has such value.

(7) To another government agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States for a civil or criminal law enforcement activity if the activity is authorized by law, and if the head of such government agency or instrumentality has submitted a written request to the Department specifying the record desired and the law enforcement activity for which the record is sought.

(8) To an individual pursuant to a showing of compelling circumstances affecting the health or safety of any individual if a notice of the disclosure is transmitted to the last known address of the subject individual.

(9) To either House of Congress, or to the extent of matter within its jurisdiction, any committee or subcommittee thereof, any joint committee of Congress or subcommittee of any such joint committee.

(10) To the Comptroller General, or any of his authorized representatives, in the course of the performance of the duties of the General Accounting Office.

(11) Pursuant to the order of a court of competent jurisdiction.

(c) *Accounting of disclosures.* (1) An accounting of all disclosures of a record will be made and maintained by the

45 CFR Subtitle A (10–1–25 Edition)

Department for 5 years or for the life of the record, whichever is longer; *except that*, such an accounting will not be made:

(i) For disclosures under paragraphs (b) (1) and (2) of this section; and,

(ii) For disclosures made with the written consent of the subject individual.

(2) The accounting will include:

(i) The date, nature, and purpose of each disclosure; and

(ii) The name and address of the person or entity to whom the disclosure is made.

(3) Any subject individual may request access to an accounting of disclosures of a record. The subject individual shall make a request for access to an accounting in accordance with the procedures in §5b.5 of this part. A subject individual will be granted access to an accounting of the disclosures of a record in accordance with the procedures of this part which govern access to the related record. Access to an accounting of a disclosure of a record made under paragraph (b)(7) of this section may be granted at the discretion of the responsible Department official.

§5b.10 Parents and guardians.

For the purpose of this part, a parent or guardian of any minor or the legal guardian or any individual who has been declared incompetent due to physical or mental incapacity or age by a court of competent jurisdiction is authorized to act on behalf of an individual or a subject individual. Except as provided in paragraph (b)(2) of §5b.5, of this part governing procedures for verifying an individual's identity, and paragraph (c) (2) of §5b.6 of this part governing special procedures for notification of or access to a minor's medical records, an individual authorized to act on behalf of a minor or legal incompetent will be viewed as if he were the individual or subject individual.

§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.

Dept. of Health and Human Services

§5b.11

(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 systems of records.

(iv) 5 U.S.C. 552(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:

(A) The Saint Elizabeths Hospital's Court-Ordered Forensic Investigatory Materials Files; and

(B) The Investigatory Material Compiled for Law Enforcement Purposes System, HHS.

(ii) Pursuant to subsection (k)(2) of the Act:

(A) The General Criminal Investigation Files, HHS/SSA;

(B) The Criminal Investigations File, HHS/SSA; and,

(C) The Program Integrity Case Files, HHS/SSA.

(D) Civil and Administrative Investigative Files of the Inspector General, HHS/OS/OIG.

(E) Complaint Files and Log. HHS/OS/OCR.

(F) Investigative materials compiled for law enforcement purposes for the Healthcare Integrity and Protection Data Bank (HIPDB), of the Office of Inspector General. (See §61.15 of this title for access and correction rights under the HIPDB by subjects of the Data Bank.)

(G) Investigative materials compiled for law enforcement purposes for the Program Information Management System, HHS/OS/OCR.

(H) Investigative materials compiled for law enforcement purposes from the CMS Fraud Investigation Database (FID), HHS/CMS.

(I) Investigative materials compiled for law enforcement purposes from the Automated Survey Processing Environment (ASPEN) Complaints/ Incidents Tracking System (ACTS), HHS/CMS.

(J) Investigative materials compiled for law enforcement purposes from the Health Insurance Portability and Accountability Act (HIPAA) Information Tracking System (HITS), HHS/CMS.

(K) Investigative materials compiled for law enforcement purposes from the Organ Procurement Organizations System (OPOS), HHS/CMS.

(L) Investigative materials compiled for law enforcement purposes for the National Practitioner Data Bank (NPDB). (See §60.21 of this subchapter for access and correction rights under the NPDB by subjects of the Data Bank.)

(iii) Pursuant to subsection (k)(4) of the Act:

(A) The Health and Demographic Surveys Conduct in Random Samples of the U.S. Population;

(B) The Health Manpower Inventories and Surveys;

(C) The Vital Statistics for Births, Deaths, Fetal Deaths, Marriages and Divorces Occurring in the U.S. during Each Year; and,

(D) The Maryland Psychiatric Case Register.

§5b.11

(E) The Health Resources Utilization Statistics, DHHS/OASH/NCHS.

(F) National Medical Expenditure Survey Records. HHS/OASH/NCHSR.

(iv) Pursuant to subsection (k)(5) of the Act:

(A) The Investigatory Material Compiled for Security and Suitability Purposes System, HHS;

(B) The Suitability for Employment Records, HHS; and

(C) NIH Electronic Research Administration (eRA) Records, HHS/NIH/OD/OER, 09-25-0225.

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

(A) The Clinical Investigatory Records, HHS/FDA;

(B) The Regulated Industry Employee Enforcement Records, HHS/FDA;

(C) The Employee Conduct Investigative Records, HHS/FDA; and,

(D) The Service Contractor Employee Investigative Records, HHS/FDA.

(vi) Pursuant to subsection (k)(6) of the Act:

(A) The Personnel Research and Merit Promotion Test Records, HHS/SSA/OMA.

(B) [Reserved]

(vii) Pursuant to subsections (k)(2) and (k)(5) of the Act:

(A) Public Health Service Records Related to Investigations of Scientific Misconduct, HHS/OASH/ORI.

(B) Administration: Investigative Records, HHS/NIH/OM/OA/OMA.

(C) FDA Records Related to Research Misconduct Proceedings, HHS/FDA/OC, 09-10-0020.

(D) NIH Records Related to Research Misconduct Proceedings, HHS/NIH, 09-25-0223.

(viii)(A) HHS Insider Threat Program Records, 09-90-1701.

(B) [Reserved]

(ix) Pursuant to subsections (j)(2) and (k)(2) of the Act:

(A) *NIH Police Records, 09-25-0224.* (All law enforcement investigatory records are exempt from subsections (c)(3), (d)(1) through (4), (e)(1), (e)(4)(G) through (I), and (f) of the Act; criminal law enforcement investigatory records are exempt from additional subsections (c)(4), (e)(2) and (3), (e)(5), (e)(8), and (g); the access exemption for non-criminal law enforcement investiga-

45 CFR Subtitle A (10-1-25 Edition)

tory records is limited as provided in subsection (k)(2).)

(B) [Reserved]

(3) The following systems of records are exempt from 5 U.S.C. 552a(c)(3) and §5b.9(c)(3), which require a subject individual to be granted access to an accounting of disclosures of a record; and from 5 U.S.C. 552a(d)(1) through (4) and §§5b.5, 5b.7, and 5b.8, relating to notification of or access to records and correction or amendment of records.

(i) Pursuant to subsection (k)(5) of the Privacy Act:

(A) NIH Division of Loan Repayment Record System, 09-25-0165.

(B) [Reserved]

(ii) Pursuant to subsection (k)(2) of the Privacy Act:

(A) OCSE Federal Case Registry of Child Support Orders (FCR), HHS/ACF/OCSE, 09-80-0385; only records marked with the Family Violence Indicator are exempt, based on the requirements of 42 U.S.C. 653(b)(2).

(B) [Reserved]

(4) The following systems of records are exempt from the following provisions of the Act and this part: 5 U.S.C. 552a(c)(3) and §5b.9(c)(3), which require a subject individual to be granted access to an accounting of disclosures of a record; 5 U.S.C. 552a(d)(1) through (4) and (f) and §§5b.6, 5b.7, and 5b.8, relating to notification of or access to records and correction or amendment of records; and 5 U.S.C. 552a(e)(4)(G) through (I) which require inclusion of information about Department procedures for notification, access, and correction or amendment of records and categories of record sources in the notice for the systems of records.

(i) Pursuant to subsection (k)(2) of the Privacy Act:

(A) ORR Unaccompanied Children Bureau (UCB) Child Abuse or Neglect Investigation Records and Central Registry, 09-80-0323.

(B) [Reserved]

(ii) [Reserved]

(c) *Notification of or access to records in exempt systems of records.* (1) Where a system of records is exempt as provided in paragraph (b) of this section, any individual may nonetheless request notification of or access to a record in that system. An individual shall make requests for notification of or access to a

record in an exempt system of records in accordance with the procedures of §§5b.5 and 5b.6 of this part.

(2) An individual will be granted notification of or access to a record in an exempt system but only to the extent such notification or access would not reveal the identity of a source who furnished the record to the Department under an express promise, and prior to September 27, 1975 an implied promise, that his identity would be held in confidence, if:

(i) The record is in a system of records which is exempt under subsection (k)(2) of the Act and the individual has been, as a result of the maintenance of the record, denied a right, privilege, or benefit to which he would otherwise be eligible; or,

(ii) The record is in a system of records which is exempt under subsection (k)(5) of the Act.

(3) If an individual is not granted notification of or access to a record in a system of records exempt under subsections (k) (2) and (5) of the Act in accordance with this paragraph, he will be informed that the identity of a confidential source would be revealed if notification of or access to the record were granted to him.

(d) *Discretionary actions by the responsible Department official.* Unless disclosure of a record to the general public is otherwise prohibited by law, the responsible Department official may in his discretion grant notification of or access to a record in a system of records which is exempt under paragraph (b) of this section. Discretionary notification of or access to a record in accordance with this paragraph will not be a precedent for discretionary notification of or access to a similar or related record and will not obligate the responsible Department official to exercise his discretion to grant notification of or access to any other record in a system of records which is exempt under paragraph (b) of this section.

[40 FR 47409, Oct. 8, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §5b.11, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.govinfo.gov.

§5b.12 Contractors.

(a) All contracts entered into on or after September 27, 1975 which require a contractor to maintain or on behalf of the Department to maintain, a system of records to accomplish a Department function must contain a provision requiring the contractor to comply with the Act and this part.

(b) All unexpired contracts entered into prior to September 27, 1975 which require the contractor to maintain or on behalf of the Department to maintain, a system of records to accomplish a Department function will be amended as soon as practicable to include a provision requiring the contractor to comply with the Act and this part. All such contracts must be so amended by July 1, 1976 unless for good cause the appeal authority identified in §5b.8 of this part authorizes the continuation of the contract without amendment beyond that date.

(c) A contractor and any employee of such contractor shall be considered employees of the Department only for the purposes of the criminal penalties of the Act, 5 U.S.C. 552a(i), and the employee standards of conduct listed in appendix A of this part where the contract contains a provision requiring the contractor to comply with the Act and this part.

(d) This section does not apply to systems of records maintained by a contractor as a result of his management discretion, *e.g.*, the contractor's personnel records.

§5b.13 Fees.

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