Department of Veterans Affairs Veterans Health Administration Washington, DC 20420 VHA HANDBOOK 1605.1 Transmittal Sheet May 17, 2006

PRIVACY AND RELEASE OF INFORMATION

- **1. PURPOSE.** This Veterans Health Administration (VHA) Handbook revises, consolidates, and updates procedures involving the release of information.
- **2. SUMMARY OF MAJOR CHANGES.** This Handbook provides revised instructions on compliance with the Privacy Act, the Freedom of Information Act, and the release of information from drug and alcohol abuse, infection with the human immunodeficiency virus, and sickle cell anemia medical records. This Handbook also establishes VHA policy regarding the provisions of the Standards of Privacy of Individually-Identifiable Health Information, Title 45 Code of Federal Regulations (CFR) Parts 160 and 164.
- **3. RELATED ISSUES.** VA Handbook 6300.3 through VA Handbook 6300.7.
- **4. FOLLOW-UP RESPONSIBILITY.** The VHA Office of Information, Office of Health Data and Informatics, is responsible for the contents of this Handbook. Questions may be referred to the VHA Privacy Officer at 727-320-1839.
- **5. RESCISSIONS.** VHA Handbook 1605.1, dated December 31, 2002, is rescinded.
- **6. RECERTIFICATION.** This Handbook is scheduled for recertification on or before the last working day of May 2011.

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PRIVACY AND RELEASE OF INFORMATION

1. PURPOSE

This Veterans Health Administration (VHA) Handbook establishes guidance on privacy practices and provides procedures for the use and disclosure of individually-identifiable information and individual's rights in regards to VHA data. This Handbook covers the responsibilities and requirements for compliance with all Federal confidentiality and privacy laws and regulations. When using or disclosing VHA information, all applicable laws and regulations must be reviewed and applied simultaneously to the request. This Handbook is the reference to be used to document and facilitate the appropriate use and disclosure of information residing under the care of VHA.

2. BACKGROUND

- a. VHA, as a component of a government agency, and as a health plan and health care provider, must comply with all applicable privacy and confidentiality statutes and regulations. However, six statutes and sets of regulations are most commonly encountered; these legal provisions are addressed in subparagraph 2b. Questions concerning other confidentiality and privacy legal requirements need to be addressed to local counsel. Generally, the same rules on privacy apply across the Department of Veterans Affairs (VA). However, with the passage of the Health Insurance Portability and Accountability Act (HIPAA) of 1996, there is a distinction between VHA and VA in regards to privacy practices. VHA, for purposes of this Handbook, needs to be considered a separate entity.
- b. There are six statutes that govern the collection, maintenance, and release of information from VHA records. They are:
- (1) The Freedom of Information Act (FOIA), Title 5 United States Code (U.S.C.) 552, implemented by Title 38 Code of Federal Regulations (CFR), Sections 1.550-1.559. FOIA compels disclosure of reasonably described VHA records or a reasonably segregated portion of the records to any person upon written request, unless one or more of nine exemptions apply to the records (see 38 CFR 1.554(a)(1)-(9)). A FOIA request may be made by any person (including foreign citizens), partnerships, corporations, associations, and foreign, State, or local governments. VHA administrative records are made available to the greatest extent possible in keeping with the spirit and intent of FOIA. All FOIA requests must be processed in accordance with the statute, applicable regulations, and paragraph 32 of this Handbook.
- (2) The Privacy Act, 5 U.S.C. 552a, implemented by 38 CFR Section 1.575-1.584. Generally, the Privacy Act provides for the confidentiality of individually identified and retrieved information about living individuals that is maintained in a Privacy Act system of records and permits disclosure of Privacy Act-protected records only when specifically authorized by the statute. The Privacy Act provides that the collection of information about individuals is limited to that which is legally-authorized, relevant, and necessary. All information must be maintained in a manner that precludes unwarranted intrusion upon individual privacy. Information is collected directly from the subject individual to the extent

possible. At the time information is collected, the individual must be informed of the authority for collecting the information, whether providing the information is mandatory or voluntary, the purposes for which the information will be used, and the consequences of not providing the information. The Privacy Act requires VHA to take reasonable steps to ensure that its Privacy Act-protected records are accurate, timely, complete, and relevant. *NOTE:* The information collection requirements of the Paperwork Reduction Act must be met, where applicable.

- (3) The VA Claims Confidentiality Statute, 38 U.S.C. 5701, implemented by 38 CFR Section 1.500-1.527. This statute provides for the confidentiality of all VA patient and claimant names and home addresses (and the names and home addresses of their dependents) and permits disclosure of the information only when specifically authorized by the statute. Title 38 CFR Sections 1.500-1.527, are not to be used in releasing information from patient medical records when in conflict with 38 CFR 1.575-1.584, 38 CFR 1.460-1.496, or 45 CFR Parts 160 and 164.
- (4) Confidentiality of Drug Abuse, Alcoholism and Alcohol Abuse, Human Immunodeficiency Virus (HIV) Infection, and Sickle Cell Anemia Medical Records, 38 U.S.C. 7332, implemented by 38 CFR Section 1.460-1.496. This statute provides for the confidentiality of certain patient medical record information related to drug and alcohol abuse, HIV infection, and sickle cell anemia and permits disclosure of the protected information only when specifically authorized by the statute.
- (5) **HIPAA** (Public Law (Pub. L.) 104-191) implemented by 45 CFR Parts 160 and 164. This statute provides for the improvement of the efficiency and effectiveness of health care systems by encouraging the development of health information systems through the establishment of standards and requirements for the electronic transmission, privacy, and security of certain health information. VHA must comply with the Privacy rules when creating, maintaining, using, and disclosing individually-identifiable health information.
- (6) Confidentiality of Healthcare Quality Assurance Review Records, 38 U.S.C. 5705, implemented by 38 CFR Section 17.500-17.511. This statute provides that records and documents created by VHA as part of a designated medical quality-assurance program are confidential and privileged and may not be disclosed to any person or entity except when specifically authorized by statute.
- c. When following VHA policies, all six statutes are to be applied simultaneously. VA health care facilities need to comply with all statutes, so that the result will be application of the more stringent provision for all uses and/or disclosures of data and in the exercise of the greatest rights of the individual. When an individual requests a copy of the individual's own records, VHA must provide the records to which the individual would be entitled under the Privacy Act, FOIA, and the Right of Access under the HIPAA Privacy Rule. VHA may refuse to provide a copy of the records only where the patient is not entitled to them under any of these legal provisions.

NOTE: De-identified information is not considered to be individually identifiable; therefore, the Privacy Act, HIPAA, and VA Confidentiality statutes 38 U.S.C. 5701 and 7332 do not apply (see App. B).

3. GENERAL POLICY

a. Compliance with Federal Law, Regulation, and VHA Policy

- (1) All VHA employees must comply with all Federal laws and regulations, VA regulations and policies, and VHA policies.
- (2) All employees must conduct themselves in accordance with the rules of conduct concerning the disclosure or misuse of information in the government-wide and VA Standards of Ethical Conduct and Related Responsibilities of Employees (see 5 CFR 2635.101, 5 CFR 2635.703, and 38 CFR 0.735-10).
- (3) All health care facilities must publish a facility or office procedure consistent with the procedures and policies contained in this Handbook; this publication must be distributed to all employees.
- (4) All employees who have access to VHA records must be instructed periodically on the requirements of Federal privacy and information laws and regulations, VA regulations and policies, and VHA policy. Instructions must be provided at the time of employment and within 6 months of any significant change in Federal law, regulation, this policy, and/or facility or office procedures, and as otherwise directed in subparagraph 35h.
- (5) Information about individuals that is retrieved by a personal identifier may not be collected or maintained until proper notifications are given to Congress and the Office of Management and Budget (OMB), and until published in the <u>Federal Register</u> as required by the Privacy Act.
- (6) Each Veterans Integrated Service Network (VISN) and VA medical center or VA Health Care System must designate a Privacy Officer and a FOIA Officer (see 38 CFR 1.556). One employee can serve as both the Privacy Officer and FOIA Officer.

b. Use of Information

- (1) All VHA employees may use information contained in VHA records when they need the records in the official performance of their duties for treatment, payment, and health care operations purposes.
- (2) Where VHA has determined that it is legally permissible to provide access to information or data protected by one or more of the applicable confidentiality or privacy provisions, VHA may do so <u>only</u> after complying with the relevant legal requirements. Sharing of individually-identifiable information within VHA, or between VHA and other VA components, or VHA and VA Contractors must be conditioned on the completion of a data use form, which specifies the conditions for the provision of data. *NOTE:* For VA research see subparagraph 3b(3). A sample suggested data use form is referenced in Appendix E, VHA Data Use Form. Violation of the terms of the agreement will result in termination of the party's

right to future access of such data and may require additional legal action, including referral for criminal prosecution, or in the case of VA employees, disciplinary or other adverse action. Consequently, legal counsel needs to be consulted upon learning of any violation of this agreement.

- (a) A data use form is <u>not</u> required for sharing of individually-identifiable information to meet reporting requirements mandated by law or by VA or VHA Central Office.
- (b) A data use form is <u>not</u> required for sharing of individually-identifiable information for the performance of official VA duties within a VA medical center, VISN, or VHA Program Office, unless network or program office policy so dictates.
- (c) A data use form can be incorporated into a business associate agreement with VA Offices or VA Contractors.
- (3) Sharing of individually-identifiable information for official VA research does <u>not</u> require the completion of a data use form (see par. 13).
- (4) VHA may use a limited data set for the purpose of research, public health, or health care operations. *NOTE:* See paragraph 13 for details regarding research. VHA may use individually-identifiable information to create a limited data set pursuant to a data use agreement (see App. F).
- (5) All VHA employees must only access or use the minimum amount of information from VHA records necessary to fulfill or complete their official VA duties in accordance with VHA Handbook 1605.2.
 - (6) VHA records may be used for VA-approved research purposes as authorized by law.
- (7) Information obtained by VA employees in the performance of official VA duties must not be used for research purposes or publications without approval through appropriate VA authority in accordance with VHA Handbook 1200, 38 CFR Part 16, and this Handbook.

c. Disclosure of Information

NOTE: Throughout this Handbook, various situations are described where information may be disclosed. Such information must not be released unless it is determined that such disclosure is in the best interest of the administration and the record subject (e.g., veteran) unless disclosure is mandated by law or regulation. Questions regarding the appropriateness of such disclosure need to be referred to the local Privacy Officer or the VHA Privacy Officer in advance of the disclosure.

(1) Individually-identifiable information is to be disclosed to requestors with the understanding that it is confidential information that needs to be handled with appropriate sensitivity.

- (2) Disclosure of information must only be made from official VHA records. When the request for disclosure requires copies of official VHA records, the request must be in writing.
- (3) Information from VHA records can only be disclosed or released with the prior signed authorization of the individual or other legal authority as outlined in this Handbook. All disclosures must be covered by or listed in the Information Bulletin (IB) 10-163, VA Notice of Privacy Practices.
- (4) Any individually-identifiable information related to VHA treatment of drug abuse, alcoholism, sickle cell anemia, and testing or treatment for HIV has special protection under 38 U.S.C. Section 7332. The information can only be disclosed as authorized by 38 U.S.C. 7332, and the implementing VA regulations at 38 CFR 1.460 –1.496.
- (5) For sharing of individually-identifiable information with other Federal entities for auditing and oversight, as authorized by law and this Handbook, VHA needs to request the completion of a data use form which specifies the conditions for the provision of data (see App. E). For example, for audits performed by the General Accounting Office (GAO), a data use agreement in this situation is not required, but discretionary.
- (6) Sharing of individually-identifiable information with non-governmental organizations or individuals, as authorized by law and this Handbook, for non-VA research purposes may be conditioned on the completion of a data use form which specifies the conditions for the provision of data. A form similar to the data use form in App. E may be used for this purpose.
- (7) **Limited Data Sets.** A limited data set is protected health information excluding certain direct identifiers in accordance with 45 CFR 164.514(e). VHA may disclose a limited data set for research and public health purposes pursuant to a data use agreement (see App. F).

d. Safeguards

- (1) VHA, including each health care facility, must ensure that appropriate administrative, technical, and physical safeguards are established to ensure the security and confidentiality of individually-identifiable information and records, including protected health information (PHI) and records, and to protect against any anticipated threats or hazards to their security or integrity which would result in substantial harm, embarrassment, inconvenience, or unfairness to any individual on whom information is maintained.
- (2) Each health care facility must develop clear and explicit policies governing employees' auditory privacy when discussing sensitive patient care issues. Employees need to be conscious of when and where it is appropriate to discuss issues involving an individual's identifiable health information.
- (3) Information disclosed via facsimile (fax) or email must strictly adhere to VHA Directive 6210, Automated Information Systems Security.
 - (4) No personal copies of VHA records can be maintained by VHA employees.

4. **DEFINITIONS**

NOTE: The terms defined in statutes, Federal regulations, and this Handbook are intended to have the same meaning. The definitions in the handbook are meant to be easy to understand without changing the legal meaning of the term.

- a. <u>Access.</u> Access is the obtaining or using of information, electronically, on paper or other medium, for the purpose of performing an official function. *NOTE:* For an individual's right of access see <u>Right of Access</u> definition in subpar. 4uu.
- b. <u>Accredited Representative.</u> An accredited representative is a representative of an organization recognized by the Secretary of Veterans Affairs in the presentation of claims under the laws administered by VA, who meets the requirements of 38 CFR 14.629, is accredited by the VA General Counsel, and who holds a veteran's power of attorney.
- c. <u>Associate Chief of Staff (ACOS) for Research and Development (R&D).</u> The ACOS for R&D is the individual with delegated authority for management of the research program at facilities with large, active programs.
- d. <u>Alcohol Abuse.</u> Alcohol abuse is the use of an alcoholic beverage that impairs the physical, mental, emotional, or social well-being of the user.
- e. **Amendment.** An amendment is the authorized alteration of health information by modification, correction, addition, or deletion.
- f. <u>Business Associate</u>. A business associate is an individual, entity, company, or organization who, on behalf of VHA, performs or assists in the performance of functions or activities involving the use or disclosure of PHI or provides certain services to VHA and the provision of those services involves the disclosure of PHI by VHA (see App. A).
 - g. Consolidated Health Record (CHR). See Health Record (subpar. 4y).
- h. <u>Claimant.</u> A claimant is any individual who has filed a claim for benefits, including health benefits, under 38 U.S.C.
- i. <u>Contractor</u>. A contractor is a person who receives compensation for those services provided to VHA, such as: data processing, dosage preparation, laboratory analyses, research, or medical or other professional services.
- j. <u>Court Leave</u>. For the purpose of this Handbook, court leave is the authorized absence from official duty of an employee, without charge to leave or loss of salary, to present records in court or to appear as a witness in the employee's official capacity.
- k. <u>Court Order.</u> A directive or mandate by a judge directing that something be done or prohibiting against some action being taken.

- l. **<u>De-identified Information.</u>** De-identified information is health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual (see App. B).
 - m. **Deletion.** To delete is to remove, erase, or expunge information or data in a record.
- n. <u>Designated Record Set.</u> A Designated Record Set is a group of records maintained by or for VHA that are the medical records and billing records; enrollment, payment, claims, adjudication, and case or medical management records; or used, in whole or part, to make decisions regarding individuals. For the purposes of this Handbook, all designated record sets are covered under a System of Records (see subpar. 4bbb).
- o. <u>Diagnosis</u>. Diagnosis is the identification of a disease, condition, situation, or problem based on the systematic analysis of signs and symptoms.
- p. <u>Disclosure</u>. Disclosure is the release, transfer, provision of access to, or divulging in any other manner information outside VHA. The exception to this definition is when the term is used in the phrase "accounting of disclosures."
- q. **<u>Drug Abuse.</u>** Drug abuse is the use of a psychoactive substance for other than medicinal purposes, which impairs the physical, mental, emotional, or social well-being of the user.
- r. <u>Duly Authorized Representative.</u> The duly authorized representative is an individual authorized in writing by a competent beneficiary or legally appointed guardian to act for the beneficiary.
- s. <u>Extramural Research</u>. Extramural research as defined in Directive 1200 is research performed by investigators not in the employ of VA, but may be under contract with VA. For the purposes of this specific handbook, the privacy requirements for disclosing information to outside entities under contract with VA is covered under Intramural Research (see subpar. 13a.) when the disclosure is necessary for the entity to fulfill the terms of the contract.
- t. **Federal Fiduciary.** The Federal fiduciary is the legal custodian of a beneficiary's VA benefits (see 38 CFR 13.58).
- u. <u>FOIA Officer.</u> Normally, the Chief, Health Information Management Service (HIMS) is designated as the facility FOIA Officer.
- v. <u>Health Care Facility</u>. For the purpose of this Handbook, the term "health care facility" encompasses all offices and facilities, including but not limited to VISNs, VA medical centers, VA Health Care Systems, Community Based Outpatient Clinics (CBOCs), Readjustment Counseling Centers, and Research Centers of Excellence under the jurisdiction of VHA.
- w. <u>Health Care Operations.</u> Health care operations are any of the following activities: conducting quality assessment and improvement activities; population-based activities relating

to improving health or reducing health care costs, protocol development, case management; reviewing competence or qualifications of health care professionals, evaluating practitioner performance, health plan performance, conducting training programs, certification, licensing, or credentialing activities; conducting medical reviews, legal services, and auditing functions; business planning and development; and business management and general administrative activities including management, customer service, and the resolution of internal grievances.

- x. <u>Health Information</u>. Health information is any information created or received by a health care provider or health plan that relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or payment for the provision of health care to an individual. This encompasses information pertaining to examination, medical history, diagnosis, and findings or treatment, including such information as: laboratory examinations, X-rays, microscopic slides, photographs, prescriptions, etc.
- y. Health Record (HR). The HR consists of both the electronic medical record and the paper record, where applicable. The HR is also known as the legal health record. The HR can be comprised of two divisions, the HR and the Administrative Record. The HR includes documentation of all types of health care service provided to an individual in any aspect of health care delivery. The term includes records of care in any health-related setting used by health care professionals while providing patient care services, reviewing patient data, or documenting their own observations, actions, or instructions. The Administrative Record contains the administrative aspects involved in the care of a patient, including demographics, eligibility, billing, correspondence, and other business-related information.
- z. <u>Individually-identifiable Information</u>. Individually-identifiable information is any information, including health information maintained by VHA, pertaining to an individual that also identifies the individual and, except for individually-identifiable health information, is retrieved by the individual's name or other unique identifier. Individually-identifiable health information is covered regardless of whether or not the information is retrieved by name.
- aa. <u>Individually-identifiable Health Information.</u> Individually-identifiable health information is a subset of health information, including demographic information collected from an individual, that is:
 - (1) Created or received by a health care provider, health plan, or health care clearinghouse;
- (2) Relates to the past, present, or future condition of an individual and provision of or payment for health care; and
- (3) Identifies the individual or a reasonable basis exists to believe the information can be used to identify the individual.

NOTE: Individually-identifiable health information does not have to be retrieved by name or other unique identifier to be covered by this Handbook.

bb. <u>Infection with the Human Immunodeficiency Virus (HIV).</u> HIV infection is the presence of laboratory evidence for HIV. For the purposes of this Handbook, the term includes

information related to the testing of an individual for the presence of the virus or antibodies to the virus (including tests with negative results).

- cc. <u>Intramural Research.</u> Intramural research is research performed by VA employees or appointees (including those serving without compensation) at VA facilities and approved offsite locations.
- dd. <u>Law Enforcement Official</u>. A Law Enforcement Official is an officer or employee of any agency or authority of the United States (U.S.), a State, a territory, a political subdivision of a State, a territory, or an Indian tribe, who is empowered by law to conduct the following law enforcement activities:
- (1) Investigate or conduct an official inquiry into a violation or potential violation of law; or
- (2) Prosecute or otherwise conduct a criminal, civil, or administrative proceeding arising from an alleged violation of law.
- ee. <u>Legal Guardian.</u> A legal guardian is a person appointed by a court of competent jurisdiction to maintain and care for the property of an individual, and/or an individual who the court has declared incompetent due to physical or mental incapacity or age. A VA Federal fiduciary is <u>not</u> a legal guardian.
- ff. <u>Limited Data Set.</u> A Limited Data Set is protected health information from which certain specified direct identifiers of the individuals and their relatives, household members, and employers have been removed. These identifiers include name, address (other than town or city, state, or zip code), phone number, fax number, e-mail address, Social Security Number (SSN), medical record number, health plan number, account number, certificate and/or license numbers, vehicle identification, device identifiers, web universal resource locators (URL), internet protocol (IP) address numbers, biometric identifiers, and full-face photographic images. A limited data set is not de-identified information or data. A limited data set may be used for research, health care operations, and public health purposes. VHA may disclose a limited data set for research, health care operations, and public health purposes pursuant to a data use agreement.
- gg. <u>Maintain</u>. For the purpose of this Handbook, "maintain" includes: preserve, collect, use, and disseminate.
- hh. <u>Marketing</u>. Marketing is a communication about a product or service that encourages recipients of the communication to purchase or use the product or service. Marketing excludes communications made: to an individual for treatment, for case management; for recommending alternative treatments or therapies; for recommending alternative health care providers or settings of care; for describing health-related products or services provided by a health care provider; or for describing services, including payment for such services provided by, or included in, a plan of benefits.

- ii. <u>Medical Emergency.</u> A medical emergency is a condition that poses an immediate threat to the health or life of a person that requires immediate medical intervention.
- jj. <u>Next-of-kin.</u> A person related to an individual (e.g. spouse, son, daughter, or sibling). The next-of-kin is not automatically a personal representative of an individual.
- kk. <u>Non-official Records.</u> Non-official records are those records that are maintained and used only by the individual who wrote them. Their maintenance must remain separate from official records. They must not be shown to anyone, nor be required by or under the control of VHA so that the individual who maintains the records may destroy them at any time. These records are not subject to the FOIA. *NOTE:* Any questions concerning whether particular documents are non-official records need to be referred to legal counsel.
- ll. <u>Official Records.</u> Official records are those records that are obtained, created, and maintained by VHA.
- mm. **Patient.** A patient is a recipient of VHA-authorized care under 38 U.S.C.-Veterans' Benefits. This includes, but is not limited to, care in a: VA medical center, nursing home care unit, community nursing home, domiciliary, outpatient clinic or readjustment counseling center.
- nn. <u>Payment.</u> A payment is an activity undertaken by a health plan to obtain premiums, to determine its responsibility for coverage, or to provide reimbursement for the provision of health care including eligibility, enrollment, and authorization for services. It includes activities undertaken by a health care provider to obtain reimbursement for the provision of health care including pre-certification and utilization review. *NOTE:* VHA is both a health plan and a health care provider.
- oo. **Personal Representative.** A personal representative is a person, who under applicable law, has authority to act on behalf of the individual. This may include power of attorney, legal guardianship of an individual, the executor of the estate of a deceased individual, or someone under Federal, state, local or tribal law with such authority (e.g., parent of a minor).
- pp. **Personnel.** For the purpose of this Handbook, the term VA personnel includes those officers and employees of the Department; consultants and attendings; without compensation (WOC); contractors; others employed on a fee basis; medical students and other trainees; and uncompensated services rendered by volunteer workers, excluding patient volunteers, providing a service at the direction of VA staff. *NOTE:* Compensated Work Therapy (CWT) workers are not VHA personnel; they are patients receiving active treatment or therapy.
- qq. <u>Privacy Board.</u> "Privacy Board" is a term created by the Standards for Privacy of Individually-identifiable Health Information (45 CFR Parts 160 and 164) to describe a board comprised of members with varying backgrounds and appropriate professional competencies, as necessary, to review the effect of a research protocol on an individual's privacy rights when an Internal Review Board (IRB) does not.

- rr. **Privacy Officer.** Normally, the Chief, Health Information management Service (HIMS), is designated as the facility Privacy Officer.
- ss. <u>Protected Health Information (PHI)</u>. PHI is individually-identifiable health information maintained in any form or medium. *NOTE:* PHI excludes employment records held by a covered entity in its role as an employer.
- tt. **Psychotherapy Notes.** Psychotherapy notes are notes recorded by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session (or a group, joint, or family counseling session) and that are separated from the rest of the individual's medical record. Psychotherapy notes exclude counseling session times, modalities and frequencies of treatment, results of tests, and any summary of diagnosis, status, treatment plan, or progress to date. Psychotherapy notes are the personal session notes of the mental health professional for use in composing progress notes for the official VHA health record (see 45 CFR 164.501).
- uu. **Record.** A record is any item, collection, or grouping of information about an individual that is VHA maintained, including, but not limited to: education, financial transactions, medical history, treatment, and criminal or employment history that contains the name, or an identifying number, symbol, or other identifying particular assigned to the individual, such as finger or voice print or a photograph. "Records" include information that is stored in any medium including paper; film and electronic media; and computers, minicomputers, and personal computers, or word processors. *NOTE: Tissue samples are not considered a record.*
- vv. **Required by Law.** A mandate contained in Federal, state, local or tribal law that compels an entity to collect, create, use, or disclose PHI and is enforceable under the law. This includes, but is not limited to: court orders, court-ordered warrants, and summons issued by a governmental or tribal inspector general.
- ww. **Research.** For the purposes of this Handbook, "research" is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalized knowledge.
- xx. **Right of Access.** An individual has the right to have access to (e.g., look at, view) or obtain a copy of records pertaining to the individual which contain individually-identifiable information.
- yy. <u>Routine Use.</u> A "routine use" is a Privacy Act discretionary authority published in the <u>Federal Register</u> that permits VHA to disclose information or records from a Privacy Act-protected record without the patient's prior signed authorization. A "routine use" permits the:
- (1) Release of PHI <u>only</u> when disclosure is also authorized by other applicable legal authorities, including 45 CFR Parts 160 and 164; and

- (2) Release of drug or alcohol abuse, HIV, or sickle cell anemia medical information <u>only</u> when the disclosure is also authorized by 38 U.S.C. 7332.
- zz. **Sensitive Information.** For the purposes of this Handbook sensitive information is health information that, with a reasonable degree of medical certainty, is likely to have a serious adverse effect on an individual's mental or physical health if revealed to the individual.
- aaa. <u>Sickle Cell Anemia or Trait.</u> Sickle cell anemia or trait includes any activities relating to testing, diagnosis, treatment, or any other procedure relating to the disease of sickle cell anemia.
- bbb. <u>Subpoena Duces Tecum.</u> A "subpoena duces tecum" is a document issued by, or under, the auspices of a court that requires an individual to produce documents, records, papers, or other evidence to be brought to a judicial court for inspection. A "subpoena duces tecum" is not sufficient authority to authorize the disclosure of Privacy Act-protected records, unless the subpoena is signed by the judge of a court.
- ccc. <u>Subpoena</u>. A subpoena is a document issued by, or under the auspices of, a court to cause an individual to appear and give testimony before a court of law. A subpoena cannot require VHA to disclose Privacy Act-protected records, unless the subpoena is signed by a judge.
- ddd. **System Manager.** The System Manager is the VHA official assigned the responsibility for a Privacy Act-covered system of records as identified in the system description that is published in accordance with VA Handbook 6300.5. The health care facility official with the program assignment is responsible for the maintenance of the records at the facility.
- eee. **System of Records.** The System of Records is a group of Privacy Act-covered records that contains personal information about an individual from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to an individual. The System of Records also includes all designated record sets.
- fff. <u>Treatment</u>. Treatment is the provision, coordination, or management of heath care or related services by one or more health care providers. This includes the coordination of health care by a health care provider with a third-party, consultation between providers relating to a patient, and the referral of a patient for health care from one health care provider to another.
- ggg. <u>Use.</u> "Use" is the sharing, employment, application, utilization, examination, or analysis of information within VHA.
- hhh. Without Compensation (WOC) Appointment. A WOC appointment is a personnel appointment by which an individual contributes time to VA activities but receives no monetary compensation.

5. INDIVIDUALS' RIGHTS

a. The Individual

- (1) Individuals have the right to be provided with a Notice of the privacy practices of VHA concerning individually-identifiable health information. This notice must explain the following: how VHA may use and disclose individually-identifiable health information; the individual's rights regarding the individual's individually-identifiable health information; and VHA's legal duties with respect to individually-identifiable health information (see par. 6).
- (2) Individuals have the right to access and/or view and obtain a copy of their own individually-identifiable information, including PHI, contained in a VA system of records or retrievable by the individual's name (see par. 7).
- (3) Individuals have the right to ask VHA to amend their individually-identifiable information including PHI. This right to amendment must be granted unless authority to deny the request is present (see par. 8).
- (4) Individuals have the right to an accounting of disclosures of their individually-identifiable information (see par. 9).
- (5) Individuals have the right to request VHA send communications regarding individually-identifiable health information by alternative means or at alternative locations. VHA must accommodate reasonable requests (see par. 10).
- (6) Individuals have the right to request VHA to restrict the uses and/or disclosures of the individual's individually-identifiable health information to carry out treatment, payment, or health care operations. Individuals also have the right to request VHA to restrict disclosures of the individual's individually-identifiable health information to next-of-kin, family, or significant others involved in the individual's care. VHA is not required to agree to such restrictions, but if it does, VHA must adhere to the restrictions to which it has agreed, unless information covered under the agreed to restriction is needed to provide a patient with emergency treatment (see par. 11). VHA will not agree to a restriction on a use or disclosure required by law.
- (7) Individuals have the right to file a complaint with VHA (see subpar. 35d). Individuals also have the right to file a complaint to the Secretary of the Department of Health and Human Services (HHS) in accordance with 45 CFR 160.306 when the individual believes VHA did not comply with the provisions of 45 CFR Parts 160 and 164. The right is in addition to any rights that the individual has under the Privacy Act.
- (8) Individuals have the right to refuse to disclose their SSN to VHA. The individual shall not be denied any right, benefit, or privilege provided by law because of refusal to disclose to VHA an SSN (see 38 CFR 1.575(a)).

b. Personal Representatives of the Individual. Personal representatives of the individual are any person(s) who under applicable law has authority to act on behalf of the individual when making decisions related to health care or to act on behalf of a deceased individual. The personal representative of an individual has the ability to exercise the individual's rights stated in subparagraph 5a. A personal representative for the purposes of this Handbook does not necessarily equate to a surrogate for the informed consent process (see 38 CFR Section 17.32(e) for authorized surrogates for informed consent). The following paragraphs provide details on various types of personal representatives for the purposes of this Handbook, such as Power of Attorney (POA) or legal guardian.

(1) Power of Attorney (POA)

(a) A POA is a written document whereby an individual (i.e., principal) appoints another as the individual's agent and confers authority upon the agent to perform certain specified acts or kinds of acts on behalf of the principal. A POA that does not include decisions related to health care in its scope would not authorize the holder to exercise the individual's privacy rights.

(b) Types of POA

- 1. General Power of Attorney (GPOA). A GPOA provides broad authority for the agent to act on behalf of the principal. A GPOA is often written in very general terms often giving the agent the power to act in a variety of situations including the releasing or obtaining of information on behalf of the principal.
- 2. Special POA. A Special POA gives limited authority to an agent to do a particular purpose or function (e.g., cash a check). Two examples of a Special Power of Attorney are: VA Form 21-22, Appointment of Veterans Service Organization as Claimant's Representative, and VA Form 21-22a, Appointment of Individual as Claimant's Representative. These two types of Special Powers of Attorney enable a third-party to act on behalf of a veteran claimant seeking benefits from VA (see 38 CFR Section 14.631).
- 3. <u>Durable Power of Attorney for Health Care (Advance Directive)</u>. Pursuant to State law and VA policy, VA Form 10-0137, Durable Power of Attorney for Health Care, permits a patient to appoint a specific health care agent to make medical decisions on behalf of the patient if the patient is incapable of doing so. This includes decisions as to whether to release and/or obtain medical records and information about the patient, or how such information can be used.
- (c) Regardless of the type of POA that is presented, the reviewer needs to always carefully check the document.
 - 1. With General and Special Powers of Attorneys, the document must be:
 - a. In writing;
 - b. Signed by the individual giving the power;

- c. Dated;
- <u>d</u>. Notarized and signed by a licensed notary public unless using VA Form 21-22 or 21-22a; and
- <u>e</u>. Specifically designated by name a third party agent to act on behalf of the individual, which may be an organization or entity.
- <u>2</u>. A Durable Power of Attorney for Health Care does not have to be notarized. If the preceding conditions are met, the reviewer must review the document to determine the specified acts that the principal has authorized the agent to perform such as reviewing and/or releasing medical records. The original, signed POA is preferred; however, a photocopy of the POA may be accepted.
- <u>3</u>. If there is some question as to the competency of the principal to make decisions, the reviewer needs to determine if the POA authorizes the agent to act even if the principal is deemed to be medically or legally incompetent. If there is no language to that effect in the POA, then the POA is inoperative so long as the principal is determined to be incompetent.
- <u>4</u>. Finally, even if an original POA is presented, VHA employees are <u>not</u> required to honor the POA if there is some question as to the authenticity of the document, or if there are other legal or administrative bases for questioning whether the person holding the POA is acting in the best interest of the principal. In such cases, the local Regional Counsel's office needs to be contacted for guidance.

(2) Legal Guardian

- (a) A legal guardian is a person who has been designated by a court of competent jurisdiction to take care of and to manage the property and rights of another person (an individual) who, due to a defect of age, medical condition, understanding, or self-control, is considered by the court to be incapable of administering the individual's own affairs.
- (b) Depending on the circumstances involved, a court may appoint a legal guardian for a specific purpose. Three of the most common types of guardianships are as follows:
- 1. <u>Legal Guardian of the Person.</u> A legal guardian of the person is an individual appointed by a court of competent jurisdiction to make decisions regarding the personal welfare of the individual. This includes: making decisions regarding the incapacitated individual's health, requesting medical records and authorizing the release of such records to third parties.
- 2. <u>Legal Guardian of the Property</u>. A legal guardian of the property is an individual appointed by a court of competent jurisdiction to make decisions on behalf of another regarding property-related matters. This includes handling funds, real property, and financial transactions on behalf of the individual. Generally, a legal guardian of the property does not have the authority to release medical records unless the guardian can establish that the purpose for the release is related to property-related matters affecting the incapacitated individual.

<u>3</u>. <u>Legal Guardian of the Person and Property</u>. Often a court of competent jurisdiction will appoint an individual as both Legal Guardian of the Property and the Person. In such cases, the Legal Guardian has the authority to make all decisions regarding the person and the property of that person.

(3) Other Authority to Act on Behalf of a Living Individual

- (a) <u>Federal Law</u>. If a Federal law authorizes a person to act on behalf of a living individual, that person is considered a personal representative for the purposes of this Handbook. VHA may disclose individually-identifiable information pursuant to a written authorization from the personal representative.
- (b) Other Law. If under applicable state, local, or tribal law a person has authority to act on behalf of a living individual (e.g. parent of un-emancipated minor) that person is considered a personal representative for the purposes of this Handbook. VHA may disclose individually-identifiable information pursuant to a written authorization from the personal representative.

(4) Authority to Act on Behalf of a Deceased Individual

- (a) <u>Statutory Authority.</u> If a Federal, state, local or tribal law authorizes a person to act on behalf of a deceased individual, or the deceased individual's estate (e.g., executor), that person is considered a personal representative of the deceased for the purposes of this Handbook.

 *NOTE: For disclosures of individually-identifiable information on a deceased individual see subparagraph 31b.
- (b) <u>Next-of-kin</u>. The next-of-kin of a deceased individual, i.e., spouse, parent, adult child, and adult siblings, will be considered a personal representative of the deceased for the purposes of this Handbook. When there is more than one surviving next-of-kin, the personal representative will be determined based on the hierarchy described in 38 CFR Section 17.32(e).

NOTE: The next-of-kin is <u>not</u> a personal representative of a living individual, unless authorized by one of the provisions under subparagraphs 5b(1), 5b(2), or 5b(3).

6. NOTICE OF PRIVACY PRACTICES (see IB 10-163)

- a. An individual has the right to a copy of Information Bulletin (IB) 10-163, VA Notice of Privacy Practices. IB 10-163 includes a notice as to the uses and disclosures of the individual's individually-identifiable health information that may be made by VHA, as well as the individual's rights and VHA's legal duties with respect to individually-identifiable health information.
- b. Even if an individual has requested an electronic copy, the individual still has the right to obtain a paper copy.
- c. An individual who has questions regarding the IB 10-163 needs to be referred to the VA health care facility Privacy Officer.

7. INDIVIDUALS' RIGHT OF ACCESS

a. Verification of Identity

- (1) Individuals who request information from their VHA records must provide sufficient information to verify their identity and to provide assurance that they are not improperly given access to records pertaining to someone else. When an individual appears in person, the requirements need to be limited to various forms of identification that an individual is likely to have available, such as a Veteran Identification Card (VIC), passport, driver's license or employee identification card. When individuals request information from their VHA records by regular mail, verification of identities may include the requestor providing the requestor's social security number and/or comparing the signature and address(es) on the request with the information already contained in the VHA record. *NOTE: Currently, VHA policy does not allow an individual to verify identity by email.*
 - (2) Requests for information where suitable identification is not provided will be denied.

b. Right of Access and/or Review of Records

- (1) Requests for access (to look at or to review) to, or copies of, individually-identifiable information need to be processed in accordance with all Federal laws including FOIA, Privacy Act, and HIPAA. Except as otherwise provided by law or regulation, individuals, upon written request, may gain access to, or copies of, their individually-identifiable information or any other information pertaining to them that is contained in any system of records or designated record set maintained by VHA. Individuals do not have to state a reason or provide justification for wanting to see or to obtain a copy of their requested information. *NOTE:* VA Form 10-5345a, Individual's Request For a Copy of Their Own Health Information, may be used as the written request requirement.
- (2) All requests to review must be received by direct mail, fax, in person, or by mail referral from another agency or VA office. All requests for access must be delivered to, and reviewed by the System Manager for the concerned VHA system of records, the facility Privacy Officer, or their designee. Each request must be date stamped and reviewed to determine whether the request for access should be granted.
- (3) In determining whether to grant a right of access request, the appropriate VHA employee needs to take into consideration whether the:
 - (a) Identity of the requestor can be verified (see subpar. 7a(1)).
- (b) Information requested contains sensitive information. In order to determine if the request contains sensitive information the VHA employee must complete an initial review based on criteria established by the facility Privacy Officer or System Manager for a sensitive record review. If it is determined that the request contains sensitive information, see Appendix D for the appropriate procedures to follow.

- (c) Information request fails to comply with the right of access procedures outlined in this Handbook.
- (d) Information requested has been compiled in reasonable anticipation of a civil action or proceeding.
- (e) System of records, under which the information is covered, has been exempted from the right of access in accordance with applicable laws, including the Privacy Act.
- (f) The information is created or obtained in the course of research that includes treatment. If so, the right of access may be temporarily suspended for as long as the research is in progress provided that the individual has agreed to the denial of access when the individual consented to participate in the research.
- (4) In granting a right of access request, by the System Manager for the concerned VHA system of records, the facility Privacy Officer, or designee, must take reasonable steps to limit disclosure to information pertaining only to the individual making the request. In those situations when an individual's request includes information regarding another individual, the information regarding the other individual is provided only if the information pertains to the requestor.

NOTE: Contact the VHA Privacy Office if further guidance is required.

- (5) Request for access to view a record must be processed as follows:
- (a) When individuals appear in person at a VA health care facility, they must be advised at that time whether right of access or review of records can be granted. When immediate review cannot be granted (e.g., the record contains sensitive information requiring review by a physician to ascertain whether release will adversely affect the individual's physical or mental health (see App. D); the need to retrieve the record from a National Archives and Records Administration (NARA) Records Center; time needed to make the record comprehensible to an individual, i.e., reproducing magnetic tape records in a hard copy form readable by the individual, etc.), necessary arrangements must be made for a later personal review, or if acceptable to the individual, the copies may be furnished by mail.
- (b) Mailed requests must be referred by the System Manager for the concerned VHA system of records, the facility Privacy Officer, or their designee, to the appropriate employee who determines whether the right of access request will be granted. If the record contains sensitive information the record requires review (see App. D). If additional information is required before a request can be processed, the individual must be so advised. If it is determined that a request for review of records will be granted, the individual must be advised by mail that access to view will be given at a designated location, date, and time in the facility, or a copy of the requested record will be provided by mail, if the individual has indicated that a copy is acceptable.

- (c) Fax requests will be accepted <u>only</u> after confirmation from the individual to whom the records pertain has been obtained. The request must be referred to the appropriate employee who must determine whether access will be granted and will be processed, the same as a request received via mail.
- (d) When a request for records has been transferred or referred from another Federal agency or VA office to a health care facility, the requester must be notified of the referral and the request must be processed in the same manner as a request received via mail.
- (e) Email requests will <u>not</u> be accepted until such time as VHA can authenticate the identity of the email sender and accept an electronic signature within an email.
- (6) Whenever a request for review in person of individually-identifiable information is approved, the following procedures apply:
- (a) A VHA employee must be present at all times during any personal review of a record to ensure the integrity of the record.
- (b) Pursuant to 38 CFR 1.577(a) and VA Handbook 6300.4, a person of the individual's own choosing may accompany the individual to review a record. A written statement is required from the individual authorizing discussion of the record in the accompanying person's presence. VA Form 07-5571, Authorization to Disclose a Record in the Presence of a Third Party, needs to be used for obtaining the required signed statement. If the record includes information that pertains to treatment for drug or alcohol abuse, HIV infection, or sickle cell anemia, an additional written authorization is required which meets the requirements of paragraph 14.

(7) Time Frames

- (a) VA health care facilities need to process all requests for review or copies of individually-identifiable information within 20 working days (excludes weekends and Federal holidays) of receipt whenever possible. If it is determined that the right of access request can not be processed within the 20-day time frame, the system manager for the concerned VHA system of records, the Privacy Officer, or the designee, must forward an acknowledgment letter (see subpar. 7b(7)(b)) of the request to the requestor within the same 20 working days.
- (b) When, for good cause, a facility is unable to provide the requested information in a record within the 20 working day period, the individual must be informed in writing as to the reasons why access cannot be provided within the required time frame. The facility must also state when it is anticipated that the record will be available, and this must not exceed 40 working days from receipt of request. VA Form Letter 70-17, Postal Card Acknowledgment of Request, may be used for this purpose except when circumstances in a particular case warrant a specially written letter.

(8) **Fees.** An individual requesting a copy of records or information under Right of Access must be provided the first copy of the requested record or information free of charge (see subpar. 15c).

c. Denial of Access

- (1) A right of access request for a record may be denied in limited circumstances (see subpar. 7b(3)). *NOTE:* For a denial of access due to sensitive records see Appendix D paragraph 4.
- (2) When a right of access request to a record is denied, the System Manager, or designee, for the concerned VHA system of records, the facility Privacy Officer, or designee, must promptly notify the individual of the decision. This notification must:
 - (a) State the reason for the denial;
- (b) Provide the individual's appeal rights to the Office of General Counsel (024), 810 Vermont Ave., N.W., Washington, DC 20420; and
 - (c) Be signed by the VA health care facility Director.

8. RIGHT TO REQUEST AMENDMENT OF RECORDS

- a. An individual has the right to request an amendment to any information or records retrieved by the individual's name or other individually-identifiable information contained in a VA system of records, which includes designated record sets, as provided in 38 CFR 1.579 and 45 CFR 164.526. The right to seek an amendment of this information or records is a personal right of the individual to whom the record pertains.
- b. The request must be in writing and adequately describe the specific information the individual believes to be inaccurate, incomplete, irrelevant, or untimely and the reason for this belief.
- (1) The written request needs to be mailed or delivered to the VA health care facility that maintains the record.
- (2) The individual must be asked to clarify a request that lacks specificity in describing the information for which an amendment is requested in order that a responsive decision may be reached.
- c. A request for amendment of information contained in a system of records must be delivered to the System Manager, or designee, for the concerned VHA system of records, and the facility Privacy Officer, or designee, to be date stamped; and be filed appropriately. In reviewing requests to amend or correct records, the System Manager must be guided by the criteria set forth in VA regulation 38 CFR 1.579. That is, VA must maintain in its records only such information about an individual that is accurate, complete, timely, relevant, and necessary

to accomplish a purpose of VA, as required by law, regulation, executive order of the President, or a government-wide or VA policy implementing such a purpose. These criteria must be applied whether the request is to modify a record, to add material to a record, or to delete information from a record.

- d. When an individual requests amendment of clinical or health information in a medical record maintained at a health care facility, the System Manager for the concerned VHA system of records or designee, and/or the facility Privacy Officer, or designee, must refer the request and related record to the health care provider or physician who is the author of the information to determine if the record needs to be amended. If the health care provider, or physician, is no longer on station, a physician(s) designated by the health care facility Director must determine if the record needs to be amended.
- e. A request to amend a record must be acknowledged in writing within 10 workdays of receipt. If a determination has not been made within this time period, the System Manager for the concerned VHA system of records or designee, and/or the facility Privacy Officer, or designee, must advise the individual when the facility expects to notify the individual of the action taken on the request. The review must be completed as soon as possible, in most cases within 30 workdays from receipt of the request. If the anticipated completion date indicated in the acknowledgment cannot be met, the individual must be advised, in writing, of the reasons for the delay and the date action is expected to be completed. The delay may not exceed 90 calendar days from receipt of the request.
- f. When a request to amend a record is approved by the health care facility Director, the System Manager for the concerned VHA system of records or designee, and/or the facility Privacy Officer, or designee, must take the following actions:
- (1) Any information to be deleted must be made illegible. Any new material must be recorded on the original document. The words "Amended-Privacy Act and/or 45 CFR Part 164" must be recorded on the original document. The new amending material may be recorded as an addendum, if there is insufficient space on the original document. The original document must clearly reflect that there is an addendum and care must be taken to ensure that a copy of the addendum accompanies the copy of the original document whenever it is used or disclosed. If the original document cannot be amended and an addendum cannot be attached, then a link to the location of the amendment must be provided. The amendment must be authenticated with the date, signature, and title of the person making the amendment.
- (2) The individual making the request for amendment must be advised in writing that the record has been amended and provided with a copy of the amended record. The System Manager for the concerned VHA system of records, the facility Privacy Officer, or their designee, must notify the relevant persons or organizations whom had previously received the record about the amendment. If 38 U.S.C. 7332-protected information was amended, the individual must provide written authorization to allow the sharing of the amendment with relevant persons or organizations.

(3) If the record has been disclosed prior to amendment, the recipient, including business associates, must be informed of the correction and provided with a copy of the amended record.

NOTE: The agency accounting of disclosures may be utilized for determining recipients of the information subject to the amendment.

- g. When a request to amend a record is denied, the System Manager for the concerned VHA system of records or designee, and/or the facility Privacy Officer, or designee, must promptly notify the individual making the request of the decision. The written notification must:
- (1) State the reasons for the denial. VHA may deny a request to amend a record if VHA finds that the individually-identifiable information or record requested to be amended:
- (a) Was not created by VHA and the originator of the individually-identifiable information is another Federal agency available to act on the request. In this instance, the individual will be informed that the individual needs to request that the originating Federal agency of the individually-identifiable information amend the record. If, however, the originating Federal agency of the individually-identifiable information is no longer available to act on the request, or authorizes VA to decide whether to amend the record, then VHA must do so.
 - (b) Is accurate, relevant, complete, or timely in its current form.
 - (c) Is not part of a VHA system of records or designated record set.
- (2) Advise the individual that the denial may be appealed to Office of the General Counsel (OGC) (see subpar. 8i) and include the procedures for such an appeal.
- (3) Advise the individual that if an appeal is not filed and a statement of disagreement is not submitted, the individual may still request the VA health care facility provide the individual's request for amendment and the denial with all future disclosures of the information. This request needs to be submitted in writing to the System Manager for the concerned VHA system of records or designee, and/or the facility Privacy Officer, or designee.
- (4) Describe how the individual may complain to VHA or to the Secretary, HHS. The description must include the name or title and telephone number of the contact person or office.
 - (5) Be signed by the VA health care facility Director.
- h. The System Manager for the concerned VHA system of records or designee, and/or the facility Privacy Officer, or designee, must identify the individually-identifiable information that is the subject of the disputed amendment and append or otherwise link the individual's request for an amendment and the facility's denial of the request to the individual's record.

i. Appeal of Initial Adverse Department Determination of Amendment

- (1) An individual may appeal a denial, in whole or in part, of a request for correction or amendment of individually-identifiable information in VHA Privacy Act-covered records or designated records sets to the Office of General Counsel (OGC).
- (a) The written appeal needs to be mailed or delivered to the OGC (024), Department of Veterans Affairs, 810 Vermont Avenue, NW, Washington, DC 20420.
- (b) The letter of appeal needs to clearly state the reasons why the denial needs to be reversed, and include any additional pertinent information.
- (2) When OGC finds, on appeal, that the adverse determination needs to be reversed, in whole or in part, the individual and the VA health care facility must be notified of the decision. Upon receipt of the notification, the System Manager for the concerned VHA system of records or designee, and/or the facility Privacy Officer, or designee, must amend the record as instructed in the notification. *NOTE:* The procedures established in subparagraphs 8a thru 8f must be followed.
- (3) If the General Counsel, or the Deputy General Counsel, sustains the adverse decision, the individual must be advised, in the appeal decision letter, of the right to file a concise written statement of disagreement with the VA health care facility that made the initial decision.
- (4) A statement of disagreement must concisely state the basis for the individual's disagreement. *NOTE:* Generally, a statement needs to be no more than two pages in length, except an individual may submit a longer statement if it is necessary to set forth the disagreement effectively.
- (5) A VA health care facility may prepare a written rebuttal to the individual's statement of disagreement. Whenever such a rebuttal is prepared, the System Manager for the concerned VHA system of records or designee, and/or the facility Privacy Officer, or designee, must provide a copy to the individual who submitted the statement of disagreement.
- (6) When an individual files a statement of disagreement, the record about which the statement pertains must be clearly annotated to note which part of the record is disputed. The individual's request for an amendment, the facility's denial of the request, the individual's statement of disagreement, if any, and facility's rebuttal, if prepared, must be appended or otherwise linked to the individual's record.
- (7) Once a statement of disagreement is filed, a review of previous disclosures of the disputed records needs to be conducted to determine the persons or organization that have received the disputed information. The System Manager for the concerned VHA system of records or designee, and/or the facility Privacy Officer, or designee, needs to obtain the individual's agreement to notify the relevant persons or organizations with which the statement of disagreement needs to be shared. If 38 U.S.C. 7332-protected information is disputed, the

individual must provide written authorization to allow the sharing of the statement of disagreement with persons or organizations that previously received the disputed information.

(8) When disclosures are made of the disputed record, a copy of the statement of disagreement must be provided. If it is determined appropriate, a copy of a concise statement of the VA's reasons for not making the amendments requested or rebuttal must also be provided.

9. ACCOUNTING OF DISCLOSURES FROM RECORDS

- a. An individual may request a list of all disclosures of information, both written and oral, from records pertaining to the individual, subject to the provisions of 38 CFR 1.576(c) and 45 CFR 162.528. VHA facilities and programs are required to keep an accurate accounting for each disclosure of a record to any person or to another agency. An accounting is not required to be maintained in certain circumstances, including when disclosure is to VHA employees who have a need for the information in the performance of their official duties (see subpar. 35c for agency accounting requirements).
- b. The request for an accounting of disclosures, or disclosure summary, must be in writing and adequately identify the VHA system of records or designated record sets for which the accounting is requested. The written request needs to be mailed, or delivered, to the VA health care facility that maintains the record.
- c. A request for an accounting of disclosures, or disclosure summary, must be delivered to the System Manager for the concerned VHA system of records or designee, and/or the facility Privacy Officer, or designee.
 - d. The individual must be provided with an accounting that includes:
 - (1) The date of each disclosure;
 - (2) Nature or description of the information disclosed;
- (3) A brief statement of the purpose of each disclosure, or in lieu of such statement, a copy of a written request for a disclosure; and
- (4) The name and, if known, address of the person or Agency to whom the disclosure was made.
- e. The accounting records of disclosures must be made available upon request to the individual to whom the record pertains within 60 calendar days after receipt of such a request; except disclosures made for law enforcement purposes, which will not be made available except as provided by 38 CFR 1.576(b)(7) and 45 CFR 164.528(a)(2)(i). If the accounting cannot be provided within the specified timeframe, the facility or program can extend the timeframe no longer than 30 calendar days, provided that the individual is given a written statement of the reasons for the delay and the date by which the accounting will be provided. *NOTE: Only one such extension of time for action on a request for an accounting is allowed.*

- f. The accounting or disclosure summary given to an individual in accordance with this paragraph (par. 9) must be provided without charge.
 - g. VHA must retain a copy of the disclosure summary provided to the individual.

10. CONFIDENTIAL COMMUNICATIONS

- a. An individual has the right to request and receive communications (correspondence) confidentially from VHA by an alternative means or at an alternative location. Before providing the information by an alternative means or at an alternative location, the responsible facility official must verify the individual's identity in accordance with the procedures contained in the right of access portion of this Handbook.
- b. VHA considers an alternative means to be in person and considers an alternative location to be an address other than the individual's permanent address listed in the Veterans Health Information Systems and Technology Architecture (VistA).
- c. VHA must accommodate reasonable requests from the individual to receive communications either at the one alternative 'confidential communications' address, or in person at the VA health care facility where the information is maintained. *NOTE:* A request to receive communications via email is considered unreasonable and therefore will be denied.
- d. All communications or correspondence must fit into one of five following correspondence types:
 - (1) Eligibility or enrollment,
 - (2) Appointment or scheduling,
 - (3) Co-payments or veteran billing,
 - (4) Medical records, and/or
 - (5) All other.
- e. Requests to have all communications, under a specific correspondence type, be sent to the "confidential communications" address must be accommodated. Individual correspondence types will not be split (i.e., all or none to one location). Requests to split communications under a correspondence type must be considered unreasonable and therefore must be denied.

11. RIGHT TO REQUEST RESTRICTION

a. An individual has the right to request VHA to restrict its use or disclosure of individually-identifiable health information to carry out treatment, payment, or health care operations. An individual also has the right to request VHA to restrict the disclosures of the

individual's individually-identifiable health information to next-of-kin, family, or significant others involved in the individual's care.

- b. VHA is not required to agree to such restrictions, but if it does, VHA must adhere to the restrictions to which it has agreed, unless information covered by the agreed-to restriction is needed to provide a patient with emergency treatment.
 - c. The request must:
 - (1) Be in writing;
 - (2) Identify which information is to be restricted;
- (3) Indicate for what purposes (e.g., use for payment) the identified information is to be restricted; and
 - (4) Be signed by the individual to whom the records pertain.
- d. All requests for restrictions of individually-identifiable health information need to be reviewed on a case-by-case basis and the VHA Privacy Officer, Department of Veterans Affairs, 810 Vermont Ave., NW, Washington, DC 20420, needs to be consulted.
- e. If a request for restriction is granted, VHA must adhere to the restriction until the individual revokes the restriction it in writing.
- f. If a request for restriction is denied, VHA must notify the individual in writing of the denial.

12. TREATMENT, PAYMENT, AND HEALTH CARE OPERATIONS

a. **VHA**

- (1) For purposes of this Handbook, individually-identifiable information may be used on a need to know basis within VHA for purposes of treatment, payment, and/or health care operations without the written authorization of the individual.
- (2) Within VHA, use of information on a need-to-know basis for purposes <u>other than</u> treatment, payment, or health care operations requires a written authorization or other authority as described in paragraphs 13 and 16.
 - (3) For use of Psychotherapy Notes by VHA see subparagraph 34j.

b. VA Entities

(1) **Individually-identifiable Information Excluding Health Information.** VHA may disclose or share individually-identifiable information <u>excluding</u> health information to any

component of VA that needs the information for the purposes of fulfilling the agency's mission, without written authorization.

(2) Individually-identifiable Health Information

- (a) VHA may disclose individually-identifiable health information to other VA components including the Veterans Benefit Administration (VBA) for its use in the determination of eligibility for, or entitlement to, benefits under the laws administered by the Secretary of Veterans Affairs without the written authorization of the individual. A business associate agreement is required in order to disclose individually-identifiable health information to VBA without written authorization for other purposes.
- (b) VHA may disclose individually-identifiable health information within VA, including to General Counsel, for the purposes of treatment, payment, and/or health care operations without the written authorization of the individual as long as a business associate agreement (see App. A) is in effect.

NOTE: Before disclosing such information, contact the VHA Privacy Office or check http://vaww.vhaco.va.gov/privacy to confirm the existence of a business associate agreement.

(c) Disclosure of individually-identifiable health information by VHA to other VA components for purposes other than treatment, payment, and/or health care operations requires other authority as described in paragraph 16, and potentially a data use form (see subpar. 3b).

c. VA Contractors

- (1) VHA may disclose or release individually-identifiable information to VA contractors for the purpose of the contractor performing a service under the contract related to VA treatment, payment, and/or health care operations without the written authorization of the individual, as long as the disclosure is within the scope of the contract. *NOTE:* For contract requirements see subparagraph 35i.
- (2) Disclosure of individually-identifiable health information by VHA to VA contractors for purposes other than treatment, payment, and/or health care operations requires other authority as described in paragraph 16, and potentially a data use form (see subpar. 3b).
 - (3) If a contractor is also considered a business associate see Appendix A.
- d. <u>Non-VA Entities.</u> VHA may disclose information outside VA for any purpose including treatment, payment, and/or health care operations, as long as appropriate authority as described in paragraph 17 and corresponding paragraphs, is obtained.

13. RESEARCH

This paragraph is meant to provide guidance only in regards to the Federal privacy and confidentiality laws affecting research endeavors. The facility needs to establish a review

process to ensure these privacy requirements are met. This policy does not negate or supersede any research statutes, regulations, or policies. Research Investigators must still ensure that appropriate authority to conduct a research study is obtained and appropriate protection of research subjects is ensured.

a. Release of Information (ROI) to VHA Investigators (Intramural). All research within VHA must be conducted by a VHA Investigator. A VHA Investigator must be a VHA employee (which includes official WOC employees) or VA-contracted personnel. NOTE: To determine if a researcher is a VHA Investigator contact the ACOS for Research and Development (R&D). For requests for de-identified information see Appendix B.

(1) Reviews Preparatory to Research

- (a) If the VHA Investigator is conducting a review of individually-identifiable information to prepare a research protocol, R&D Committee approval is not required.
- (b) Neither written authorization from the research subject nor an Institutional Review Board (IRB) or Privacy Board waiver of authorization is required for a VHA Investigator to conduct a review of individually-identifiable information in preparation of a research protocol (see 45 CFR 164.512(i)(1)).

NOTE: The contacting of potential research subjects or conducting pilot studies are not activities Preparatory to Research.

(2) VHA-Approved Research

- (a) All research activities conducted by VHA Investigators must be approved by an R&D Committee prior to initiation of the research in accordance with VHA Directive 1200, the applicable 1200 series handbooks, and 38 CFR Part 16. Prior to R&D Committee approval, IRB approval must be obtained, when required.
- (b) All VHA Investigators conducting VHA-approved research must obtain the authority to use individually-identifiable information as follows:
- <u>1</u>. VHA individually-identifiable health information involving non-employee research subjects may be used by a VHA Investigator for research purposes provided there is a prior written authorization. A prior written authorization may be incorporated into an informed consent for participation in research.
- <u>2</u>. If there is no prior written authorization, VHA individually-identifiable health information involving non-employee research subjects may be used by a VHA Investigator for research purposes when there is an IRB or Privacy Board waiver of authorization in accordance with 45 CFR 164.512(i).
- <u>3</u>. VHA individually-identifiable information including health information involving employee research subjects, in their capacity as an employee, may be used by a VHA

Investigator for research purposes in accordance with VHA Directive 1200, applicable 1200 series handbooks, and 38 CFR Part 16.

- (c) VHA Investigators conducting VHA-approved research may use a limited data set provided a Data Use Agreement (see App. F) is obtained. *NOTE:* For a definition of a "limited data set" see subparagraph 4ff.
- (d) VHA Investigators may only use the requested data in a manner consistent with the approval research protocol for which the information was requested.
- b. **ROI to Non-VHA Investigators (Extramural).** VHA has authority to disclose individually-identifiable information to non-VHA Investigators in accordance with this Handbook. The Chief R&D Officer must also approve the request per VHA Handbook 1200.5. This requirement applies to information requested from national, VISN, and local databases or sources. If the research involves human subjects, the requesting non-VHA Investigator must have received IRB approval for the research. If the research does not meet the definition of Human Subject Research per the Common Rule, the non-VHA Investigator's institution must approve the research. Requests for de-identified information from non-VHA Investigators must be in writing and meet the requirements of Appendix B.

(1) Information from Research Subjects Who are Not VHA Employees

- (a) VHA may disclose the individually-identifiable health information of research subjects who are not VHA employees to non-VHA Investigators for research purposes provided there is a prior written authorization. A prior written authorization may be incorporated into an Informed Authorization Notice or Informed Consent (see VHA Dir. 1200).
- (b) If there is no prior written authorization, VHA may disclose individually-identifiable health information, excluding 38 U.S.C. 7332-protected information, to Federal investigators (e.g., Department of Defense, etc.) if the Under Secretary for Health, or designee, has approved the research, and an IRB or Privacy Board has waived the authorization requirement in accordance with 45 CFR 164.512(i) prior to the request for the PHI. For the disclosure of individually-identifiable health information including 38 U.S.C. 7332-protected information see subparagraph 13b(1)(d).
 - (c) If there is no prior written authorization, VHA may disclose:
- <u>1</u>. Individually-identifiable health information, <u>excluding</u> 38 U.S.C. 7332-protected information and names and addresses of the individual subjects, to non-Federal investigators, if there is VHA approval both by the Under Secretary for Health, or designee; and IRB or Privacy Board waiver of authorization.
- <u>2</u>. Individually-identifiable health information, including names and addresses of the individual subjects, but <u>excluding</u> 38 U.S.C. 7332-protected information, to non-Federal investigators, if: the Non-Federal Investigators provide the names and addresses of the individual subjects; there is VHA approval by both the Under Secretary for Health, or designee; and there is an IRB or Privacy Board waiver of authorization.

- <u>3</u>. For the disclosure of individually-identifiable health information <u>including</u> 38 U.S.C. 7332-protected information see subparagraph 13b(1)(d).
- (d) Title 38 U.S.C. 7332-protected information may be disclosed without written authorization, if in addition to the requirements of subparagraph 13b(1)(b), or subparagraph 13b(1)(c), the requirements of 38 CFR 1.488 are met. Specifically, the research protocol must indicate:
- <u>1.</u> The information must be maintained in accordance with the security requirements of 38 CFR Section 1.466, or more stringent requirements;
 - 2. The information will not be re-disclosed except back to VA; and
- <u>3</u>. The information will not identify any individual patient in any report of the research, or otherwise disclose patient identities.
- (e) VHA may disclose a limited data set for research pursuant to a Data Use Agreement. **NOTE:** For the Data Use Agreement for Limited Data Sets for Research see Appendix F.

(2) Information from Research Subjects in their Capacity as VHA Employees

- (a) VHA may disclose the individually-identifiable information of research subjects in their capacity as VHA employees, excluding health information, to non-VHA Investigators for research purposes without written authorization, and only in accordance with the Privacy Act and applicable VA privacy policy (see par. 33).
- (b) VHA employee health information is to be disclosed using the same privacy processes as veteran health information.

14. AUTHORIZATION REQUIREMENTS

a. Written Authorization Necessary

- (1) A written authorization signed by the individual to whom the information or record pertains is required when:
- (a) VA health care facilities need to utilize individually-identifiable health information for a purpose other than treatment, payment, and/or health care operations and other authority, as specifically notated by this Handbook, does not exist;
- (b) VA health care facilities disclose information for any purpose where other legal authority does not exist; and
- (c) VA health care facilities conduct marketing except when communicated face-to-face to an individual.

(2) The written authorization must comply with the requirements of subparagraphs 14b through 14g.

b. Requirements of an Authorization to Release Information

- (1) When an authorization of the individual is required to release individually-identifiable information, the authorization must be in writing and include the following information:
- (a) The identity, i.e., name and social security number, of the individual to whom the information pertains.
- (b) A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion. If HIV, sickle cell anemia, drug and/or alcohol abuse treatment information is to be disclosed, this information must be specifically identified in the description.
- (c) The name, or other specific identification, of the person(s), class of persons, or office designation(s) authorized to make the requested use or disclosure.
- (d) The name or other specific identification of the person(s), class of persons, or office designation(s) to whom the agency may make the requested use or disclosure.
- (e) A description of each purpose of the requested use or disclosure. A statement "at the request of the individual" is sufficient when an individual initiates the authorization and does not, or elects not to, provide a statement of the purpose.
- (f) An expiration date or event that relates to the individual or the purpose of the use or disclosure. Examples of appropriate expiration date language are as follows:
- <u>1</u>. The statement "end of the research study" or similar language is sufficient if the authorization is for use or disclosure of individually-identifiable health information for research.
- <u>2</u>. The statement "none" or similar language is sufficient if the authorization is for the agency to use or disclose individually-identifiable health information, including for the creation and maintenance of a research database or research repository.
- (g) The signature of the individual, or someone with the authority to act on behalf of the individual, and date signed.
- (h) A statement that the individual has the right to revoke the authorization in writing except to the extent that the entity has already acted in reliance on it, and a description of how the individual may revoke the authorization (e.g., to whom the revocation is provided).
- (i) A statement that treatment, payment, enrollment, or eligibility for benefits <u>cannot</u> be conditioned on the individual completing an authorization. Participation in a research study may be conditioned on the individual signing the authorization (see 45 CFR 164.508(b)(4(i)).

- (j) A statement that individually-identifiable health information disclosed pursuant to the authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.
 - (2) Authorization may be given:
- (a) On VA Form 10-5345, Request for and Authorization to Release Medical Records or Health Information, or any subsequent authorization form approved to replace this form;
- (b) In correspondence requesting a release signed by the individual, or a person authorized to act for the individual, on any stationary or forms of the individuals, agencies, or organizations to whom the information is to be released, provided it meets the requirements of preceding subparagraph 14b(1).

NOTE: Photocopies, scanned documents, or faxes of authorizations are acceptable after the validity of the form has been verified.

(3) An authorization for the use or disclosure of individually-identifiable health information for a research study may be combined with any other type of written permission for the same research study, including the Informed Consent or consent to participate in research.

c. Invalid Authorization

- (1) Information will not be disclosed on the basis of an authorization form that:
- (a) Fails to meet all of the requirements set forth in preceding subparagraph 14b;
- (b) Has expired;
- (c) Is known to have been revoked;
- (d) Has been combined with another document except as described in subparagraph 14b(3) to create an inappropriate compound authorization; or
- (e) That is known, or in the exercise of reasonable care needs to be known, to VHA personnel to be false with respect to any item of the authorization requirements.
- (2) If an authorization form is invalid, notify the requestor of the deficiencies except for 38 U.S.C. 7332-protected information (see subpar. 14f).

d. Who May Sign An Authorization

- (1) Written authorization for release of information is valid when signed by:
- (a) The individual.

- (b) A court-appointed legal guardian. *NOTE:* A VA Federal fiduciary administratively appointed by VBA to administer a beneficiary's VA monetary benefits is not empowered to exercise privacy rights of the VA beneficiary who is the subject of that appointment including granting authorization.
- (c) A person legally authorized in writing by the individual (or the individual's legal guardian) to act on behalf of the individual (i.e., POA).
- (d) If the individual is deceased, then Executor of Estate, next-of-kin, or other person who has authority to act on behalf of the individual (see par. 31).
- (2) When VHA requests an individual to sign an authorization form, a copy of the completed signed authorization must be provided to the individual.

e. **Duration Of Authorization**

- (1) An authorization for an ROI is only valid for the period specified in the authorization. An authorization that does not contain an expiration date, a specified ascertainable event, or condition (i.e., death) is not valid and needs to be returned to the requestor (see subpar. 14b(1)(h) for language regarding the duration of a research authorization).
- (2) Generally, individually-identifiable information need not be disclosed if it was created after the date the authorization was signed. However, when an individual authorizes disclosure of information created after the date the authorization was signed, VHA may disclose such information upon the request(s) of the designated recipient in accordance with the original authorization.

f. <u>Authorization Content Requirements For HIV, Sickle Cell Anemia, Drug and/or</u> Alcohol Information

- (1) When a person presents VHA with an insufficient authorization for records protected by 38 U.S.C. Section 7332, VA must, in the process of obtaining a legally-sufficient authorization, correspond only with the individual whose records are involved, or the legal guardian of an incompetent individual, or the person who is authorized to act on behalf of the individual (e.g., next-of-kin of a deceased patient (see par. 31)), and not with any other person.
- (2) Unless the authorization description expressly covers 38 U.S.C. 7332-protected information, no person or entity, except for the individual to whom the information pertains may be advised that individually-identifiable health information relates to drug abuse, alcoholism, or alcohol abuse, tests for or infection with HIV, or sickle cell anemia.

g. Prohibition on Re-disclosure

(1) Whenever a written disclosure of 38 U.S.C. 7332-protected information is made with the individual's written authorization, the disclosure must be accompanied by the following written statement:

"This information has been disclosed to you from records protected by Federal confidentiality statute 38 U.S.C. 7332. Federal rules prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written authorization of the person to whom it pertains or as otherwise permitted by 38 U.S.C. 7332. A general authorization for the release of medical or other information is <u>not</u> sufficient for this purpose. The Federal rules restrict any use of the information to criminally investigate or prosecute any human immunodeficiency virus, sickle cell anemia, or alcohol or drug abuse patient."

- (2) The person to whom name and address information is disclosed must be notified in writing that the information may not be re-disclosed or used for a purpose other than that for which the disclosure was made under 38 U.S.C 5701(f).
- (3) The notification must inform the person that anyone who violates any provision of 38 U.S.C. 7332, will be fined up to \$5,000 in the case of a first offense, and up to \$20,000 in the case of a subsequent offense.

15. PROCESSING A REQUEST

a. General

- (1) Anyone may request VHA to disclose any record. Any request for information maintained in VHA records must be processed under all applicable confidentiality statutes and regulations (see subpar. 2b).
- (2) The request must be in writing and describe the record(s) sought, so it may be located in a reasonable amount of time.
 - (3) Determine who is making the request for information.
- (a) If the requestor is the individual to whom the records pertain, follow the guidance in paragraph 7.
- (b) If the requestor is other than the individual to whom the record pertains (third party), determine what information or record is requested as outlined in subparagraph 15a(4) and for what purpose.
 - (4) Determine what information is being requested.
- (a) If the record requested does <u>not</u> contain individually-identifiable information, process the request in accordance with paragraph 32.
- (b) If the record requested contains individually-identifiable information, review the applicable paragraphs of this Handbook (par. 16 through par. 30) for guidance directed at the specific requestor and/or purpose. For example, for a request from a Congressional Member see paragraph 18. If upon review, disclosure of individually-identifiable information is <u>not</u> permitted, process the request in accordance with paragraph 32.

- (c) If the record requested contains individually-identifiable information and the guidance in paragraphs 18 through 30 is not applicable, process the request by reviewing the applicable Federal privacy laws and regulations as indicated in paragraph 17.
- (d) If the request is on a deceased individual, process the request in accordance with paragraph 31.
- (5) Process requests from a third party for individually-identifiable information within the time standards outlined in subparagraph 15b, and charge the applicable fees as outlined in subparagraph 15c.
- (6) A third party may request VHA disclose or provide individually-identifiable information in an electronic format, such as on Compact Disk (CD), in lieu of paper copies. When the records requested exist electronically and can be reproduced in the request format, VHA must accommodate such a request.

NOTE: If the paragraph in this Handbook applicable to a particular request for individually-identifiable information cannot be identified, contact the facility Privacy Officer.

b. Time Standards

- (1) Requests for copies of individually-identifiable information, including health information, must be answered within 20 workdays from the date of receipt.
- (2) When, for good cause shown, the information cannot be provided within 20 workdays from the date the request was initially received, the requester must be informed in writing as to the reason the information cannot be provided and the anticipated date the information will be available.
- (3) Any requests for copies of individually-identifiable health information from the individual to whom the records pertain must be processed within the timeframes indicated in subparagraph 7(b)(7).

c. Fees

- (1) **Photocopying Charges.** A fee will not be charged for any search or review of a record except for certain FOIA requests (see subpar. 32). Upon request, the individual to whom a record pertains must be provided with one free copy of their VA Benefits record or information. When charges are made for additional copies of records, the fee as stated in 38 CFR 1.577(f) or subsequent regulations will be charged (see Table of Fees in subpar. 15c(3)).
- (2) **Certification of Papers and Documents.** The VA health care facility Director delegates to a VA health care facility employee, normally the Chief, HIMS, the authority to certify information released from records on VA Form 4505, Identification Card, Delegation of Authority. When requested, the following certification must be furnished:

"Certification - under 38 CFR 2.2, and certification authority delegated I certify that this is a true copy of the original document in VA files."	by the facility Director,
rectury that this is a true copy of the original accument in virines.	
(Typed Name of Employee)	(Date Signed)

(3) Table of Fees.

Individuals first paper copy of own VA benefits records including medical records under Right of Access	Free copy	
Paper one-sided copies (8 ½" x 11"; 8 ½" x 14")	\$0.15 per page after first 100 one-sided pages	
Non-paper copies (x-rays, video tapes, slides, microfilm)	Actual direct cost of duplication*	
Electronic copies (CD-ROM, disk, computer files, etc.)	Actual direct cost of duplication*	
Abstracts or copies to insurance companies for other than litigation purposes	\$10.00 per request	
Attestation under the seal of the Agency	\$3.00 per document so certified	
All other reproduction or copies	Actual direct cost of duplication*	

- *NOTE: Actual direct cost is calculated by determining the cost of operating the duplication equipment and the cost of the employee's time (base hourly rate of pay plus 16 percent multiplied by number of hours). Actual direct cost does not include the overhead cost of operating the facility or building, including utilities, where the equipment is located.
- d. <u>Requests for Information Requiring Referral to Regional Counsel.</u> The following types of requests for information must be reviewed with the Regional Counsel and any release of information will be made only in compliance with the instructions of Regional Counsel:
- (1) Requests for medical information that is to be used in suits against the U.S. Government or in a prosecution against a patient that has been instituted or which is being contemplated.
- (2) Subpoenas for medical records issued by or under the auspices of a court or quasijudicial body not accompanied by an authorization from the patient.
- (3) Requests for information, which indicate possible liability for the cost of hospitalization and medical services (such as tort-feasor, worker's compensation, or other third party cases), as categorized in M-1, Part I, Chapter 15, Charges and Payments for Medical Care.

16. ROI WITHIN VA FOR PURPOSES OTHER THAN TREATMENT, PAYMENT, AND/OR HEALTH CARE OPERATIONS WITHOUT AUTHORIZATION

This paragraph covers the disclosure of individually-identifiable information from VHA records to VA entities without prior written authorization for purposes <u>other than</u> treatment, payment, or health care operations.

a. OGC

- (1) VHA may provide all VHA information, including individually-identifiable information to OGC for any official purpose authorized by law.
- (2) VHA Central Office must maintain a Memorandum of Understanding with OGC for authorizing the sharing of individually-identifiable health information with OGC for legal counsel provided to VHA.

b. Inspector General

- (1) Subject to subparagraph 16b(2), VHA must provide any information, including individually-identifiable information to the VA Inspector General for any official purpose authorized by law. This includes individually-identifiable health information for the purpose of health care oversight (see 45 CFR 164.512(d)). Unless otherwise specified by the VA Inspector General, all requests for VHA individually-identifiable health information must be for health care oversight activities.
- (2) For guidance on disclosures to the VA Inspector General for purposes of law enforcement activities see subparagraph 21g (see 45 CFR 164.512(f)).
- c. <u>Office of Resolution Management.</u> VHA may disclose individually-identifiable information to the Office of Resolution Management when necessary for determining compliance with Equal Employment Opportunity (EEO) requirements.

d. VBA

- (1) VHA may disclose veteran individually-identifiable information to VBA for eligibility for, or entitlement to, or to provide benefits under the laws administered by the Secretary of Veterans Affairs (see 45 CFR 164.512(k)). Such benefits include adjudication of claims and entitlement to VA health care.
- (2) VHA may disclose all other non-veteran VHA records or information to VBA for any official purpose authorized by law.
- e. <u>Board of Veterans Appeals (BVA).</u> VHA may disclose veteran individually-identifiable information to BVA for eligibility for, or entitlement to, or that provide benefits under the laws administered by the Secretary of Veterans Affairs (see 45 CFR 164.512(k)). *NOTE:* Such benefits include processing adjudication of claims appeals.

f. <u>National Cemetery Administration (NCA)</u>. VHA may disclose individually-identifiable information to NCA for eligibility for, or entitlement to, or that provide benefits under the laws administered by the Secretary of Veterans Affairs (see 45 CFR 164.512(k)). For example, VHA may provide NCA claimant information for burial benefits.

g. VA Contractors

- (1) VHA may disclose non-veteran individually-identifiable information to a VA contractor for the purposes of fulfilling the contract.
- (2) Contact the VA health care facility Privacy Officer prior to the release of any veteran individually-identifiable information to a VA contractor to ensure appropriate authority is in place.
 - (3) All contracts must contain the appropriate privacy language (see subpar. 35i).
- (4) All contracts that provide for the maintenance of a system of records on behalf of VA to accomplish a Department function, or provide for the disclosure of information from a VA system of records to the contractor, must include wording that makes the provisions of the Privacy Act apply to the contractor. Such notifications and clauses must conform to those prescribed by Federal Acquisition Regulations (FAR), and VA Acquisition Regulations (VAAR). Health care facilities must comply with these requirements.
- (5) When a contract provides for access to, or maintenance of, information protected by other confidentiality statutes, (e.g., 38 U.S.C. 5705 and 7332) the contract must provide notification to the contractor that the records are protected by these confidentiality provisions which restricts the disclosure of the information and the purposes for which the information may be used.
- (6) **Contract Nursing Homes.** A nursing home with which VHA has a contract may be provided individually-identifiable information including health information for the purposes of fulfilling the contract for providing medical care to veterans housed in its facility.
- h. <u>Office of Employment Discrimination, Complaints, and Adjudication (OEDCA).</u> VHA may disclose individually-identifiable information to OEDCA when necessary for determining compliance with EEO requirements.

i. Unions

(1) VA unions, in the course of fulfilling their representational responsibilities, may make a request to management to provide copies of facility records pursuant to its authority under 5 U.S.C. Section 7114(b)(4). Unions may request any records that are maintained by a VHA facility. This might include releasable portions of completed boards of investigation, patient medical records, or an employee's personnel records. However, under certain circumstances, unions may not be legally entitled to receive individually-identifiable health information, or information protected by other statutes, such as the Privacy Act.

- (2) **Types of Requests.** There is no specific format that must be used by a Union to make a request for agency information or records from management. Generally, a Union makes a written or oral request for "information" citing 5 U.S.C. Section 7114(b)(4) and/or citing a particular Article and/or Section of the union contract. Some unions request documents or information citing the provisions of the "Freedom of Information Act," or without citing any particular statutory or contractual provision.
- (3) **Processing of Request.** Regardless of the format of the request, upon receipt of a request by a Union for facility records, the servicing Human Resources Management (HRM) office and the Regional Counsel's office needs to be contacted immediately. The Regional Counsel's office must assist management officials in determining whether facility records (or information from agency records) are exempt from release pursuant to Federal law and regulations. HRM and Regional Counsel staff can refer to paragraph 33, for guidance in how to process Union requests for information and/or agency records.
- j. <u>Compensated Work Therapy (CWT) Workers.</u> VHA may <u>not</u> disclose or release any individually-identifiable information to a CWT Worker, as they are not VA personnel, without the signed written authorization of the individual to whom the information pertains.

k. VA Researchers

- (1) VHA may use employee information including health information for official VHA research studies in accordance with VHA Directive 1200 and 38 CFR Part 16.
- (2) For use or disclosure of individually-identifiable health information involving nonemployee research subjects for research purposes (see par. 13).

1. VA Human Resources Management Services (HRMS)

- (1) VHA may disclose individually-identifiable information to VA HRMS as authorized by law.
- (2) VHA may disclose individually-identifiable health information of non-employees to VA HRMS only for purposes of managing the VHA work force under a business associate relationship.

m. VA Police Service

- (1) VHA may provide VA Police Service with individually-identifiable information as necessary to carry out security functions. Security functions include, but are not limited to: issuing employee badges, securing VA premises, and escorting certain individuals to their VA Medical Center appointments. No special request or other documentation is needed.
- (2) VHA may disclose individually-identifiable information for purposes of law enforcement activities such as: issuing parking tickets or speeding tickets on the premises;

responding to auto accidents; responding to suspected criminal activity (e.g., theft from the Retail Store); and reporting fugitive felons seeking care from the VA Medical Center. For these law enforcement functions, the facility VA Police Service must follow polices outlined in subparagraph 21g.

- (3) VHA may provide VA Police Service with individually-identifiable information regarding a serious or imminent threat to the health or safety of an individual (e.g., employee) or the public (e.g., bomb threat) as long as the VA Police Service is reasonably able to prevent or lessen the threat.
- (4) Disclosure of individually-identifiable information from VA Police Records must be made in accordance with Federal privacy and confidentiality statutes and regulations, as well as VA Police policy (see par. 33).

17. ROI OUTSIDE VA, FOR ANY PURPOSE

a. Disclosure with Authorization

- (1) If VHA receives a request for individually-identifiable information that is accompanied by a written authorization signed by the individual to whom the records pertain, disclosure needs to be made in accordance with the authorization once it has been determined that the authorization is valid (see subpar. 14b).
- (2) Disclosure is mandatory when a <u>valid</u> written authorization signed by the individual is provided except to the extent that the information is sensitive under Appendix D. Information that is disclosed must be limited to the information that is needed to satisfy the purpose of the request.

b. Disclosure without Individual's Authorization

- (1) Paragraph 18 through paragraph 30 involve the disclosure of individually-identifiable information (including health information) to entities outside VA, where prior written authorization is not always needed. To the extent possible, this paragraph identifies the disclosure policies involving specific entities (e.g., Courts, Congress, and Federal or state agencies).
- (2) If VHA receives a request or wishes to make disclosure to an entity outside VA that has not been identified in paragraph 18 through paragraph 30, VHA needs to analyze whether it has lawful authority to make the disclosure. Specifically, before making a disclosure of any individually-identifiable information (including health information) to an outside entity, VHA needs to determine the type of information involved. The following four questions determine the type of information involved:
- (a) Does the information involve drug, alcohol abuse, sickle cell anemia, or HIV information (protected by 38 U.S.C. 7332)?

- (b) Does the information involve the disclosure of a name or address of a Title 38 claimant or the claimant's dependents (protected by 38 U.S.C. 5701)?
- (c) Is the information individually filed and retrieved by an individual identifier (i.e., Privacy Act, 5 U.S.C. 552a)?
- (d) Does the information involve health information (protected by HIPAA, and 45 CFR Parts 160 and 164)?
- (3) VHA needs to determine whether legal authority exists under each of the aforementioned statutes and regulations, where applicable, prior to making the disclosure. For example, if the information is protected by the provisions of the Privacy Act, there must be Privacy Act authority such as a published routine use in the applicable systems of records authorizing the disclosure. If the legal authority in all applicable statutes and regulations is not found, VHA may not make the disclosure.
- (4) Disclosure is not mandatory under these provisions, and in questionable situations, the signed authorization of the individual needs to be obtained. Information that is disclosed will be limited to the information that is needed to satisfy the purpose of the request.

c. Required by Law Exception

- (1) VHA may use individually-identifiable health information to the extent that such use is mandated or required by law and the use complies with, and is limited to, the relevant requirements of such law.
- (2) VHA may disclose individually-identifiable health information without an individual's authorization when mandated or required by law, e.g., statute, regulation, court order, and when there is appropriate authority under Privacy Act and 38 U.S.C.

18. CONGRESS

a. <u>Member Acting in an Individual Capacity on Behalf, and at the Request, of the</u> Individual to Whom the Information Pertains

- (1) VHA may disclose individually-identifiable information, including health information, to a Member of Congress (including a staff member acting on the Member's behalf) when responding to an inquiry from a Congressional office that is made at the request of the individual to whom the information pertains under the following conditions:
- (a) If prior written authorization has not been provided, the Member needs to provide a copy of the original correspondence from the individual requesting the member's assistance.
- (b) If a prior written authorization is provided, the authorization must conform with the requirements of a valid authorization as described in subparagraph 14b.

(2) An inquiry on behalf of the individual's family does not allow for the disclosure.

b. Member of an Oversight Committee or Subcommittee for Oversight Purposes

- (1) VHA may disclose individually-identifiable information to a Veterans' Affairs Committee or a Member of a Subcommittee of the House of Representatives, the United States Senate, or to the Chair of a Congressional Committee or Subcommittee having oversight jurisdiction extending to that information, without the individual's written authorization provided that the Chair makes the request, in writing, on behalf of the Committee or Subcommittee, (e.g., House Government Operations Committee, Senate or House Appropriations Committees, Senate Governmental Affairs Committee) on committee letterhead for committee or subcommittee oversight functions.
- (a) When individually-identifiable information is provided, the Committee or Subcommittee needs to be advised, in writing, that the information is being released for official purposes only; and that given its private, confidential nature, the information needs to be handled with appropriate sensitivity.
- (b) If the request does not involve committee or subcommittee oversight, but merely "casework" of the Member, it needs to be processed in accordance with the guidance provided in preceding subparagraph 18a.
- (2) If it is determined that information about an individual being released for oversight purposes to a Member of the House or a Member of Senate Veterans' Affairs Committee (or Chairman or Member of another oversight committee or subcommittee) is sensitive under 38 CFR 1.577(d) (see par. 7), the committee or subcommittee must be advised that it has been medically determined that information being disclosed to it could be harmful to the individual and therefore should not be released directly to the individual.

c. Member of Congress Acting on Behalf of a Third Party

- (1) VHA may not disclose individually-identifiable information upon an inquiry from a Member of Congress on behalf of a third party (e.g., spouse, family member, friend, etc.).
- (2) The Member of Congress needs to be advised that the written authorization of the individual about whom the information pertains, is required for VHA to disclose the information requested.

19. CONSUMER REPORTING AGENCY

a. VHA may disclose individually-identifiable information, including health information, to consumer reporting agencies, including credit reporting agencies, for purposes of assisting in the collection of indebtedness to VA provided that the provisions of 38 U.S.C. 5701(g)(4) have been met as described in the following:

- b. Information may be released concerning an individual's indebtedness to a consumer reporting agency for the purpose of making information available for inclusion in consumer reports regarding the individual, if VA, in accordance with 38 CFR 1.900-1.970, has:
- (1) Made reasonable efforts to notify the individual of the individual's right to dispute, through prescribed administrative processes, the existence or amount of such indebtedness and of the individual's right to request a waiver of such indebtedness under 38 U.S.C. 5302;
 - (2) Afforded the individual a reasonable opportunity to exercise such rights;
 - (3) Made a determination with respect to any such dispute or request; and
- (4) Thirty calendar days have elapsed after the day on which VA made a determination that reasonable efforts have been made to notify the individual that VA intends to release the information for such purpose.

20. COURTS, QUASI-JUDICIAL BODIES, AND ATTORNEYS

a. Non-claimant Individually-identifiable Information

- (1) VA has authority to disclose any non-claimant individually-identifiable information including health information (e.g., employee records) pursuant to a court order from a Federal, State, or local court of competent jurisdiction (see par. 33 for guidance on non-VHA records maintained at VA health care facilities).
- (2) VA may disclose any non-claimant individually-identifiable information to a quasi-judicial body in accordance with Federal policy and the law (see VA Handbook 6300.4).

b. <u>Claimant Individually-identifiable Information Excluding 38 U.S.C. 7332</u> Information

$(1) \ \ Release \ of \ Individually-identifiable \ Information \ to \ Courts, \ Quasi-judicial \ Bodies, \\ and \ Attorneys$

- (a) <u>Litigation not Involving VA in U.S. Courts.</u> Individually-identifiable information will be released for use in proceedings in a Federal court in response to a court order, a subpoena that is issued or approved by a judge of the court (see subpar. 20b(2)), or written authorization in accordance with 38 CFR 1.511 and 38 CFR 14.800-14.811. When the request is not on behalf of the U.S., the cost of producing and reproducing the record, as well as the cost for a VA employee to appear in court to present the record, must be paid in advance. Such fee must be sent to the U.S. Treasury in accordance with established procedures.
- (b) <u>Litigation not Involving VA in State, County and Municipal Courts, and Administrative Agencies Functioning in a Quasi-judicial Capacity.</u> Individually-identifiable information may be released for proceedings in these courts in response to a court order, a subpoena that is issued or approved by a judge of the court, or written authorization. Additionally, an affidavit from the

attorney desiring the information or records may be required by Regional Counsel. Contact the appropriate Regional Counsel regarding when such an affidavit is required.

- 1. The affidavit must state:
- a. The character of the proceedings.
- b. The purpose for which the requested information or records are to be used in evidence.
- <u>2</u>. When the information is to be used against the claimant, evidence must be produced that furnishing of the information or records is necessary to prevent perpetration of fraud or other injustice. Any requests for documents or records for a use adverse to the claimant must be referred to Regional Counsel.
- <u>3</u>. If the subpoena includes a copy of the attorney's motion in which the issuance of the subpoena is sought and the motion includes information that is sufficient to serve the purpose of the affidavit, an affidavit is not required.
- $\underline{4}$. The person who obtained the court order or subpoena, issued or approved by a judge of the court, must be furnished requested copies of the information or record after payment of the proper fee.
- (c) <u>Release to Attorneys for Use in Suits not Involving the Government.</u> Direct requests from attorneys for copies of individually-identifiable information for use in such suits must be accompanied by the signed written authorization of the claimant.

(2) Subpoena for Individually-identifiable Information on Claimants

- (a) A subpoena is not sufficient authority to disclose individually-identifiable information, including health information, unless the subpoena is signed by the judge of a court, or it is accompanied by the written authorization of the individual whose records are the subject of the subpoena. This applies to Federal, State, municipal, and administrative agency subpoenas.
- (b) Regional Counsel must be notified in all cases where a VA health care facility receives a court order for the production of records or a subpoena for records. When a subpoena for individually-identifiable information is received which is not issued or approved by the judge of a court, or accompanied by the written authorization of the individual, upon advice from the Regional Counsel, either personnel from the VA health care facility or the Regional Counsel must notify the party responsible for the issuance of the subpoena that VHA is not authorized to disclose the information in response thereto. They must be advised that for VHA to have disclosure authority with regard to such subpoenaed information, the requester must have the written authorization of the specific individual, a court order, or a request that complies with other applicable authority under law (i.e., law enforcement request).

(3) Producing Individually-identifiable Information in Court or in Quasi-judicial Proceedings

- (a) VHA records must remain in the custody of a VA employee at all times. An employee who merely brings records to a judicial proceeding must promptly report their presence to the clerk of the court. The employee may be requested to take the witness stand but will limit testimony to identification of the record and must not comment on the content of the record (see subpar. 20b(1) and subpar. 20c for guidance on producing copies for court or quasi-judicial bodies).
- (b) Original VHA information or records must never be relinquished (i.e., physically turned over) to courts or quasi-judicial bodies. It is advisable to prepare a photocopy of the information or record. If the judge or the attorney requests the entire original record or part of the record to be held in evidence, permission needs to be obtained to substitute the copy so that the original remains in VA custody. *NOTE:* If the court insists on retaining the original records or any portion thereof, immediately contact Regional Counsel for assistance.
- (c) When a VHA employee is requested to testify to the facts contained in the record and the facts are within the employee's knowledge, a determination must be made as provided in 38 CFR 1.522 whether disclosure of any part of the record would be detrimental to the physical or mental health of the claimant. When the record contains information which has been determined injurious to the claimant, the employee must ask the court that the contents of the record not be disclosed and that the employee not be required to testify.
- (d) VA health care facilities must develop procedures related to employees presenting testimony and/or VHA records in court. The assistance of the Regional Counsel must be requested in developing these procedures to ensure compliance with VA regulations and State requirements.

c. Individually-identifiable Information Protected by 38 U.S.C. 7332

(1) Legal Effect of Court Order

- (a) Individually-identifiable information or records that relate to treatment for drug abuse, alcoholism or alcohol abuse, or sickle cell anemia, or testing and treatment for HIV, may be disclosed if authorized by an appropriate order of a court of competent jurisdiction (Federal, State or local) under the provisions of 38 CFR 1.490. An application for a court order must use a fictitious name such as "John Doe" to refer to any claimant. A subpoena is not sufficient authority to authorize disclosure of these records. An order requiring a disclosure that is issued by a Federal court compels disclosure of the information record. However, such an order from a State or local court only acts to authorize the VA health care facility to exercise discretion to disclose the records (see preceding subpar.20b(1)(b)).
- (b) In assessing a request to issue an order, the court is statutorily required to weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services. To assist the court in weighing the interests involved in deciding whether to issue a court order, a VA health care facility, after consultation with Regional Counsel, may provide the court expert evidence from VHA health care professionals explaining the effect a court order could have on a claimant's privacy, the patient-physician relationship, and the continued viability of the treatment program. Upon granting an

order, the court, in determining the extent to which any disclosure of all, or any part, of any record is necessary, is required by statute to impose appropriate safeguards against unauthorized disclosure (see 38 U.S.C. 7332(b)(2)(D)). A Federal, state, or local court order to produce records is not sufficient, unless the order reflects that the court has imposed appropriate safeguards to protect the information from unauthorized disclosures (see 38 CFR 1.493(e)).

(2) **Information Obtained for Research, Audit, and/or Evaluation Purposes (Nontreatment).** A court order may not authorize any person or entity that has received 38 U.S.C. 7332-protected information from VHA for the purpose of conducting research, audit, and/or evaluation to disclose this information in order to conduct any criminal investigation or prosecution of a claimant without the claimants' written authorization. However, a court order may authorize disclosure from VHA and the subsequent use of such records to investigate or prosecute VA personnel.

(3) Disclosures of 38 U.S.C. 7332 Information for Non-criminal Purposes

- (a) A court order authorizing the disclosure of claimant information records for purposes other than criminal investigation or prosecution may be applied for by any person having a legally-recognized interest in the disclosure which is sought. The application may be filed separately, or as part of a pending civil action in which it appears that the claimant information or records are needed to provide evidence. An application must use a fictitious name to refer to any claimant and may not contain, or otherwise disclose, any claimant identifying information unless the claimant is the applicant or has given a written authorization (meeting the requirements of par. 14) to disclosure or the court has ordered the record of the proceeding sealed from public scrutiny.
- (b) The patient and VA must be given adequate notice and an opportunity to file a written response to the application, or to appear in person, for the limited purpose of providing evidence on whether the statutory and regulatory criteria for the issuance of the court order are met.
- (c) Any oral argument, review of evidence, or hearing on the application must be held in the judge's chambers or in some manner which ensures that patient identifying information is not disclosed to anyone other than a party to the proceeding, the patient, or VA, unless the patient requests an open hearing in a manner which meets the written authorization requirements. The proceeding may include an examination by the judge of the patient records.
- (d) An order directing disclosure of 38 U.S.C 7332-protected records may be entered only if the court determines that good cause exists. To make this determination the court must find that other ways of obtaining the information are not available, or would not be effective, and the public interest and need for the disclosure outweigh the potential injury to the patient, the physician-patient relationship, and the treatment services.
- (e) An order authorizing a disclosure must limit disclosure to: those parts of the patient's record which are essential to fulfill the objective of the order, and those persons whose need for the information is the basis for the order. The order must include such other measures as are necessary to limit disclosure for the protection of the patient, the physician-patient relationship,

and the treatment services (such as sealing from public scrutiny the record of any proceeding for which disclosure of a patient's record has been ordered).

(4) Use of Undercover Agents and Informants in a 38 U.S.C. 7332 Program

- (a) An order authorizing the placement of an undercover agent or informant in a VA drug or alcohol abuse, HIV infection, or sickle cell anemia treatment program as an employee or patient may be applied for by any law enforcement or prosecutorial agency which has reason to believe that employees, or agents of the VA treatment program, are engaged in criminal misconduct. The health care facility Director must be given adequate notice of the application and an opportunity to appear and be heard (for the limited purpose of providing evidence on the statutory and regulatory criteria for the issuance of the order). The order may be granted without notice if the application asserts a belief that the Director is involved in the criminal activities, or will intentionally or unintentionally disclose the proposed placement to the employees or agents who are suspected of the activities.
- (b) An order may be entered only if the court determines that good cause exists. To make this determination the court must find: that there is reason to believe that an employee or agent of VA is engaged in criminal activity; that other ways of obtaining evidence of this criminal activity are not available, or would not be effective; and that the public interest and need for the placement of an agent or informant outweigh the potential injury to patients of the program, physician-patient relationships, and the treatment services.
- (c) The order must specifically authorize the placement of an agent or informant and limit the total period of the placement to 6 months. The order must prohibit the agent or informant from disclosing any patient identifying information obtained from the placement, except as necessary to criminally investigate or prosecute employees or agents of the treatment program. The order must also include any other measures that are appropriate to limit:
 - 1. Any potential disruption of the program by the placement; and
- <u>2</u>. Any potential for a real or apparent breach of patient confidentiality, such as sealing from public scrutiny the record of any proceeding for which disclosure of a patient's record has been ordered.
- (d) No information obtained by an undercover agent or informant may be used to criminally investigate, or prosecute any patient, or as the basis for an application for an order to criminally investigate or prosecute a patient.

d. To Criminally Investigate or Prosecute 38 U.S.C. 7332 Patients

(1) A court order authorizing the disclosure or use of patient records to criminally investigate or prosecute a patient may be applied for by VA or by any person conducting investigative or prosecutorial activities with respect to the enforcement of criminal laws. The application may be filed separately as part of an application for a compulsory process, or in a pending criminal action. An application must use a fictitious name to refer to any patient and

may not contain or otherwise disclose patient identifying information unless the court has ordered the record of the proceeding sealed from public scrutiny.

- (2) Unless an order under subparagraph 20d(3)(e) is sought with an order under this subparagraph (20d), VA must be given adequate notice of an application by a person performing a law enforcement function. In addition, VA must be given an opportunity to appear and be heard for the limited purpose of providing evidence on the statutory and regulatory criteria for the issuance of the court order, and be represented by counsel. Any oral argument, review of evidence, or hearing on the application must be held in the judge's chambers, or in some other manner which ensures that patient identifying information is not disclosed to anyone other than a party to the proceedings, the patient or VA. The proceeding may include an examination by the judge of the patient records.
- (3) A court may authorize the disclosure and use of patient records for the purpose of conducting a criminal investigation, or for the prosecution of a patient, only if the court finds that all of the following criteria are met:
- (a) The crime involved is extremely serious, such as one which causes or directly threatens loss of life or serious bodily injury, including: homicide, rape, kidnapping, armed robbery, assault with a deadly weapon, and child abuse and neglect.
- (b) There is a reasonable likelihood that the records will disclose information of substantial value in the investigation or prosecution.
 - (c) Other ways of obtaining the information are not available or would not be effective.
- (d) The potential injury to the patient, to the physician-patient relationship, and to the ability of VA to provide services to other patients is outweighed by the public interest and the need for the disclosure.
- (e) If the applicant is a person performing a law enforcement function, VA has been represented by counsel independent of the applicant.
- (4) Any order authorizing a disclosure, or use, of patients' records must limit disclosure and use to those parts of the patient's record which are essential to fulfill the objective of the order, and to those law enforcement and prosecutorial officials who are responsible for, or are conducting, the investigation or prosecution. The order must limit their use of the records to the investigation and prosecution of the crime, or suspected crime, that is specified in the application. The order must include any other measures that are necessary to limit disclosure and the use of information to only to the amount of information found by the court to be needed in the public interest.

e. Disclosure of 38 U.S.C. 7332 Information to Investigate or Prosecute VA

(1) An order authorizing the disclosure or use of patient records to criminally or administratively investigate or prosecute VA, or employees or agents of VA, may be applied for by an administrative, regulatory, supervisory, investigative, law enforcement, or prosecutorial

agency that has jurisdiction over VA activities. The application may be filed separately or as part of a pending civil or criminal action against VA (or agents or employees) in which it appears that the records are needed to provide material evidence. The application must use a fictitious name to refer to any patient and may not contain or otherwise disclose any patient identifying information unless the court has ordered the record of the proceeding sealed from public scrutiny or the patient has given a written authorization to the disclosure.

- (2) An application may, at the discretion of the court, be granted without notice. Although no express notice is required to VA, or to any patient whose records are to be disclosed, upon implementation of an order that is granted, VA or the patient must be given an opportunity to seek revocation or amendment of the order. This opportunity is limited to the presentation of evidence on the statutory and regulatory criteria for the issuance of the court order.
- (3) The order must be entered in accordance with, and comply with, the requirements of subparagraph 20c(3) and subparagraph 20c(4). The order must require the deletion of patient identifying information from any documents that are made available to the public.
- (4) No information obtained as a result of the order may be used to conduct any investigation or prosecution of a patient; or be used as the basis for an application for an order to criminally investigate or prosecute a patient.

f. Notification to Individual of Disclosures Under Compulsory Legal Process

- (1) When information is disclosed from an individual's record in response to a court order, and the issuance of that court order is made public by the court that issued it, reasonable efforts must be made to notify the individual of the disclosure.
- (2) At the time an order for the disclosure of a record is served at a VA health care facility, efforts must be made to determine whether the issuance of the order has already been made a matter of public record. If the order has not been made a matter of public record, a request must be made to the court that the facility be notified when it becomes public.
- (3) Notification of the disclosure must be accomplished by informing the individual to whom the record pertains, by mail, at the last known address. The letter must be filed in the record if returned as undeliverable by the U.S. Postal Service.
- g. <u>Leave, Fees, and Expenses Related to Court Appearances.</u> The policies concerning court leave, employees appearing as witnesses, temporary duty travel of employees appearing as witnesses, and the charging of fees related to such appearances are contained in MP-1, Part II, Chapter 2, Employee Travel Management, and VA Handbook 5011, Part III.

h. Competency Hearings

(1) VHA may disclose individually-identifiable health information to private attorneys representing veterans rated incompetent or declared incapacitated for a competency hearing when a subpoena, discovery request, or other lawful process is provided, as long as the

individual has been given notice of the request. *NOTE:* A subpoena does <u>not</u> meet the Privacy Act requirement. The Privacy Act authority for this disclosure is Routine Use #8 under the "Patient Medical Records-VA," 24VA19 system of records. The subpoena is the authority under the HIPAA Privacy Rule since Privacy Act routine uses, by themselves, are not adequate authority for disclosure under the HIPAA Privacy Rule.

- (2) VHA may disclose individually-identifiable health information to a court, magistrate, or administrative tribunal in the course of presenting evidence in matters of guardianship in response to a subpoena, discovery request, or other lawful process, when satisfactory assurance in accordance with 45 CFR 164.512 (e)(ii) has been received.
- (3) VHA may disclose individually-identifiable information for competency hearings pursuant to a court order.

NOTE: There is no authority to disclose individually-identifiable health information directly to the patient's next-of-kin for a competency hearing unless the next-of-kin is a personal representative of the patient (see par. 5b).

21. LAW ENFORCEMENT ENTITIES

This paragraph covers disclosures to Federal, state, county, local, or Tribal law enforcement entities, agencies, authorities, or officials.

a. Parole Office

- (1) With the written authorization of the patient, information may be disclosed to those persons within the criminal justice system who have made participation in a treatment program a condition of the disposition of any criminal proceedings against the patient, or of the patient's parole, or other release from custody. Disclosure may be made only to those individuals within the criminal justice system who have a need for the information in connection with their duty to monitor the patient's progress (e.g., a prosecuting attorney who is withholding charges against the patient, a court granting pre-trial or post-trial release, probation or parole officers responsible for supervision of the patient).
- (2) The written authorization must meet the requirements of paragraph 14, and must state the period during which it remains in effect. The period must be reasonable, taking into account:
 - (a) The anticipated length of the treatment;
- (b) The type of criminal proceeding involved, the need for the information in connection with the final disposition of that proceeding, and when the final disposition will occur; and
- (c) Other such factors considered pertinent by the facility, the patient, and the person(s) who will receive the disclosure.

- (3) The written authorization must state that it is revocable upon the passage of a specified period of time or the occurrence of a specified, ascertainable event. The time or occurrence upon which authorization becomes revocable may be no earlier than the individual's completion of the treatment program and no later than the final disposition of the conditional release or other action in connection with which the authorization was given.
- (4) Information disclosed to individuals within the criminal justice system under this paragraph may be re-disclosed and used only to carry out that person's official duties with regard to the patient's conditional release or other action in connection with which the authorization was given.

b. Routine Reporting to Law Enforcement Entities Pursuant to Standing Letters

- (1) Individually-identifiable information, excluding 38 U.S.C. 7332-protected information, may be disclosed to officials of any criminal or civil law enforcement governmental agency or any official instrumentality charged under applicable law with the protection of public health or safety (see par. 27) in response to standing written request letters. These law enforcement agencies are charged with the protection of public safety and the implementation of reporting laws of a State which seek reports on the identities of individuals whom VA has treated or evaluated for certain illnesses, injuries, or conditions.
- (2) A qualified representative of the agency must make a written request which states the information is requested, the specific law enforcement purpose for which the information is needed, and the law which authorizes the law enforcement activity for which records are sought.
- (3) The health care facility Director must acknowledge the receipt of an agency's standing request letter and advise the agency of the penalties (see subpar. 35j) regarding the misuse of the information and that the request letter must be updated in writing every 3 years. A file must be maintained on each agency that submits a standing written request letter for information under the provisions of this subparagraph.
- (4) Information disclosed in response to a standing written request letter is provided for the purpose of cooperating with a State law enforcement reporting requirement. Law enforcement entities routinely require reporting from VHA records for suspected child abuse, suspected elder abuse, gun shot wounds, and other administration action, e.g., suspension or revocation of a driver's license.
- (5) Patient names and addresses that are disclosed may be used only for the purpose stated in the standing written request letter. Title 38 U.S.C. 5701(f)(2) imposes penalties on any organization or member who willfully uses the information for purposes other than those so specified in the request. The penalties include a fine of not more than \$5,000 in the case of a first offense and not more than \$20,000 in the case of any subsequent offense.

c. Specific Criminal Activity

- (1) VHA may disclose individually-identifiable information in response to a request received from a law enforcement agency (e.g., Federal Bureau of Investigation, local Police Department) when such a request is for information needed in the pursuit of a focused (individual specific and/or incident specific) activity such as a civil or criminal law enforcement investigation authorized by law. The request must be:
 - (a) In writing;
 - (b) Specify the particular portion of the record desired;
 - (c) Specify the law enforcement activity or purpose for which the record is sought;
 - (d) State that de-identified data could not reasonably be used; and
 - (e) Be signed by the head of the agency.
- <u>1</u>. A written request may be signed by an official other than the head of the agency provided that individual has been specifically delegated authority to make requests for information under the authority of 5 U.S.C. 552a(b)(7). A general delegation of authority is not sufficient to authorize an individual to make requests for information under this disclosure authority. The delegation may only be to an official of sufficient rank to ensure that the request for the records has been the subject of a high-level evaluation of the investigatory need for the information versus the invasion of personal privacy involved. The requester must supply a copy of the written delegation of authority or provide a reference to the delegation such as a CFR Regulation citation.
- <u>2</u>. Questions as to whether a requester qualifies as the "head of an agency" or an appropriate delegate must be referred to the appropriate Regional Counsel for resolution.
- <u>3</u>. Written requests from VA Offices or Programs performing law enforcement activities (e.g., VA OIG, VA Police) only need to be signed by an individual authorized to request the information.
- (2) Generally, a request for all records pertaining to an individual would not qualify for release under this subparagraph. A request for records pertaining to an individual or a group of individuals must be specific as to the type of records sought, i.e., records for certain types of injuries, for certain time periods, etc.
- (3) Patient names and addresses that are disclosed may be used only for the purpose stated in the request. Title 38 U.S.C. 5701(f)(2) imposes penalties on any organization or member who willfully uses the information for purposes other than those so specified in the request. The penalties include a fine of not more than \$5,000 in the case of a first offense and not more than \$20,000 in the case of any subsequent offense.

d. Identification and Location of Criminals

- (1) VHA may disclose limited individually-identifiable information (see subpar. 21d(2)) to a law enforcement agency or official for the purpose of identifying or locating criminals in response to a written request that meets the requirements of preceding subparagraph 21c.
- (2) In response to a request by law enforcement for the purpose of identifying or locating a suspect, fugitive, material witness, or missing person, VHA may provide or disclose only the following information:
 - (a) Name and address;
 - (b) Date and place of birth;
 - (c) Social security number;
 - (d) A, B, and O blood type and RH factor;
 - (e) Type of injury;
 - (f) Date and time of treatment;
 - (g) Date and time of death, if applicable; and
 - (h) Description of physical characteristics.

e. Breath Analysis and Blood Alcohol Test

- (1) Requests by law enforcement officers and/or government officials for the taking of a blood sample from patients at VA health care facilities for analysis to determine the alcohol content, must be denied. In these situations the requester must be advised that VA personnel do not have authority to withdraw blood from a patient, with or without their authorization, for the purpose of releasing it to anyone for determination as to its alcohol content.
- (2) If a blood alcohol analysis is conducted for treatment purposes, then these results may be released with the patient's prior written authorization. Prior to releasing any blood or alcohol information in response to a valid written request from a civil or criminal law enforcement activity that is made under the provisions of preceding subparagraph 21c, VHA needs to carefully determine whether this information is protected by 38 U.S.C. 7332 (i.e., testing was done as part of a drug, alcohol, sickle cell anemia, and/or HIV treatment regimen). If so protected, then the provisions of paragraph 14 must be followed.
- (3) VA medical personnel have no authority to conduct chemical testing on patients for law enforcement purposes. However, VA personnel need not deny access to VA patients to State and local authorities who, in the performance of their lawful duties, seek to conduct blood alcohol or breath analysis tests (or other similar tests) for investigative or law enforcement purposes, unless the conduct of such tests would create a life-threatening situation for the patient. VA personnel should not assist State or local law enforcement officials in the performance of police functions that are outside the official's authority. In every case where the authority of the law enforcement official is unclear, Regional Counsel needs to be contacted for guidance.

f. Serious Threat to Individual or the Public

- (1) VHA may disclose individually-identifiable information, excluding health information, to law enforcement agencies (e.g., Federal, state, local, and/or Tribal authorities) charged with the protection of the public health for reporting a serious threat to the health and safety of an individual or the public without a standing written request letter or written request if upon such disclosure notification is transmitted to the last known address of the individual to whom the information pertains.
- (2) VHA may disclose individually-identifiable health information, excluding 38 U.S.C. 7332-protected information, to law enforcement agencies charged with the protection of the public health for reporting a serious threat to the health and safety of an individual or the public without a standing written request letter or written request if:
 - (a) The law enforcement agency is reasonably able to prevent or lessen the threat; and
- (b) Notification is transmitted to the last known address of the individual to whom the information pertains.
- (3) VHA may disclose individually-identifiable information, excluding 38 U.S.C. 7332-protected information, necessary for a Federal law enforcement agency to identify or apprehend an individual because of a statement by the individual admitting participation in a violent crime that VHA reasonably believes may have caused serious physical harm to the victim. **NOTE:** For assistance with a disclosure to a non-Federal law enforcement agency contact the VHA Privacy Office.
- (4) VHA may not make a disclosure using the authority under subparagraph 21f(3) when the information was learned in the course of treatment to affect the propensity to commit the criminal conduct or through a request by the individual to initiate or to be referred for treatment, counseling, or therapy for the criminal conduct (see 45 CFR 164.512(j)(2)).
- g. <u>VA Law Enforcement Activities (VA OIG and VA Police).</u> VHA may disclose individually-identifiable information, including health information, to a VA law enforcement authority or official in accordance with the following paragraphs.
- (1) <u>Routine Reporting.</u> VHA may disclose individually-identifiable information pursuant to a standing request letter (e.g., fugitive felons reporting (see VHA HB 1000.2). For national standing request letters see http://vaww.vhaco.va.gov/privacy/VACOAuthority.htm.
- (2) Specific Criminal Activity. VHA may disclose individually-identifiable information in response to a written request received from a VA office conducting law enforcement activities when such a request is for information needed in pursuit of a specific criminal investigation. The request must meet the requirements of subparagraph 21c. As indicated under subparagraph 21c(1)(e)3, the request only needs to be signed by a VA official authorized to request the information.

- (3) <u>Location and Identification of Criminals.</u> VHA may disclose limited individually-identifiable health information (see subpar. 21d(2)) to VA offices performing law enforcement activities for the purpose of identifying or locating criminals in accordance with the requirements of subparagraph 21d.
- (4) <u>Crimes on VA Premises.</u> VHA may disclose individually-identifiable information to VA Police when VHA believes the information constitutes evidence of criminal conduct that occurred on VHA grounds.

22. MEDICAL CARE COST RECOVERY

a. Third-Party Claims (Tort Feasor, Worker's Compensation)

- (1) The individual's signature and assignment of claim on VA Form 4763, Power of Attorney and Agreement, constitutes proper authority to release individually-identifiable information including health information, from the record to the extent required to effect recovery of the costs for medical care provided to patients in cases of tort feasor, worker's compensation, automobile accident reparation insurance, and crimes of personal violence.
- (2) The authorization on VA Form 4763 is not sufficient to disclose information related to treatment for drug or alcohol abuse, HIV, and sickle cell anemia.

b. Third-Party Insurance Claims

- (1) VHA may disclose individually-identifiable health information, excluding 38 U.S.C. 7332-protected information, to any third party or Federal agency and government-wide third-party insurer responsible for payment of the cost of medical care in order for VA to seek reimbursement for the cost of medical care without authorization.
- (2) For 38 U.S.C. 7332-protected information (drug or alcohol abuse, HIV, or sickle cell anemia health information), the individual's signed written authorization must be obtained to permit the disclosure of the information to the third party or Federal agency and government-wide third-party insurer for payment purposes.
- (3) Medical care cost recovery action (e.g., submission of a claim) will not be initiated if the individual's signed written authorization is not obtained to permit the disclosure of 38 U.S.C. 7332-protected information. However, in cases where a substantial bill is involved (i.e., \$25,000 or more) consideration may be given to seeking a court order (see 38 U.S.C. 7332(b)(2)(D)) to permit disclosure. Such cases must be discussed with the Regional Counsel.
- (4) For the purpose of collecting the cost of medical care, individually-identifiable health information, excluding 38 U.S.C. 7332-protected information, may be disclosed to a Federal agency or non-VA health care institution or provider that referred the patient when the medical care is rendered by VA under the provisions of a contract, sharing agreement, or individual authorization. Such disclosures may be made without written authorization. The patient's written authorization must be obtained to disclose 38 U.S.C. 7332-protected information.

c. Disclosures to Debt Collection Agencies

- (1) VHA may contract for services to collect a debt owed to VHA. Individually-identifiable information may be provided to a contracted collection agency without an authorization for this purpose.
- (2) VHA may disclose individually-identifiable information to an agency to assist in the collection of a debt owed to VHA without an authorization.

NOTE: VHA cannot provide individually-identifiable information to a collection agency, contracted or otherwise, for such services until there is a debt owed VHA. For example, a facility cannot use these agencies to verify information that was submitted on the 10-10EZ, Application for Health Benefits, prior to the incurring a cost for care.

23. NEXT-OF-KIN, FAMILY AND OTHERS WITH A SIGNIFICANT RELATIONSHIP

a. General Inquiry

- (1) Appropriate VHA personnel may disclose general information on individuals to the extent necessary and on a need to know basis consistent with good medical and/or ethical practices to the next-of-kin or person(s) with whom the individual has a meaningful relationship.
- (2) VHA may disclose general information to a member of the public regarding the location or condition of the individual and to a member of the clergy regarding religious affiliation without the written authorization of the individual, as long as the individual is included in the VA Patient Directory (also known as the Facility Directory).

b. Inquiries in Presence of Individual

- (1) VHA may disclose individually-identifiable information including health information to next-of-kin, family members, and others identified by the individual to whom the information pertains in the presence of the individual if:
- (a) VHA provides the individual with the opportunity to object to the disclosure, and the individual does not express an objection; or
- (b) It is reasonably inferred from the circumstances, based on the exercise of professional judgment, the individual does not object to the disclosure.
- (2) VHA employees are encouraged to document the decision to share information when good medical and ethical practices dictate.

c. Inquiries Outside Presence of the Individual

- (1) VHA may disclose individually-identifiable information including health information to next-of-kin, family members, and others with a significant relationship to the individual to whom the information pertains, without authorization, when in the exercise of professional judgment VHA determines the disclosure is in the best interests of the individual. The disclosure must be limited to information directly relevant to the person's involvement with the individual's health care.
- (2) Inquiries may include, but are not limited to, questions or discussions concerning: medical care and/or home-based care; picking up medical supplies (i.e., wheelchair) and filled prescriptions; and providing forms or other information relevant to the care of the individual. Providing a copy of medical records to next-of-kin, family members, or any other person still requires the written authorization of the individual to whom the records pertain.
- (3) VHA employees are encouraged to document the decision to share information when good medical and ethical practices dictate.

d. HIV Status Notification to the Spouse or Sexual Partner of the Patient

- (1) The treating physician, or a professional counselor, may disclose information indicating that a patient is infected with HIV if the disclosure is made to the spouse of the patient, or to a person whom the patient has identified as being a sexual partner during the process of professional counseling for testing to determine whether the patient is infected with the virus (see 45 CFR 164.512(j)).
- (2) Disclosure may be made only if the treating physician or counselor, after making reasonable efforts to counsel and encourage the patient to provide the information to the spouse or sexual partner, concludes the following:
 - (a) Reasonably believes that the patient will not provide the information; and
 - (b) That the disclosure is necessary to protect the health of the spouse or sexual partner.
- (3) Disclosure may be made by another physician or counselor, if the treating physician or counselor who counseled the patient about providing the information to the spouse or sexual partner is unavailable due to absence, extended leave, or termination of employment.
- (4) Before any patient gives authorization to being tested for the HIV, as part of pre-test counseling, the patient must be informed fully about this notification provision.
- (5) In each case of a patient with a positive HIV test result who has a spouse or has identified a person as a sexual partner, the treating physician or professional counselor must document in the progress notes of the medical record, the factors that are considered which lead to a decision as to whether an un-consented disclosure of the HIV infection information needs to be made to the patient's spouse or sexual partner. Any disclosure must be fully documented in the progress notes of the patient's medical record.

e. <u>Serious Threat to Family and Others</u>. VHA may disclose individually-identifiable information in accordance with 5 U.S.C. 552a(b)(8) and 45 CFR 164.512(j) to a family member (e.g., spouse) or significant other pursuant to showing compelling circumstances affecting the health or safety of such individual if, upon disclosure, written notification is transmitted to the last known address of the person to whom the individually-identifiable information pertains.

24. NON-VA HEALTH CARE PROVIDER (PHYSICIANS, HOSPITALS, NURSING HOMES)

- a. VHA may disclose individually-identifiable health information, excluding 38 U.S.C. 7332-protected information, to a non-VA health care provider for the purposes of VA paying for services.
- b. VHA may disclose individually-identifiable health information, excluding 38 U.S.C. 7332- protected information, to a non-VA health care provider without the prior written authorization of the individual to whom the information pertains for treatment of such individual, including a veteran, veteran beneficiary, member of the armed forces, or any other person who has received care from VA.
- c. VHA may disclose individually-identifiable health information, excluding 38 U.S.C. 7332, to resident care homes, assisted living facilities, and home health services for the purposes of health care referrals without the written authorization of the individual to whom the information pertains.
- d. VHA may disclose 38 U.S.C.7332-protected information to a non-VA health care provider including home health services, resident care homes, and assisted living facilities only with the written authorization of the individual to whom the information pertains.
- e. VHA may disclose individually-identifiable information, including health information, to a non-VA health care provider caring for an individual under emergent conditions. A notification of the disclosure must be mailed to the patient at the last known address (see 5 U.S.C. 552a(b)(8)).
- f. VHA may disclose individually-identifiable information, including relevant health information excluding 38 U.S.C. 7332-protected information, to welfare agencies, housing resources, and utility companies in situations where VHA needs to act quickly to prevent the discontinuation of services that are critical to the health and care of the individual.

25. ORGAN PROCUREMENT ORGANIZATION (OPO)

a. VHA may disclose relevant individually-identifiable health information, excluding 38 U.S.C. 7332-protected information and the name and address of the patient, to the local Organ Procurement Organization (OPO), or other entity designated by the OPO for the purpose of determining suitability of a patient's organs or tissues for organ donation without prior written authorization of the patient or personal representative.

- b. OPOs, or their designees, may perform the medical chart reviews required in making these determinations only if the facility's designated requestor has removed any 38 U.S.C. 7332-protected information and the name and address of the patient from the chart or has obtained authorization from the patient or personal representative.
- c. VHA may not disclose individually-identifiable health information containing 38 U.S.C. 7332-protected information without prior written authorization from the patient. *NOTE:* If Congress enacts legislation allowing for the disclosure of information protected by 38 U.S.C. 5701 and 38 U.S.C. 7332, the authorization requirements in this paragraph may no longer apply. Contact the VHA Privacy Office for additional information.

26. OTHER GOVERNMENT AGENCIES

- a. <u>Federal Agencies</u>. VHA may disclose individually-identifiable information, excluding health information, to another Federal agency if the information is needed in order to perform a function of the requesting agency and if one or more of the disclosure provisions of the Privacy Act permits the disclosure (e.g., routine use disclosure statement under an applicable VHA system of records).
- (1) For reporting to the HHS National Practitioner Data Bank (NPDB) refer to VHA Handbook 1100.17, and 38 CFR Part 46.
 - (2) For reporting to NARA refer to VA Handbook 6300 and 5 U.S.C. 552a(b)(6).
- (3) VHA may disclose individually-identifiable health information, excluding 38 U.S.C. 7332-protected information, to another Federal agency for the purpose of treatment, payment, and/or health care operations, as long as a routine use disclosure statement under the applicable VHA system of records or other Privacy Act authority can be applied.
- (4) VHA may only disclose 38 U.S.C. 7332-protected information to another Federal agency pursuant to the law and this Handbook.
- b. <u>National Security</u>. VHA may disclose individually-identifiable information, excluding 38 U.S.C. 7332-protected information, to authorized Federal officials for the conduct of lawful intelligence or counter-intelligence, the protective services of the President, and/or other national security activities:
 - (1) Upon its own initiative when VHA becomes aware of a national security issue; or
 - (2) Pursuant to a written request letter meeting the requirements of subparagraph 21c.

27. PUBLIC HEALTH AUTHORITIES

a. <u>HIV Reporting.</u> Information relating to an individual's infection with HIV may be disclosed from a record to a Federal, State, or local public health authority that is charged under Federal or State law with the protection of the public health. A Federal or State law must require disclosure of the information for a purpose that is authorized by law and a qualified

official of the public health authority must make a written request for the information (see subpar. 27c for request requirements.)

b. Food and Drug Administration (FDA)

(1) Routine Reporting

- (a) VHA may disclose individually-identifiable information including health information to the FDA, or a person subject to the jurisdiction of the FDA, with respect to an FDA-regulated product for purposes of activities related to the quality, safety, or effectiveness of such FDA-regulated product. Such purposes include:
- $\underline{1}$. To report adverse events, product defects or problems, or biological product deviations if the person is required to report such information to the FDA;
 - 2. To track products if the person is required to track the product by the FDA;
 - 3. To conduct post-marketing surveillance to comply with requirements of FDA; and/or
 - 4. To enable product recalls, repairs, or replacement.
- (b) With written authorization, VHA may disclose individually-identifiable information for the same purposes as in preceding subparagraph 27b(1)(a) to a product manufacturer or any person and/or organization subject to FDA regulations.

(2) FDA Audit

- (a) Upon their official written request, authorized FDA agents and investigators are permitted access to individually-identifiable health information in order to carry out their program oversight duties under the Federal Food, Drug, and Cosmetic Act. However, in the event these activities shift from audit to investigation, VHA may not disclose individually-identifiable information covered by 38 U.S.C. 7332 unless the FDA obtains a court order.
- (b) FDA agents may be provided with individuals' names and addresses for the sole purpose of auditing or verifying records. FDA agents must exercise all reasonable precautions to avoid inadvertent disclosure of patient identities to third parties and may not compile any information in a registry or data bank.

c. All Other Public Health Reporting

- (1) VHA may disclose individually-identifiable information, excluding 38 U.S.C. 7332-protected information, to Federal, State, and/or local public health authorities charged with the protection of the public health or safety pursuant to a standing request or other applicable legal authority (see subpar. 27a for disclosing 38 U.S.C. 7332-protected HIV information). Standing requests are valid for 3 years, at which time they must be reissued.
 - (2) Examples of public health reporting requiring a standing request or letter include:

- (a) Communicable diseases (e.g., hepatitis, tuberculosis, sexually transmitted diseases, etc.);
 - (b) Vital statistics (e.g., deaths, etc.); and
 - (c) Other State reporting requirements (e.g., animal bites).

28. REGISTRIES

a. <u>State Central Cancer Registries.</u> VHA may disclose individually-identifiable health information, excluding 38 U.S.C. 7332-protected information, to any State Central Cancer Registry upon the written request of the State when required by State law. The written request must meet the requirements of following subparagraph 28b(1)(b). The written request may be considered a standing request for ongoing reporting to the State Central Cancer Registry if continuous reporting is requested. A standing request is valid for 3 years, at which time it must be reissued.

b. Other Public Registries

- (1) VHA may disclose individually-identifiable health information, excluding 38 U.S.C. 7332-protected information, to any other public registry (e.g., Federal, State, local) upon request when required by law under the following conditions:
- (a) <u>Federal Registries</u>. The head of the requesting Federal agency, or designee, must submit a written request which indicates that the information is needed in order to accomplish a statutory purpose of that agency.

(b) State or Local Registries

- <u>1</u>. Disclosure of individually-identifiable information, including name and address, may be made to other governmental (state or local) registries only if: the law of the State under which the requesting registry operates requires health care providers who are subject to State law to report name, address, and medical record data to the registry; and the registry is operated by a State public health service or state health or safety agency which has law enforcement authority.
- <u>2</u>. A qualified representative of the agency must make a written request that the name(s) and/or address(es) and medical record data be provided for a purpose required by law and identify the law involved.
- <u>3</u>. When disclosure of information is made under the provisions of this subparagraph, the requester must be aware of the penalty provisions of 38 U.S.C. 570l(f). If the requester does not indicate awareness of this penalty provision in the request, disclosure of medical information under subparagraph 28b(1)(b) must be accompanied by a precautionary written statement worded similarly to the following:

"This information is being provided to you in response to your request (each VA health care facility needs to appropriately identify the request). Please be advised that under the provisions of Title 38, United States Code, Section 5701(f), if you willfully use the patient's name and/or address for any purpose other than for the purpose specified in your request, you may be found guilty of a misdemeanor and fined not more than \$5,000 in the case of a first offense and not more than \$20,000 in the case of any subsequent offense."

- (2) Prior to disclosure of the requested information, the assistance of the Regional Counsel may be sought, when appropriate, in evaluating the applicable law relative to the statutory authority of a governmental agency to gather information on individuals.
- c. <u>Private Registries.</u> VHA may not disclose individually-identifiable information to private registries without the prior written authorization of the individual to whom the information pertains.

29. STATE VETERAN HOMES

a. VHA may disclose a patient's individually-identifiable health information, excluding 38 U.S.C. 7332-protected information, to a State Veterans Home for the purpose of medical treatment and/or follow-up at the State Veterans Home. VA must be paying a per diem rate to

the State Veterans Home for the patient receiving care at such Home and the patient must be receiving VA medical care.

- b. VHA may disclose 38 U.S.C. 7332-protected information to a State Veterans Home with the written authorization of the individual.
- c. If there is no written authorization, VHA may disclose 38 U.S.C. 7332-protected information to the State Veterans Home when a State Veteran Home refers an individual for treatment of 38 U.S.C. 7332 conditions to a VA medical center and the individual returns to the State Veteran Home in order for the State Veterans Home to provide continuity of care and treatment to the patient.

30. VETERAN SERVICE ORGANIZATIONS (VSO)

- a. VHA may disclose individually-identifiable information including health information to a Veterans Service Organization (VSO) for purposes of obtaining benefits under 38 U.S.C. provided an appropriate POA has been filed with the VA health care facility that maintains the information.
- b. If the VSO does not have an appropriate POA, disclosure may be made only pursuant to a written authorization from the individual to whom the information pertains.
- c. VSO's <u>cannot</u> be provided a copy of a VA health care facility's Gains and Losses sheet since there is no authority to disclose this information. Questions from VSOs on this matter need to be forwarded to the VHA Privacy Officer.

31. DECEASED INDIVIDUALS

For the purposes of this paragraph, the personal representative of a deceased individual has the same rights as the deceased individual that the personal representative is representing. If, under applicable law, an executor, administrator, or other person has authority to act on behalf of a deceased individual or on behalf of the deceased individual's estate, VHA must disclose to the personal representative the individually-identifiable health information, but only to the extent that the individually-identifiable health information is relevant to such personal representation. Refer to paragraph 5b., Representatives of the Individual, for more information on personal representatives.

a. General Rule

(1) VHA must protect the individually-identifiable health information about a deceased individual to the same extent as required for the individually-identifiable health information of living individuals with the exception of the applicability of the Privacy Act for as long as VHA maintains the records. *NOTE:* See Records Control Schedule (RCS) 10-1 for retention requirements of VHA records.

- (2) VHA may disclose individually-identifiable health information, excluding 38 U.S.C 7332 information (see following subpar. 31b), about a deceased individual under the following circumstances:
- (a) To a law enforcement official for the purpose of alerting law enforcement of an individual's death if VHA has a suspicion that such a death may have resulted from criminal conduct. A standing letter must be on file (see subpar. 21b).
- (b) To a coroner or medical examiner for the purpose of identifying a deceased person, determining cause of death, or for other duties authorized by law.
- (c) To a family member's physician when it is determined that it is relevant to the treatment of a decedent's family member, or consistent with applicable law.
- (d) To funeral directors, as necessary, to carry out their duties with respect to the decedent. VHA may disclose the individually-identifiable health information prior to, and in reasonable anticipation of, the individual's death.
- (e) To family members of the deceased individual when appropriate authority under FOIA permits (see subpar. 31c).
- (f) To any other party for which there is authority under the HIPAA Privacy Rule and 38 U.S.C. 5701 to make the disclosure.
- (3) VHA may use, or disclose, individually-identifiable health information, excluding 38 U.S.C. 7332-protected information, of a decedent for research purposes without authorization by a personal representative, and absent review by an IRB or privacy board, as long as VHA receives the following:
- (a) Oral or written representation that the individually-identifiable health information sought will be used or disclosed solely for research on decedents.
 - (b) Documentation of the death of such individual, if requested by VHA.
- (c) Representation that the individually-identifiable health information for which use or disclosure is sought is necessary for the research purposes.

NOTE: One needs subparagraphs 31a(3)(a) or 31a(3)(b), and 31a(3)(c).

b. Deceased Veterans with 38 U.S.C. 7332 Information

(1) Authorization for disclosures from the record of a deceased patient treated for drug or alcohol abuse, HIV, or sickle cell anemia may be given by the next-of-kin or other personal representative only for the purpose of obtaining survivorship benefits for the deceased patient's survivor(s). This would include not only VA benefits, but also payments by the Social Security Administration (SSA), Worker's Compensation Boards or Commissions, other Federal, State, or local government agencies, or non-government entities, such as life insurance companies.

- (2) Under the survivorship benefit provision, sickle cell anemia information may be released to a blood relative of a deceased veteran for medical follow-up or family planning purposes.
- (3) Disclosures may be made without written authorization in order to comply with Federal or state laws requiring the collection of death and other vital statistics.
- (4) Information may be disclosed to a coroner or medical examiner in response to a standing request letter or written request in order to permit inquiry into a death for the purpose of determining cause of death.
- (5) Information may only be disclosed for research purposes, pursuant to the provisions of subparagraph 13b(1)(d).

c. Family Members Requesting Deceased Veterans' Records

- (1) VHA may disclose individually-identifiable health information, excluding 38 U.S.C. 7332-protected information, about a deceased individual pursuant to a family member's FOIA request when such disclosure is not an unwarranted invasion of the personal privacy of any surviving family members. Family members may include spouse, parents, children, and siblings.
- (2) When an individual is deceased, FOIA Exemption 6 no longer applies to the personal privacy of the individual, it applies to protecting the individual's surviving family members from an unwarranted invasion of personal privacy.

NOTE: FOIA Exemption 6 cannot be used to protect the privacy of a family members from themselves (e.g., cannot use Exemption 6 to protect the surviving spouse when the spouse is making the FOIA request).

32. FREEDOM OF INFORMATION ACT (FOIA)

a. General

- (1) The FOIA requires disclosure of VA records, or any reasonably segregable portion of a record, to any person upon written request. A FOIA request may be made by any person (including foreign citizens), partnerships, corporations, associations, and foreign, State, or local governments. Requests for records by Federal agencies and their employees acting in their official capacity are not FOIA requests. Requests for records by fugitives from justice seeking records related to their fugitive status are not FOIA requests.
- (2) VHA administrative records not retrieved by name, social security number, or other identifier must be made available to the greatest extent possible in keeping with the spirit and intent of the FOIA. Before releasing records in response to a FOIA request, the record must be reviewed to determine if all or only parts of it cannot be released. For example, a requester may

ask for copies of correspondence on a particular subject. If VA has one or more letters that are applicable and can be released, but the letters contain names of individuals and other personal information, the personal identifying information can be withheld. The remaining parts of the letter(s), with the personal information deleted, may be required to be released. Consequently, VA may release the letters, but the personal information will be deleted. This process of deleting portions of documents before releasing them is referred to as "redaction."

b. Requests for Copies of Records

- (1) Records or information customarily furnished to the public in the regular course of the performance of official duties may be furnished without a written request. A request for access to official records under the FOIA must be in writing over the signature of the requester and reasonably describe the records so that they may be located. This procedure should not be waived for reasons of public interest, simplicity, or speed. Written requests provide a basis to support a possible appeal. Generally, the request does not have to be designated a FOIA request and the individual does not have to explain why access to official records is desired. Requests from individuals for information about themselves, that is retrieved by their names or other personal identifiers, need to be processed under both the FOIA and the Privacy Act. The record sought must be reasonably described so that it can be located with a reasonable amount of effort by an employee who is familiar with the subject area of the request. If the request does not give enough information to identify the record, the requester needs to be contacted for additional information. The fact that a request involves searching a large number of records does not, in and of itself, entitle a facility to deny the request on the basis that the records are not reasonably described.
- (2) VA is not required to create or to analyze a record or answer interrogatories under FOIA. VA has no legal obligation to write, revise, reassemble, catalogue, or to obtain or produce new documents for a requester. However, writing a computer program in order to extract data from an existing automated database is not the creation of a record. If an individual requests another agency's records which are in VA's possession, the individual must be advised that the request has been referred to that agency or that additional time will be required for VA to consult with that agency before a determination can be provided.
- (3) VA must provide requested records in any form or format requested (if feasible), if the records already exist in that form or format or are readily reproducible in that form or format with reasonable efforts.

c. Fees and Fee Reductions and Waivers

(1) There are four categories of FOIA requesters: commercial use requesters; educational and non-commercial scientific institutions requesters; requesters who are representatives of news media; and all other requesters. Specific levels of fees must be charged for each of these categories in accordance with 38 CFR 1.555. When records are requested for commercial use the fee must be limited to reasonable standard charges for document search, duplication, and review. Requesters of records for commercial uses must be charged for all search and duplication, regardless of the amount of time spent searching or the number of pages duplicated. When records are requested by an educational or noncommercial scientific institution for a

scholarly or scientific research purpose and not for commercial use, or by a representative of the news media, the fee is to be limited to the reasonable standard charges for document duplication after the first one hundred one-sided pages. All other requesters are to be charged fees that recover the full reasonable direct cost of searching for and reproducing the records, but will not be charged for the first two hours of search time or for the first one hundred one-sided pages of duplication.

(a) Commercial Use Requesters

- <u>1</u>. A commercial use request means a request from, or on behalf of, one who seeks information for a use or purpose that furthers the commercial, trade, or profit interests of the requester or the person on whose behalf the request is made. To determine whether a request properly belongs in this category, consideration must be given to the use to which a requester will put the documents requested. Where the use of the records sought is not clear in the request, or where there is reasonable cause to doubt the use to which the requester will put the records sought, additional information must be obtained from the requester before assigning the request to a specific category.
- 2. The full direct costs of searching for, reviewing for release, and duplicating the records must be charged to a commercial use requester. Such requesters are not entitled to 2 hours of free search time nor 100 free one-sided pages of reproduced documents. Moreover, the commercial use requester must be charged the cost of searching for and reviewing records even if there is ultimately no disclosure of records. Review is the process of examining documents located in response to a FOIA request in order to determine whether the documents must be disclosed under FOIA, and for the purposes of withholding any portions exempt from disclosure under FOIA. Review costs may not include time spent resolving general legal or policy issues regarding the application of exemptions.

(b) Educational and Non-commercial Scientific Institution Requesters

- <u>1</u>. An educational institution is a pre-school, a public or private elementary or secondary school, an institution of graduate higher education, an institution of professional education, and an institution of vocational education which operates a program or programs of scholarly research. To determine whether a request properly belongs in this category, the request must be evaluated to ensure that it is apparent from the nature of the request that it serves a scholarly research goal of the institution, rather than an individual goal of the requester or a commercial goal of the institution. This institutional versus individual test applies to requests from students as well. For example, a student who makes a request in furtherance of the completion of a course of instruction is carrying out an individual research goal and the request does not qualify under this category.
- <u>2</u>. A non-commercial scientific institution is one that is not operated on a commercial basis (as that term is referenced under commercial use request) and which is operated solely for the purpose of conducting scientific research, the results of which are not intended to promote any particular product or industry.

- <u>3</u>. These requesters must be charged only for the cost of reproduction, excluding charges for the first 100 one-sided pages. In order to be considered a member of this category, a requester must show that the request is being made as authorized by and under the auspices of a qualifying institution and that the records are not sought for a commercial use. If the request is from an educational institution, the requester must show that the records sought are in furtherance of scholarly research. If the request is from a non-commercial scientific institution, the requester has to show that the records are sought in furtherance of scientific research. Information necessary to support a claim of being an educational or non-commercial scientific institution requester must be provided by the requester.
- (c) Representative of the News Media. A representative of the news media is any person actively gathering news for an entity that is organized and operated to publish or broadcast news to the public. The term "news" means information that is about current events or that would be of current interest to the public. Examples of news media entities include television or radio stations broadcasting to the public at large, and publishers of periodicals (but only in those instances when they can qualify as disseminators of "news") who make their products available for purchase or subscription by the general public. Freelance journalists may be regarded as working for a news organization if they can demonstrate a solid basis for expecting publication through that organization, even though not actually employed by it. A publication contract would be the clearest proof, but the requester's past publication history can be considered also. These requesters will be charged for the cost of reproduction only, excluding charges for the first 100 one-sided pages. To be included in this category, a requester must meet the criteria described above and the request must not be made for commercial use. A request for records supporting the news dissemination function of the requester will not be considered to be a request that is for commercial use.
- (d) <u>All Other Requesters.</u> Any requester that does not fit into any of the categories described in the preceding paragraphs must be charged fees which recover the full reasonable direct cost of searching for and reproducing records that are responsive to the request, except that the first 100 one-sided pages of reproduction and the first 2 hours of search time will be furnished without charge.
- (2) Any FOIA requester may ask for a waiver or reduction of the fees for processing a request. Records must be furnished without any charge or at a reduced charge, if disclosure of the information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester. Requests for reduction or waiver of the fees must be considered in view of the criteria established in 38 CFR 1.555(f). Fees will not be charged if the costs of routine collection and processing of the fees are likely to equal or exceed the amount of the fees. If it is determined that the fees are likely to exceed \$25, the requester must be notified of the estimated amount of fees unless the requester has indicated in advance a willingness to pay fees as high as those anticipated. The requestor will be offered the opportunity to confer with VA personnel with the object of reformulating the request to meet the requester's needs at a lower cost in accordance with 38 CFR 1.555(b)(2). A requester may be requested to make an advance payment of fees when the allowable charges to be assessed are likely to exceed \$250, or when a requester has previously failed to pay a fee charged in a timely fashion (i.e., within 30 days of the date of the billing). Where the requester has a history of

prompt payment of FOIA fees and the charges to be assessed are likely to exceed \$250, the requester must be notified of the likely charge and asked to provide satisfactory assurance of full payment. Where allowable charges are likely to exceed \$250, a requester with no history of payment must be required to make payment of an amount up to the full estimated charges.

d. Processing a FOIA Request

(1) A request for records received at a health care facility must be promptly referred for action to the facility's FOIA Officer. The requester must be notified in writing within 20 workdays after receipt of the request whether the request will be granted or denied. The 20-day time limitation begins upon receipt of the request by the office which is responsible for replying. Once the requester has been notified of a determination to comply with the request, the document(s) must be made available promptly.

NOTE: Any request for records created or provided by the VA Office of Inspector General must be referred to the VA Office of Inspector General for response. The requestor must be informed in writing that the request is being referred to the VA Office of Inspector General for response.

- (2) A written response which denies a request for information must include the statutory authority (exemption) which provides for the withholding (e.g., 5 U.S.C. 552(b)(6) disclosure would constitute a clearly unwarranted invasion of personal privacy), and include an estimate as to the number of pages and documents completely withheld from the FOIA requester. The requester must also be advised of the right to appeal an adverse determination, including a "no records found" determination, to the Office of General Counsel (024), Department of Veterans Affairs, 810 Vermont Avenue, NW, Washington, DC 20420. When FOIA exemptions are invoked, the exempted portions of the record must be redacted with the statutory exemption inserted (e.g., Exemption 6). The segregable non-exempt portions must be released.
- (3) In unusual circumstances, extensions of not more than 10 workdays may be granted in advising a requester whether VA will grant or deny the request when one of the following conditions exist:
- (a) There is a need to search for and collect the requested records from field facilities that are separate from the office processing the request;
- (b) There is a need to search for, collect, and examine a voluminous amount of separate and distinct records which are demanded in a single request; or
- (c) There is a need for consultation with another agency having substantial interest in the determination of the request or among two or more components of VA having substantial subject-matter interest therein.
- (4) If an extension of time is required to respond to a request, the requester must be advised in writing of the extension, the reasons for the extension, and the date on which a determination is to be provided.

- (5) A FOIA requestor may make a request for expedited processing with a certification of "compelling need."
 - (a) A compelling need is defined as:
 - 1. Involving an "imminent threat to the life or physical safety of an individual," or
- <u>2</u>. In the case of a request made by a person primarily engaged in disseminating information, "urgency to inform the public concerning actual or alleged Federal government activity."
- (b) VA needs to grant such requests whenever a compelling need is shown. VA is required to make a determination and notify the requestor of its decision whether or not to grant expedited processing within 10 calendar days after receipt of the request. If expedited processing is granted, VA must give priority to that FOIA requester, and process the requested records for disclosure "as soon as practicable."
- (c) If the request is denied, the requestor must be given notice of appeal rights to the OGC as mentioned in subparagraph 32d(2).

e. Exhaustion of Administrative Remedies

- (1) The requester must comply with the administrative procedures established by the FOIA regarding the initial, as well as the appellate request.
- (2) If VA fails to comply with the time limitations for response to an initial or appellate request or fails to advise a requestor of the requester's appeal rights where any adverse determination is given, then it will have "exhausted the administrative remedies" of that FOIA requestor.
- (3) A requester may file a lawsuit in a Federal district court when VA does not meet the time limitations imposed by the FOIA or fails to provide a requestor's appeal rights when applicable.

f. Exemptions from Public Access to VHA Records

(1) Under FOIA, 5 U.S.C. 552 (b), there are nine exemptions which permit withholding of certain information from disclosure (see 38 CFR 1.554(a)). Although it is VA policy to disclose information from VA records to the maximum extent permitted by law, there are circumstances, however, when a record should not or cannot be disclosed in response to a FOIA request. When such an occasion arises, the FOIA permits records or information, or segregable portions thereof, to be withheld under one or more of the exemptions. These exemptions need to be invoked in denying a request only after careful review and consideration of all factors surrounding the request. The exemptions are:

(a) Exemption (1)

- <u>1</u>. This exemption allows VA to exempt from mandatory release national defense or foreign policy information that has been properly classified pursuant to an appropriate Executive Order. As stated in VHA Handbook 1907.1, which includes VA policy on the handling of classified information, VA does not have original classification authority. "Original classification" is the initial determination that information requires protection against unauthorized disclosure in the interest of national security and a designation of the level of classification. Requests for records that were originated and originally classified by another agency need to be referred to the originating agency for processing and the requester notified of the referral. *NOTE:* If VHA is in possession of classified documents or information sought under the FOIA, contact the VHA FOIA Officer before responding in any way to the FOIA request.
- 2. Requests for information that was previously classified by an original classification authority that is incorporated, paraphrased, restated, or generated in new form in a VA document and has received a derivative classification (a determination that information is in substance the same as information that is currently classified, and a designation of the level of classification) must be processed as follows. The classified information must be deleted and the FOIA Officer and the office that generated the document must make a determination as to the extent any or all of the remainder of the information can be disclosed. The information must be redacted and/or disclosed accordingly. A redacted version of the disclosed document which includes the classified information must be referred to the originating agency for processing and the requester must be notified of the referral. Also, the requester must be advised of all withholding of information, the exemption(s) which provides for such withholdings, and that the denial may be appealed to the General Counsel.
- (b) **Exemption (2).** This exemption has been interpreted to encompass two distinct categories of information:
- <u>1</u>. Internal matters of a relatively trivial nature (material which is so mundane or trivial that the public would not have legitimate interest in the information), and
- <u>2</u>. More substantial internal matters the disclosure of which would allow circumvention of a statute or agency regulation (e.g., manuals and documents relating to law enforcement investigations, instructions, procedures and techniques, computer security codes, etc.).
- (c) **Exemption (3).** This exemption directly involves the application of other statutes that, by their terms, require that certain information must be withheld or it refers to particular types of matters to be withheld. Examples of statutes that may be cited under this exemption are 38 U.S.C. 5701 (VA claimant and dependent name and address information only), 38 U.S.C. 5705 (medical quality assurance information), and 38 U.S.C. 7332 (drug abuse, alcoholism or alcohol abuse, HIV infection, or sickle cell anemia medical treatment information).
- (d) **Exemption (4).** This exemption concerns privileged or confidential trade secrets and commercial or financial information obtained from parties outside the Government. For such information to be subject to withholding under this exemption, it must be shown that:

- <u>1</u>. Disclosure is likely to impair the Government's ability to obtain necessary information in the future; or
- <u>2</u>. There is likelihood that release will cause the submitter of the information substantial competitive harm.

NOTE: Subparagraph 32h provides procedures to be followed when responding to FOIA requests for business information.

- (e) **Exemption (5).** This exemption provides that VA records and documents need not be disclosed if they are "interagency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency." The words "memorandums" and "letters" are usually interpreted quite broadly by the courts and include virtually any document VA produces, including reports, audits, records, contract reports, forms, etc.
- 1. Protected by this exemption are records that are commonly withheld in civil litigation by the attorney-client privilege, the attorney work-product privilege, and the deliberative process privilege. The last privilege protects pre-decisional VA records and documents created as part of the deliberative (decision-making) process. If a document constitutes or reflects a VA decision or final opinion, it is clearly not pre-decisional and so not exempt under this privilege. The pre-decisional character of a document is not lost because a final agency decision has been made on the matter. Information may be deleted from documents which are created as part of the deliberative decision-making process which reflect an employee's advice, recommendations, opinions, or proposals so long as such advice, recommendations, opinions, or proposals remain pre-decisional and are not "incorporated by reference" into final Department decisions. **NOTE:** "Incorporated by reference" means that the document which reflects the final decision on the matter makes specific reference to the pre-decisional document as the source or basis for the decision, or that the final decision is recorded directly on the pre-decisional document. Predecisional documents may lose their exempt status under this exemption if VA chooses expressly to adopt, or to incorporate by reference, such documents in a final decision or opinion, in statements of policy or interpretations adopted by VA, or instructions to staff that affect a member of the public.
- <u>2</u>. In general, it is very difficult to apply this exemption to protect pre-decisional factual information; ordinarily, factual material must be disclosed if the only withholding basis for consideration is the deliberative process privilege. However, factual information may be protected where it has been selected out of a larger group of factual information and this selecting out is deliberative in nature. It may also be withheld under this privilege where the factual material is so inextricably connected to the deliberative process that revealing the factual material would be tantamount to revealing the Department's deliberations. In actual application of this exemption, the requested document must be reviewed and the releasable factual information segregated by redacting the exempt information. *NOTE:* Facts that are so intertwined with exempt portions may be exempted from release where it is not possible, following the editing of withholdable material, to leave in meaningful portions of factual information.

- (f) **Exemption** (6). This exemption allows for the withholding of personal information that may be contained in any Department record (including personnel, medical files, and similar files) where the disclosure would constitute a clearly unwarranted invasion of personal privacy. This exemption needs to be considered for information of a personal nature regardless of what type of file it is located in, or even if it exists in a tangible form but not in a file.
- 1. Application of this exemption requires a balancing between an individual's right to privacy and the public interest in the material requested. An employee's job title, grade, salary, and other information identified in 5 CFR 293.311 are open to public review when requested under FOIA, while home address information generally is not. The first step in the Exemption 6 balancing process requires an assessment of the privacy interests at issue. In some instances, the disclosure of information may involve little or no invasion of privacy because no expectation of privacy exists. Once it has been determined that a privacy interest is threatened by disclosure, the second step in the balancing process requires an assessment of the public interest in disclosure. The measure of the public interest is whether the disclosure of the information in question sheds light directly on the Department's performance of its statutory duties. Information that reveals little or nothing about the Department's own conduct does not meet this public interest standard. If the information meets this standard then, for purposes of Exemption 6, it must be disclosed unless such disclosure would constitute a clearly unwarranted invasion of personal privacy. Intimate, personal details of an individual's life, for example, have been withheld even when there is some public interest, of the type discussed in the preceding sentences, in that information. Individuals who seek records for their own benefit are not acting to further a public interest.
- <u>2</u>. Where personal information, such as names or personal identifiers is contained in records that would otherwise be releasable, such individual names, other identifiers, and information that would reasonably tend to identify them may be redacted, citing this exemption, where there is not an overriding public interest in disclosing such names or identifiers (see par. 15 for application of this exemption to records protected by the Privacy Act and 45 CFR Parts 160 and 164).
- (g) **Exemption (7).** This exemption provides that VA may withhold investigatory records and documents which are prepared for law enforcement purposes, but only to the extent that disclosure of the records or information:
 - 1. Could reasonably be expected to interfere with on-going law enforcement proceedings;
 - 2. Would deprive a person of a right to a fair trial or an impartial adjudication;
 - 3. Could reasonably be expected to constitute an unwarranted invasion of personal privacy;
- <u>4</u>. Could reasonably be expected to disclose the identity of a confidential source (including a State, local, or foreign agency or authority or any private institution which furnished information on a confidential basis);

- <u>5</u>. Would disclose techniques and procedures for law enforcement investigations or prosecutions, or would disclose guidelines for law enforcement investigations or prosecutions if such disclosure could reasonably be expected to risk circumvention of the law; or
 - <u>6</u>. Could reasonably be expected to endanger the life or physical safety of any individual.
- (h) **Exemption (8).** This exemption concerns Federal agencies involved in the regulation of financial institutions and is not applicable to VA operations.
- (i) **Exemption (9).** This exemption concerns geological and geophysical information and has no direct application to VA.
- (2) All requested records must be reviewed, on a line by line, page by page basis, prior to disclosure. Appropriate withholding and/or deletion (redacting) of information must be made in accordance with the exemptions. The amount of information deleted must be indicated on the released portion of the record unless that indication would harm an interest protected by the applicable exemption. VA needs to specify in its denial letters the volume of what is withheld in numbers of entire pages, documents, or some other applicable form of measurement except in such cases where disclosing the volume of records withheld would be harmful, e.g. in a "neither confirm or deny" case (see subpar. 32d). All segregable portions of a record must be provided to any person who requests it. A request for records cannot be denied solely on the basis that a request concerns a large amount of documents or a time-consuming review of material for appropriate withholding of information.
- (3) A copy must be retained of any redacted records that are disclosed. This copy, and a copy of the un-redacted records, as well as the request itself and the VA's response, must be retained in accordance with RCS 10-1. These files will be made available to the OGC for review in the event of an appeal of the decision to withhold information from disclosure or any adverse determination.
- (4) A FOIA log must be maintained for all FOIA requests in accordance with 38 CFR 1.556.
- g. <u>FOIA Exemption 3 Statutes.</u> The following statutes, with the exception of 5 U.S.C. 552a (the Privacy Act), must be considered in determining whether requested information must be withheld under exemption 3 (subpar. 32f(1)(c)), or released.
- (1) **Title 38 U.S.C. Section 5701.** Title 38 U.S.C. Section 5701 applies to all claimants' records and lists the special circumstances in which identifying information on a claimant may be released. The only claimant or patient information that can be withheld from a FOIA request under exemption 3 are the names and addresses of active duty members, veterans, and their dependents.
- (2) **Title 38 U.S.C. Section 5705.** Title 38 U.S.C. Section 5705 prohibits the unauthorized disclosure of certain medical quality assurance records which are identified in 38 CFR 17.500-17.511, implementing VHA Directives, and facility documents.

- (3) **Title 38 U.S.C. Section 7332.** Title 38 U.S.C. Section 7332 prohibits the unauthorized disclosure of medical record information maintained by VA on individuals who have applied for, been offered, or have participated in any program or activity relating to drug and alcohol abuse, infection with the HIV virus, or sickle cell anemia. **NOTE:** The disclosure provisions for these records are found in 38 CFR 1.460-1.496 and throughout this Handbook.
- (4) **Title 5 U.S.C. Section 552a, The Privacy Act.** This statute controls disclosures from records that pertain to individuals that are filed and retrieved by an individual identifier, such as a name or Social Security Number. This statute may not be cited under exemption 3, however, as the basis for withholding information. When the disclosure of individually-identifiable personal Privacy Act record information would constitute a clearly unwarranted invasion of personal privacy under the balancing test described in subparagraph 32f(1)(f), VHA must withhold the information under FOIA exemption 6. Similarly, under the same balancing test, when disclosure would not constitute an invasion of personal privacy, or when the public interest outweighs the privacy interests of the individual, Privacy Act information must be disclosed under FOIA.
- (5) **Title 41 U.S.C. Section 253b(m).** Title 41 U.S.C. Section 253b(m) prohibits agencies from releasing under the FOIA any proposal submitted by a contractor in response to the requirements of a solicitation for a competitive proposal unless that proposal is set forth or incorporated by reference in a contract entered into between the agency and the contractor who submitted the proposal. The effect of this prohibition is two-fold.
- <u>1</u>. First, it provides blanket protection for the proposals submitted by unsuccessful offerors in response to a solicitation because they would not, by definition, be set forth or incorporated by reference in a contract entered into between the agency and that offeror.
- <u>2</u>. Second, it even prohibits the release of proposals submitted by a successful offeror, provided that such a proposal is not actually set forth or incorporated by reference in the ensuing contract. The term "proposal" includes a technical, management, or cost proposal submitted by a contractor in response to the requirements of a solicitation for a competitive proposal.

NOTE: Until such time as this matter is resolved by the Courts, VHA should not consider HIPAA and its implementing regulations, 45 CFR Parts 160 and 164, as qualifying as an exemption 3 statute.

h. FOIA Requests for Records Containing Business Information

(1) During the conduct of its business, VA acquires proprietary information and trade secrets from businesses, corporations, or entities. The information can either be given voluntarily by businesses so that VA can accomplish its mission or it may be a required submission. For example, business information must be provided in response to an Agency Request for Proposal (RFP) for services, equipment, or other goods and services. The decision to participate in an RFP is voluntary, but once that decision is made the information provided is considered a required submission. Once acquired, VA has a responsibility to protect sensitive

business information. It may do so by withholding business information under FOIA exemption number 4 (5 U.S.C. 552(b)(4)).

- (2) When documents provided by a business submitter that may include confidential commercial information are requested under FOIA, and it is determined that the health care facility may be required to disclose the records, the FOIA Officer must so notify the record submitter.
 - (a) The notification must:
- <u>1</u>. Be sent by certified mail, return receipt requested, and describe the exact nature of the record(s) requested, or it must provide to the submitter copies of the record(s) or portions thereof that contain the requested confidential commercial information.
- <u>2</u>. Advise that the submitter or its designee may object to the disclosure of any specified portion of the record.
- (b) The submitter must be given 10 work days in which to submit a written objection to the disclosure.
 - (c) The submitter, or designee, needs to be specifically advised that:
- <u>1</u>. The submitter, or designee, may object to the disclosure of any specified portion of the record and must identify the specific record or portion of the records that should not be disclosed.
- <u>2</u>. If it was required to submit the information or record requested and the submitter wishes it withheld, the submitter needs to explain in detail why disclosure of the specified records could reasonably be expected to cause substantial competitive harm.
- (d) If the submitter was not required to submit the information requested, but provided it to the VA voluntarily, the FOIA Officer needs to advise the submitter that the submitter needs to explain whether it does or does not customarily disclose such information to the general public.
- **NOTE:** The FOIA Officer must evaluate, on a case-by-case basis, any claims of competitive harm that might be made by submitters regarding their unit prices.
- (3) At the same time the submitter is provided notification, the FOIA Officer must notify the FOIA requester that the submitter has been offered an opportunity to comment. The FOIA requester must also be notified that as a result of this process, there may be a delay in making a decision on disclosure.
- (4) Prior to making a determination on the disclosure of the information or records, careful consideration must be given to all grounds for nondisclosure that are presented for consideration by the submitter. Because of the commercially-sensitive information which may be involved, where there is any difference of opinion about disclosure between the information

submitter and VA personnel, the facts are to be discussed with the VHA FOIA Officer prior to taking further action on the request.

- (5) When a determination is made that disclosure of the confidential commercial information would cause substantial competitive harm in the case of required submissions or is not customarily disclosed to the general public in the case of voluntary submissions, the requester must be advised of the decision to withhold the harmful portions from disclosure. The requester must be provided with a copy of any records or portion of a record that is requested and that is not commercially sensitive or otherwise exempt from required disclosure under any of the other FOIA exemptions (see 5 U.S.C. 552, Sections (b)(1) through (9)). The confidential commercial information must be withheld under FOIA exemption 4, 5 U.S.C. 552(b)(4). If any record request is denied or partially denied, the requester must be advised that the denial may be appealed to the General Counsel.
- (6) In all instances where the submitter has expressed objections to the disclosure of the record and the determination is made by VA personnel that disclosure must take place, the FOIA Officer must provide the submitter with a written statement explaining why the submitter's objections are not sustained, a description or copy of the information or records that will be disclosed, and the specified disclosure date. The disclosure date must not be less than 10 work days from the date the notice is mailed. This notice will allow the submitter the opportunity to consider any judicial action that might be taken to prevent release of the records. Notification of the final decision must also be sent to the requester, but must not contain any of the specific information that may be protected under exemption 4.
- (7) In any case where a FOIA requester brings suit seeking to compel disclosure of confidential commercial information, the FOIA Officer must promptly notify the submitter. Conversely, in any case where the submitter obtains a Court Order enjoining VA from making a contested disclosure (termed a reverse-FOIA), the FOIA Officer must promptly notify the requestor.
- i. <u>Coordination of Releases with Regional Counsel.</u> In any case where a FOIA request involves matters or subjects involved in ongoing or anticipated litigation, administrative proceedings, or criminal or civil investigation, health care facility personnel must coordinate the facility's response to the FOIA request with the Regional Counsel. If a request involves matters pertaining to ongoing litigation, the Regional Counsel must be informed of the request to ensure coordination of the VA's position in the litigation with any release of documents. If no litigation is pending, but can be reasonably anticipated in the future, the FOIA request needs to be reviewed with the Regional Counsel in light of that likelihood. If the FOIA request concerns records related to an ongoing civil or criminal investigation, health care facility personnel must coordinate with Regional Counsel to ensure that the response to the FOIA request is coordinated with the appropriate authorities. In all such cases, records need to be maintained that identify the documents or portions of documents considered in response to the FOIA request and documents or portions of document withheld or released pursuant to the request. Discretionary disclosures need to be coordinated with the Regional Counsel rather than relying solely on the existing FOIA release procedures.

j. Annual Report of Compliance with FOIA

- (1) FOIA requires each agency to submit to the Congress a report on or before March 1 of each year of its activities and efforts to administer the FOIA during the preceding fiscal year.
- (2) Each facility is required to submit an annual report on VA Form 0712, Annual FOIA Report, via the VA Intranet for use in compiling the Department report. The information must be reported for the preceding fiscal year no later than the 15th workday of November.
- (3) The instructions for the preparation of the health care facility annual FOIA report are contained in the VHA Directive annually announcing the reporting requirement.

33. RELEASE FROM NON-VHA SYSTEMS OF RECORDS

- a. Within VHA facilities there are several non-VHA systems of records that are subject to the provisions of the Privacy Act of 1974, VA confidentiality statutes, and/or HIPAA; for example, VHA maintains personnel records on its Title 5 employees within the facility. These records are technically under the control of the Office of Personnel Management. Similarly, though VHA generates medical records regarding a patient's claim for disability, these medical disability records are technically under the control of the local VBA Regional Office. As a final example, law enforcement investigation records are under the control of the CO VA Police and Security Service. *NOTE:* A list of some non-VHA systems of records that are normally maintained within a VHA facility are provided in Appendix C.
- b. It is VHA policy that when a question arises concerning right of access, amendment, or release of non-VHA records and/or information, the non-VHA System Manager who has responsibility over these records must be contacted. Whether or not right of access, amendment, or release of the information is granted is determined based on Federal privacy and confidentiality statutes, VA regulations, and official policies of the non-VHA entity, either by the facility FOIA and/or Privacy Officer or the VA Office responsible for the records (e.g., HRM Service).
- (1) For policy on VA HRM controlled personnel records see MP-5, Part I, Chapter 294, Availability of Official Information, and Chapter 297, Protection of Privacy in Personnel Records.
- (2) Contact the VHA Privacy Officer or the System Manager of non-VHA system of records if further guidance is required.
- c. Records maintained in a VHA system of records will be released in accordance with the policies outlined in this Handbook. For a list of VHA systems of records contact the VHA Privacy Officer.
- d. Record requests received by facilities that are not the legal custodian of the records should be referred to the FOIA Officer. The FOIA Officer should refer the request back to the legal custodian of the records.

34. OTHER TYPES OF DISCLOSURES AND RELEASES

a. Audit and Evaluation Purposes

- (1) To the extent that individually-identifiable information, including name and address information, is relevant and necessary to the conduct of an audit or evaluation, records may be reviewed by or disclosed to the following:
- (a) VA personnel who need the information for such purposes as: special purpose or site visits, audits and reviews under the Health Systems Review Organization (HSRO) Program, clinical and administrative audits, and audits and investigations by VA Office of Inspector General staff.
- (b) The GAO, if the records or information pertain to any matter within its jurisdiction (see 45 CFR 164.512(d)).
- (c) Evaluation agencies under contract with VA which are charged with facility-wide monitoring of all aspects of patient care (such as the Joint Commission on Accreditation of Healthcare Organizations) pursuant to a business agreement.
- (d) Evaluation agencies under contract with VA that are charged with more narrowly-focused monitoring (e.g., College of American Pathologists, American Association of Blood Banks, etc.) to the extent that the information is relevant to their review pursuant to a business agreement.
- (e) Members and staff of Congressional committees and subcommittees, if the record pertains to subject matter for which the committee or subcommittee has oversight responsibility as discussed in subparagraph 18b(3) (see 45 CFR 164.512(d)).
- (2) Individuals who conduct an audit or evaluation and receive or review individually-identifiable information must be advised that the information is disclosed for audit or evaluation purposes only and that given its private, confidential nature, the information needs to be handled with appropriate sensitivity.

b. Release of Autopsy Findings

- (1) For purposes of this paragraph the personal representative of a deceased individual has the same rights as the deceased individual that the personal representative is representing. If under applicable law an executor, administrator, or other person who has authority to act on behalf of a deceased individual or on behalf of the deceased individual's estate. A copy of the autopsy clinical finding summary and the listing of clinical-pathological diagnoses on Standard Form (SF) 503, Medical Record-Autopsy Protocol, may be disclosed when requested by the personal representative of the individual.
- (2) In all cases where the autopsy protocol reveals drug abuse, alcoholism or alcohol abuse, HIV infection, or sickle cell anemia information which is subject to additional disclosure restrictions, the autopsy protocol must not be disclosed to the next-of-kin unless the facility

Director determines that such disclosure is necessary for the survivor to receive benefits. These records may be released for other than survivorship benefit purposes if those portions relating to drug or alcohol abuse, infection with HIV, or sickle cell anemia information can be appropriately deleted. Under the survivorship benefit provision, sickle cell anemia information may be released to a blood relative of the deceased veteran for medical follow-up or family planning purposes.

- (3) The autopsy protocols may be released to a private physician when specifically requested in writing by the next-of-kin.
- (4) When the next-of-kin requests a report of the autopsy findings, a letter containing the pathological diagnosis in lay terminology must be prepared by the primary physician, or if the primary physician is unavailable, by a designee of the Chief of the Bed Service where the patient expired. The Chief, Laboratory Service, must ensure the expeditious completion of the autopsy protocol and promptly provide the concerned Chief of the Bed Service with the gross autopsy findings. The Chief, HIMS, or designee, must ensure that a copy of the letter to the next-of-kin is filed in the patient medical record.
- (5) If the next-of-kin subsequently requests a copy of the autopsy protocol, the autopsy protocol must be released unless the Chief of Bed Service, or designee, determines that release could be injurious to the life or safety of the person in whose behalf the information is sought. If the reviewing physician determines the autopsy protocol does contain such information, the autopsy protocol will not be disclosed directly to the next-of-kin. On the advice of the reviewing physician, the Chief, HIMS, or designee, must take one of the following actions:
- (a) Arrange for the next-of-kin to discuss the autopsy protocol with the primary physician, or designee, at a time and date mutually agreeable; or
- (b) Send a copy of the autopsy protocol to a physician selected by the next-of-kin. The physician must be advised of the reason for the referral.
- (6) If there is any indication that the requested information will be used in a lawsuit, the Regional Counsel must be informed promptly of the circumstances. No further actions can be taken without guidance from the Regional Counsel.

c. ROI from Claims Folder

- (1) Requests for release of medical or health information in veterans' claims folders are normally handled by the FOIA and/or Privacy Act Officers at VBA Regional Offices. Copies of compensation and pension examinations that are maintained in the patient medical record may be released by the health care facility.
- (2) When a request for access to individual records by the record subject involves medical information in a claims file and the Regional Office official responsible for the records concludes that the record may include medically-sensitive information that may be harmful to the individual, the request and related information must be referred to the nearest VA medical

facility for processing. *NOTE:* The request must be processed in accordance with the provisions of paragraph 15.

d. Release of Credentialing and Privileging Records

- (1) VHA provider credentialing and privileging records are considered VHA records and are covered under the VHA system of records "Health Care Provider Credentialing and Privileging Records-VA" (77VA10Q).
- (2) Requests for VHA provider credentialing and privileging information or records need to be processed in accordance with VHA Handbook 1100.19, Credentialing and Privileging, Privacy Act, FOIA, and the provisions of this Handbook.
- (a) Requests from VHA providers for copies of their records maintained in their Credentialing and Privileging folder (77VA10Q), need to be processed in accordance to paragraph 7.
- (b) Requests from third parties for copies of credentialing and privileging information need to be processed in accordance with paragraph 15.

e. Federal Parent Locator Service

- (1) The HHS operates the Federal Parent Locator Service that was established to obtain and transmit to authorized State agencies information as to the whereabouts of any absent parent in order to locate such a person for the purpose of enforcing child support obligations.
- (2) Individual State parent locator agencies should not contact VA health care facilities directly for address information on absent parents. Any requests received by VA health care facilities for assistance in locating an absent parent must be returned to the requesting agency and provided with the address of the Federal Parent Locator Service:

Director, Parent Locator Service Division Office of Child Support Enforcement Department of Health and Human Services 370 L'Enfant Promenade SW, Fourth Floor Washington, DC 20447

f. Providing Medical Opinions

(1) VHA health care providers are required, when requested and under certain limited circumstances, to provide descriptive statements and opinions for VA patients with respect to patients' medical condition, employability, and degree of disability (see 38 CFR Section 17.38 and current VHA policy).

(2) Support of VA Benefits Claims

- (a) Individuals may request statements from VHA health care providers regarding their medical conditions and/or opinions for submission in support of their claims for VA benefits.
- (b) In response to such a request, VHA health care providers must provide a statement or opinion describing a patient's medical condition.
- (c) When the health care provider is the individual's treating physician, and is unable, or deems it inappropriate, to provide an opinion or statement, such physician must refer the request to another health care provider for the opinion or statement.

(3) Medical Opinions for Non-VA Purposes

- (a) Individuals may also ask VHA health care professionals for opinions to assist them in filing claims with other agencies.
- (b) These opinions may be provided in the same manner and under the same restrictions as opinions furnished for VBA claim purposes.
- (4) **Exception.** This does not include completion of SSA forms for examination where SSA would pay a private practitioner, but is prohibited from paying other Federal agencies such as VA (see 38 CFR 17.38(a)(1)(xiv)).

g. ROI from Outside Sources

- (1) Private hospital or physician records that have been incorporated into the individual's health records are considered part of the VHA records and are subject to the disclosure provisions of the Privacy Act, the HIPAA Privacy Rule, and FOIA.
- (2) An individual requesting this type of record needs to be encouraged to obtain the information from the hospital or physician's office that has released the information. However, if the individual insists on obtaining a copy from VHA, the request needs to be processed under the policies in this Handbook.
- (3) Requests for information in the record that was originated by another Federal agency must be referred to the agency that created the documents. The individual must be advised of the referral and that additional time will be needed for VA to consult with the other agency before a determination can be provided. Information from medical records of beneficiaries of

other Federal agencies and allied governments treated or examined in VA health care facilities can only be released under the policies provided in this Handbook.

h. Patient Identification Cards and Public Signs

- (1) A health care facility may not request, or require, a patient carry an identification card or possess another form of identification while away from the facility premises which would identify the individual as a patient being treated for drug abuse, alcoholism or alcohol abuse, HIV, or sickle cell anemia.
- (2) A health care facility may maintain cards, tickets, or other devices to ensure positive identification of patients, correct recording of attendance or medication, or for other proper purposes, provided that no pressure is brought on any patient to carry any device when away from the facility. Drug or alcohol abuse, HIV, or sickle cell anemia patients may not be required to wear pajamas, robes, wrist bands, etc., that are different from other patients and which would identify them to health care facility staff or others as being treated for one or more of these conditions.
- (3) Treatment locations are not to be identified by signs that would identify individuals entering or exiting these locations as patients enrolled in a drug or alcohol abuse, HIV infection, or sickle cell anemia program or activity.

i. Release of Photographs and Health Information Concerning Individuals to the News Media

- (1) Photographs and medical information concerning individual patients may be released to news media with the signed authorization of the patient on VA Forms 10-3203, Consent for Use of Picture and/or Voice for Photographs, and VA Form 10-5345, Request for and Authorization to Release Health Information from Medical records. In the case of a patient with a psychiatric condition, the responsible physician must certify that the patient has sufficient understanding and capacity to comprehend the nature of the information to be disclosed, and the purpose of the contemplated disclosure. In those instances where the patient has been declared legally incompetent, photographs or information may be released if written authorization of the courtappointed legal guardian has been obtained.
- (2) Photographs and health information concerning individual patients in drug or alcohol abuse, HIV infection, and sickle cell anemia treatment programs may be released to news media only with the prior written authorization of the individual, provided the authorization was given voluntarily and the disclosure would not be harmful to the individual. The written authorization must comply with the provisions of paragraph 14 (see MP-1, Pt. I, Ch. 4, subpar. 4b(2)). There also must be signed authorization for the re-disclosure by the media entity or reporter.
- (3) Before releasing any information to news media, the VA health care facility Public Affairs Office and public affairs policy as contained in MP-1, Part I, Chapter 4, must be consulted.

NOTE: Consent or permission is not required to take a photograph for treatment purposes. Photographs taken for treatment are part of the patient medical record.

j. Release of Psychotherapy Notes

- (1) VHA may use psychotherapy notes to carry out the following treatment, payment, and/or health care operations:
 - (a) Use by the originator of the psychotherapy notes for treatment;
- (b) Use in VHA training programs to train students or practitioners in mental health programs; and
 - (c) In defense of a legal action as authorized by other paragraphs of this Handbook.
- (2) VHA may not <u>use or disclose</u> psychotherapy notes for any other purpose without the prior written authorization of the individual to whom the notes pertain.
- (3) VHA may not <u>disclose</u> psychotherapy notes without the prior written authorization of the individual to whom the notes pertain. This authorization may not be combined with any other authorization.

k. Release of Name and/or Address (RONA)

- (1) The name and address of a patient or the patient's dependents, wherever found in medical or other records, must not be released without the patient's written authorization, unless such disclosure is authorized by one or more of the disclosure provisions of the Privacy Act (see 38 CFR 1.576(b)), 38 U.S.C. 5701, and 45 CFR Parts 160 and 164.
- (2) Any organization that wants to receive a list of names and addresses of present or former patients and their dependents must make written application under the provisions of 38 CFR 1.519 and VA Handbook 6300.6 to the Director, Records Management Service (005E3) at VA Central Office, 810 Vermont Avenue, NW, Washington, DC 20420.
- (3) Requests for lists of educationally-disadvantaged veterans must be addressed to the Director of the nearest VA Regional Office as provided in 38 CFR 1.519 and VA Handbook 6300.6.
- (4) When a request is received from private organizations or individuals for names of patients for the purpose of distributing gifts, the facility Director may furnish names of patients only with the patients' prior written authorization.
- (5) When disclosure of the patient's address is not permissible under the preceding guidelines, the requester may be advised that a letter, enclosed in an unsealed envelope showing the name of the beneficiary but no return address, and bearing sufficient postage, will be

forwarded by VA (see 38 CFR 1.518(c)). Letters for the purpose of debt collection, canvassing, or harassing a patient will not be forwarded.

1. ROI from Retired Records

- (1) Requests for information from records that have been retired for storage to a NARA records storage center or the VA Records Center and Vault (RC&V) must be processed by the facility that retired the record.
- (2) When appropriate, the information must be furnished from pertinent documents in the Perpetual Medical Records (PMR) envelope. PMRs are maintained at the medical center, NARA facilities, and RC&V. *NOTE:* VHA did not create PMRs after August 17, 1992.
- (3) When the requested information in the PMR envelope is not sufficient to respond to a request, the retired record must be recalled from the NARA center or RC&V and the information furnished. Requests to the NARA or RC&V must contain sufficient information to identify the requested records. Patients or individuals acting on behalf of the patient will not be advised to request information directly from the NARA center or RC&V.
- (4) VHA may not charge the requestor for any fees NARA assesses to retrieve the file. *NOTE:* VHA records are no longer maintained by NARA centers.

m. Requests for Original or Copies of X-ray Films

- (1) VHA Manual M-2, Part XI, outlines policy and procedures for the loan of VA X-ray film for treatment purposes, upon request. A copy of M-2, Part XI can be obtained from http://vaww.vhaco.va.gov/privacy/laws.htm.
- (2) X-ray films loaned to VA health care facilities by private physicians and/or non-VA institutions and agencies must be properly identified and safeguarded to prevent loss or destruction. The Chief, HIMS, in conjunction with the Chief, Radiology Service, must set up controls to ensure the prompt return of films when they are no longer needed.
- (3) VHA may provide copies of X-ray films, upon request, with an appropriate written authorization. Fees for copies of X-ray films consist of the actual direct cost of producing the X-ray film (see par.15).

35. GENERAL OPERATIONAL PRIVACY REQUIREMENTS

a. Designation of Privacy Official

- (1) VHA must retain a full-time Privacy Officer.
- (2) Each VISN and VA medical center must designate a facility Privacy Officer. The Privacy Officer duties may be a collateral duty.

b. Management of Release of Veteran Information

- (1) Release of information from the veteran medical record is a complex function, requiring trained and qualified employees and expert guidance. The function is normally assigned to HIMS.
- (2) The Chief, HIMS, must provide for the prompt identification and indexing of incoming requests for veteran individually-identifiable health information. To ensure timely and informed release of information, it is recommended that all requests be processed through a central point.
- (3) The Chief, HIMS, must conduct a comprehensive systematic review of the release of information activity within the medical center not less frequently than once every 12 months.
- (4) Such factors as workload, processing time, etc., need to be reviewed periodically to identify backlogs and expedite responses to requests for information.
- (5) The health care facility's Chief of Staff must establish guidelines for personnel in reviewing medical records to determine if such records contain sensitive information (see App. D).
- (6) The Regional Counsel at the appropriate Regional Office must resolve legal questions concerning the release of veteran individually-identifiable health information.

c. Agency Accounting of Disclosure Responsibilities

- (1) VA health care facilities are required to maintain an accounting of all disclosures of individually-identifiable information including those for state reporting and research. Disclosure of de-identified data, or a limited data set, does not require an accounting.
- (2) VHA is <u>not</u> required to maintain an "accounting of disclosures" made to VHA employees in the performance of their official duties, or an accounting of VHA's use of individually-identifiable health information.
- (3) The accounting must include the date of each disclosure, nature or description of the individually-identifiable information disclosed, purpose of each disclosure, and the name and, if known, address of the person or agency to who the disclosure was made.
- (4) The accounting must be retained for 6 years after the date of disclosure or for the life of the record (see RCS 10-1), whichever is longer.
- (5) The accounting record may be maintained via automated ROI Tracking Software or manually on VA Form 70-5572, Accounting of Records/Information Disclosure. *NOTE:* VA Medical Centers must use the ROI Records Management software to account for disclosures of health information. The accounting record must be maintained via automated ROI software from which the disclosure was made. The procedures established for maintaining an accounting

of disclosures must provide for the maintenance of appropriate records to collect disclosure data to be used in the preparation of the Annual FOIA Report.

- (6) The accounting records of disclosures must be made available upon request to the individual to whom the record pertains within 60 days after receipt of such a request, except for disclosures made for health oversight activities or law enforcement purposes as authorized by 38 CFR 1.576(b)(7) and 45 CFR 164.528(a)(2)(i). If the accounting cannot be provided within the specified timeframe the facility or program can extend the timeframe no longer than 30 days provided that the individual is given a written statement of the reasons for the delay and the date by which the accounting will be provided. Only one such extension of time for action on a request for an accounting is allowed. The individual must be provided information consisting of the date, nature, and purpose of each disclosure, and the name and address of the person or agency to whom the disclosure is made.
- (7) VHA must retain a copy of the disclosure summary provided to the individual. This disclosure summary can be retained in the VHA systems of records, or the designated record set from which it was generated, or in the automated ROI Tracking Software.
 - (8) The accounting or disclosure summary must be provided to an individual free of charge.

d. Complaints

- (1) Individuals have the right to file a complaint regarding VHA privacy policies or practices. The complaint does not have to be in writing, though it is recommended.
- (2) Complaints are to be forwarded to the appropriate VA health care facility Privacy Officer, or designee, or the VHA Privacy Office, 810 Vermont Avenue, NW, Washington, DC 20402.
- (3) All privacy complaints regardless of validity must be promptly investigated and a written response provided to the complainant. In addition, all privacy complaints, regardless of validity, must be reported in the Privacy Violation Tracking System (PVTS) for audit purposes in accordance with VA Directive 6502, VA Privacy Program, and VA Handbook 6502.1, PVTS.
- (4) The VHA HIPAA Program Management Office (PMO) serves as the central authority for coordination of HIPAA Privacy complaints received by VHA from HHS Office for Civil Rights. Any HIPAA privacy complaints received by VA health care facilities should be forwarded to the VHA HIPAA PMO.

e. Faxes

(1) VA health care facilities should <u>only</u> transmit individually-identifiable information via facsimile (fax), when no other means exists to provide the requested information in a reasonable manner or timeframe. VA health care facilities need to ensure individually-identifiable information is sent on a machine that is not accessible to the general public.

- (2) The VA health care facility must take reasonable steps to ensure the fax transmission is sent to the appropriate destination.
- (a) The VA health care facility needs to check the fax confirmation slip to be sure that the confidential individually-identifiable information went to the proper destination. If there has been an error, the incorrect recipient must be immediately contacted and requested to return or destroy the fax.
- (b) The VA health care facility needs to verify the fax number before faxing individually-identifiable information. Pre-program and test destination numbers need to be utilized whenever possible to eliminate errors in transmission from misdialing. Periodically remind those who are frequent recipients of individually-identifiable information to notify the facility if their fax number is to change (for example, include a piece in medical staff newsletters where transcriptionists automatically fax reports to physician offices).
- (c) The VA health care facility needs to notify the recipient before faxing the individually-identifiable information to ensure that someone is there to receive, file or deliver it. Do not fax individually-identifiable information unless someone is there to receive the information or the fax machine is in a secured location (e.g., locked room).
- (3) A confidentiality statement needs to be on the cover page when transmitting individually-identifiable information. The statement needs to instruct the recipient of the transmission to notify VHA if received in error.

f. E-mail

- (1) Electronic mail (e-mail) and information messaging applications and systems are to be used as outlined in VA policy (see VA Directive 6301, VA Directive 6210, and VA Handbook 6210).
- (2) E-mail messages must contain only non-individually-identifiable information, unless the data and accompanying passwords or other authentication mechanisms are appropriately secured (see VHA Directive 6210).

g. Health Information from Non-VA Physicians and Facilities

- (1) The Chief, HIMS, or designee, is responsible for the prompt dispatch of requests for health information available from outside sources and needed in the examination and treatment of VHA patients.
- (2) Upon receipt, requested material must be made available to the health care practitioner without delay, when possible. If the material is received in an electronic format, i.e., Compact Disk (CD), then the Chief, HIMS, or designee, should work with the facility Information Resource Management Service (IRMS) to check the CD for viruses and to ensure the facility has the appropriate software to open the files for review.

(3) The health care practitioner must review the material to determine if inclusion in the individual's health record is warranted. If the health care practitioner determines the material should be included in the individual's health records, the Chief, HIMS, or designee, should determine the appropriate manner for inclusion in accordance with VHA Handbook 1907.1.

NOTE: Health information obtained from outside sources, once incorporated into the individual's health record, is considered part of the VHA record and is subject to the disclosure provisions of this Handbook.

h. Training of Personnel

- (1) All VHA personnel including employees, volunteers, and students must be trained, at least annually, on privacy policies to include the requirements of Federal privacy and information laws, regulations, and VHA policy.
 - (2) New personnel must be trained within 30 days of employment.
- (3) At a minimum, instruction must be provided within 6 months of significant change in Federal law, regulation, this policy, and/or facility or office procedures.
- (4) VA health care facilities must track completion of privacy training and be prepared to report privacy training completion figures to the VHA Privacy Office.

i. Contracts

- (1) All contracts must meet contracting requirements as dictated by VA's Office of Acquisition and Material Management and the Federal Acquisitions Regulations (FAR).
- (2) Any contract between VHA and a contractor for the design, development, operation, or maintenance of a VHA system of records or any contract which necessitates the use of individually-identifiable information must conform to the policies and procedures in FAR Subpart 24.1, Protection of Individual Privacy.
- (3) Organizations with whom VHA has a contract for services, on behalf of VHA, where individually-identifiable health information is provided to or generated by the contractors, may be considered business associates (see App. A). Business associate agreements must meet the requirements of 45 CFR 164.504(e).
 - (4) Business associates must follow VHA privacy policies and practices.
 - (5) All contractors and business associates must receive privacy training annually.
- (a) For contractors and business associates who do not have access to VHA computer systems, this requirement is met by receiving VHA National Privacy Policy training, other VHA approved privacy training or contractor furnished training that meets the requirements of

the HHS Standards for Privacy of Individually-identifiable Health Information as determined by VHA. Proof of training is required.

(b) For contractors and business associates who are granted access to a VHA computer system, this requirement is met by receiving VHA National Privacy Policy training or other VHA approved privacy training. Proof of training is required.

j. Penalties

- (1) Violations of the Privacy Act expose the violator to a maximum possible penalty of:
- (a) \$5000. A VA employee who knowingly and willfully violates the provisions of 5 U.S.C. 552a(i) is guilty of a misdemeanor and can be fined not more than \$5,000, when the employee:
- <u>1.</u> Knows that disclosure of records which contains individually-identifiable information is prohibited and willfully discloses the information in any manner to any person or agency not entitled to receive it;
- <u>2.</u> Willfully maintains records concerning identifiable individuals that have not met the Privacy Act notice requirements (see par. 36); or
- <u>3.</u> Knowingly and willfully requests or obtains any record concerning an individual from VA under false pretenses. *NOTE:* This provision also applies to persons who are not employees.
- (b) <u>Incident Report.</u> In the event a health care facility employee is found criminally liable of a Privacy Act violation, a written report of the incident must be provided to the VA health care facility Director.
- (2) Any person who violates any provision of 38 U.S.C. 7332 can be fined not more than \$5,000 in the case of a first offense, and not more than \$20,000 in each subsequent offense.
- (3) A VHA employee who knowingly violates the provisions of HIPAA (Pub. L. 104-191), as implemented by 45 CFR Parts 160 and 164, by disclosing individually-identifiable health information shall be fined not more than \$50,000, imprisoned not more than 1 year, or both, except:
- (a) If the offense is committed under false pretenses, then the VHA employee must be fined not more than \$100,000, and/or imprisoned not more than 5 years.
- (b) If the offense is committed with the intent to sell, transfer, or use individually-identifiable health information for commercial advantage, personal gain, or malicious harm, then the VHA employee can be fined not more than \$250,000 and/or imprisoned not more than 10 years.

- (4) In addition to the statutory penalties for the violations described in the preceding, administrative actions or disciplinary or other adverse actions (e.g., admonishment, reprimand, and/or termination) may be taken against employees who violate the statutory provisions.
- (5) Where an individual has committed one offense, any offense committed under 38 U.S.C. 7332, or any other section of these provisions, will be treated as a subsequent offense.

36. ESTABLISHING NEW SYSTEMS OF RECORDS

- a. When personal information is retrieved by an individual identifier, a system of records subject to the Privacy Act comes into existence. The Privacy Act requires agencies to publish notices in the <u>Federal Register</u> describing new or altered systems of records, and to submit reports on these systems to OMB and to Congress (see 38 CFR 1.578, and VA Handbook 6300.5).
- b. Information concerning an individual will not be collected or maintained in such a manner that information is retrieved by an individual identifier, unless a system notice is first published in the <u>Federal Register</u>. Without prior publication of a system notice, such a system would be an illegal system of records and the personnel operating it would be exposed to criminal penalties under the Privacy Act. This requirement applies to information about an individual that is maintained in any record or storage medium including paper records or documents, personal computers, computer systems, and local and national databases. *NOTE: Appendix B to VA Handbook 6300.5, contains a list of some VA systems of records notices published in the <u>Federal Register</u>.*
- c. Prior to collecting or maintaining information concerning an individual in what would be a system of records, the VA health care facility must verify the existence of a published system notice. **NOTE:** Contact the VHA Privacy Officer if assistance in this determination is needed.
- d. Prior to collecting information concerning an individual, the VA health care facility needs to ensure compliance with the Paperwork Reduction Act and 5 CFR Part 1320, Controlling Paperwork Burdens on the Public.
- e. If the collection of individually-identifiable information desired is not covered by a system notice published in the <u>Federal Register</u>, the VA health care facility must contact the VHA Privacy Officer to establish a new system of records and publish a system notice.
- (1) The VA health care facility must submit a report to the VHA Privacy Officer that includes the justification and legal authority for the proposed maintenance of the system of records.
- (2) Such records are not to be established and information collected until the system of records is approved by the Secretary of Veterans Affairs, published for public comment in the <u>Federal Register</u>, and appropriate reports are submitted to OMB and to Congress.

- (a) The System Manager designated in the system notice is responsible for ensuring the system notice reflects the existing collection of information requirements. Any modifications to the system of records must be reflected in the system notice prior to implementation.
- (b) A routine use must be published in the <u>Federal Register</u> at least 30 days before a disclosure is made pursuant to the routine use. Each system of records listed in the records inventory includes a "routine use" section. Disclosure pursuant to a routine use of individually-identified health information must also be authorized under other applicable privacy law.

37. COMPUTER MATCHING PROGRAM

The Privacy Act (as amended by Pub. L. 100-503, the Computer Matching and Privacy Protection Act of 1988, hereinafter referred to as the Computer Matching Act) includes requirements governing the conduct of VA computer matching programs. To be covered, the records must exist in automated form and the matching of the records with another Federal, or in some cases non-Federal agency, must be computerized. OMB has published guidelines (54 Federal Register (FR) 25818 dated June 19, 1989) which must be followed when conducting computer matching programs.

a. General

- (1) The Computer Matching Act covers the computerized comparison of records from:
- (a) Two or more automated systems of records (systems of records maintained by Federal agencies that are subject to the Privacy Act); or
- (b) A Federal agency's automated system of records and automated records maintained by a non-Federal (State or local government) agency or agent thereof.
- (2) VA health care facilities must not participate in computer matching programs with other Federal agencies or non-Federal agencies as a "recipient agency" or a "source agency" unless the program is:
- (a) Approved by the VA health care facility Director, VHA Privacy Officer, appropriate VA Central Office staff, and the VA Data Integrity Board; and
- (b) Conducted in compliance with the Privacy Act (as amended by the Computer Matching Act), the OMB guidelines (65 FR 77677, December 12, 2000) and applicable Department guidance (VA Handbook 6300.7).
- (3) Proposals by VA health care facilities to participate in matching programs must be submitted for review and approval in accordance with VA Handbook 6300.7.

NOTE: If approved, the proposal must be submitted for further review by appropriate VA Central Office staff, and the approval or disapproval of the VA Data Integrity Board.

b. Terms

- (1) **Computer Matching Program.** A computer matching program is the computerized comparison of two or more automated Federal systems of records or a Federal agency's automated system of records and automated records maintained by a non-Federal (State or local government) agency for the purposes described in subparagraph 37c. The records must themselves exist in automated form. Manual comparisons of printouts of two automated databases are not included in this definition. A matching program includes all of the steps associated with the match, including: obtaining the records to be matched, actual use of a computer, administrative and investigative follow-up of the individuals matched, and disposition of the personal records maintained in connection with the match.
- (2) **Recipient Agency.** Recipient agencies are Federal agencies (or their contractors) that receive records from Privacy Act systems of records of other Federal agencies or from State and local governments to be used in matching programs.
- (3) **Source Agency.** A source agency is a Federal agency that discloses records from a system of records to another Federal agency or to a State or local governmental agency to be used in a matching program. It is also a State or local governmental agency that discloses records to a Federal agency to be used in a matching program.
- (4) **Non-Federal Agency.** A non-Federal agency is a State or local governmental agency that receives records contained in a system of records from a Federal agency to be used in a matching program.
- (5) **Federal Benefit Program.** Any program funded or administered by the Federal government, or by any agent or State on behalf of the Federal government, that provides cash or in-kind assistance in the form of payments, grants, loans, or loan guarantees to U.S. citizens or aliens lawfully admitted for permanent residence.
- c. <u>Computer Matching Programs.</u> The Computer Matching Act covers matching programs that involve Federal benefit programs and matches using records from Federal personnel or payroll systems of records.

(1) Federal Benefit Program

- (a) Only Federal benefit programs providing cash or in-kind assistance to individuals are covered. A Federal benefits matching program covers only the following categories of record subjects:
 - 1. Applicants for Federal benefit programs (individuals initially applying for benefits);
- <u>2</u>. Program beneficiaries (individual program participants who are currently receiving or formerly received benefits); and

- <u>3</u>. Providers of services to support such programs (those who are not the primary beneficiaries of Federal benefit programs, but may derive income from them (for example health care providers)).
 - (b) The match must have as its real purpose one or more of the following:
 - 1. Establishing or verifying initial or continuing eligibility for Federal benefit programs;
 - 2. Verifying compliance with the statutory or regulatory requirements of such programs; or
 - 3. Recouping payments or delinquent debts under such Federal benefit programs.
- (c) All four elements (i.e., computerized comparison of data, categories of subjects covered, Federal benefit program, and matching purpose) must be present before a Federal benefit matching program is covered under the provisions of the Computer Matching Act.

(2) Federal Personnel or Payroll Records Matches

- (a) The Computer Matching Act also includes matches comparing records from automated Federal personnel or payroll systems of records, or such records with automated records of State and local governments. *NOTE:* The comparison must be done by using a computer; manual comparisons are not covered.
- (b) The Computer Matching Act does not cover routine administrative matches provided the purpose of the match is not to take any adverse action against Federal personnel.
- (3) **Excluded from Computer Matching Programs.** The following are not included under the definition of matching programs. *NOTE:* Such programs are not required to comply with the provisions of the Computer Matching Act.
- (a) Statistical matches whose purpose is solely to produce aggregate data stripped of personal identifiers.
- (b) Statistical matches whose purpose is in support of any research or statistical project, the specific data of which may not be used to make decisions that affect the rights, benefits, or privileges of specific individuals.
- (c) Pilot matches, i.e., small scale matches, are matches whose purpose is to gather benefit and/or cost data on which to premise a decision about engaging in a full-fledged matching program. *NOTE:* A pilot match may not be conducted, unless it is approved by the VA Data Integrity Board.
- (d) Law enforcement investigative matches by an agency or component whose principal statutory function involves the enforcement of criminal laws, the purpose of which is to gather evidence against a named person or persons in an existing investigation. The match must flow from a civil or criminal law enforcement investigation already underway.

- (e) Certain tax administration and debt collection via tax refund intercept matches.
- (f) Routine administrative matches using predominantly Federal personnel records, provided the purpose of the match is not to take any adverse action against Federal personnel, as defined in the Privacy Act, 5 U.S.C. 552a(a)(13).
- (g) Internal matches using only records from the Department's systems of records. However, an internal match whose purpose is to take any adverse financial, personnel, disciplinary or other action against Federal personnel is covered by the requirements of the Computer Matching Act.
 - (h) Background investigations and foreign counter-intelligence matches.

BUSINESS ASSOCIATES

- 1. <u>Business Associate (BA)</u>. A business associate (BA) is any individual or entity who, on behalf of the Veterans Health Administration (VHA), performs or assists in the performance of VHA-covered functions or activities involving the use or disclosure of individually-identifiable health information, or who provides certain services to VHA and the provision of those services involves the disclosure of individually-identifiable health information by VHA.
 - a. An individual or entity is a business associate when it is:
- (1) Using, creating, or disclosing protected health information (PHI) for, or on behalf of, VHA; or
- (2) Providing a covered function or specified service to VHA and the function or service involves disclosure of individually-identifiable health information by VHA to the individual or entity.
- **NOTE:** A BA relationship does not exist when VHA discloses individually-identifiable health information to a non-VHA health care provider for treatment purposes.
- b. The individual or entity performing or assisting in the performance of these functions or activities cannot be a member of VHA's workforce.
- **2. BA Agreements.** A business associate agreement (BAA) may be established at the national or facility level. An agreement between VHA and a BA must:
- a. Establish the permitted and required uses and disclosures of such information by the BA. The contract may not authorize the BA to use or further disclose the information in a manner that would violate the Federal privacy and confidentiality statutes.
 - b. Provide that the BA must:
- (1) Not use or further disclose the information other than permitted or required by the contract.
- (2) Use appropriate safeguards to prevent use or disclosure of the information other than provided for by its contract.
- (3) Report to VHA any use or disclosure of the information not provided for by its contract of which it becomes aware.
- (4) Ensure that any agent, including subcontractors, to whom it provides individually-identifiable health information agrees to the same restrictions and conditions in writing.

Subcontractors must adhere to the terms of the original contract for security and confidentiality statements, background checks, etc.

- (5) Make individually-identifiable health information available to the individual to whom it pertains in accordance with Federal privacy statutes, confidentiality statutes, and paragraph 7 of this Handbook.
- (6) Make individually-identifiable health information available for amendment and incorporate any amendments to individually-identifiable health information in accordance with Federal privacy statutes, confidentiality statutes, and paragraph 8 of this Handbook.
- (7) Make individually-identifiable health information available in order to provide an accounting of disclosures in accordance with Federal privacy statutes, confidentiality statutes, and paragraph 9 of this Handbook.
- (8) Make its internal practices and records relating to use and disclosure of individually-identifiable health information from, or created by, or received by, the BA on behalf of VHA, available to the Secretary of the Department of Health and Human Services (HHS) for purposes of determining compliance with Title 45 Code of Federal Regulations (CFR) Parts 160 and 164;
- (9) At termination of the contract return or destroy all individually-identifiable health information received from, or created or received by, the BA on behalf of VHA.
- c. Authorize termination of the contract by VHA, if VHA determines the BA has violated a material term of the contract.

3. Examples of BA Arrangements

- a. The VA medical center contracts with a vendor for maintenance of a dictation system that requires the ability to access dictated information. **Rationale:** The vendor is providing a service on behalf of the VA medical center. The service requires the VA medical center, a covered entity, to provide the vendor access to PHI.
- b. Outside consultant performs consulting services for VHA that involves access to (disclosure of) PHI held by VHA. Any contractors, or other entities, that needs access to health information to perform the duties of the contract or service for VHA would be an example of a BA.

4. Examples of Non-BA Arrangements

a. Health care provider (HCP) discloses PHI to health plans for payment, or a health plan discloses PHI to a HCP for payment. **Rationale:** No BA agreement is required because neither entity is acting on behalf of, nor providing a service to, the other; rather each covered entity is acting on its own behalf.

- b. A physician or other HCP with staff privileges at a hospital or institution requests PHI from the hospital in order to treat physician's patient **Rationale:** No BA agreement is needed as the hospital is disclosing PHI to the HCP for treatment purposes. This is the exception outlined in subparagraph 1a.
- c. A physician discloses PHI to a laboratory in order for the laboratory to run tests. **Rationale:** No BA agreement is needed as the physician is disclosing PHI to a laboratory (HCP) for treatment purposes.
- d. A covered entity discloses PHI to an oversight agency in order for the agency to provide oversight of a Federal program and/or health care system. **Rationale**: The oversight agency is not performing services for, or on behalf of, the covered entity. *NOTE:* An accrediting body is not an oversight agency.
- **5.** <u>List of VHA BAs.</u> VHA has several BAs with whom there are Agreements. The following list is not meant to be inclusive, but rather to provide a basic list of the BAs associated with VHA on an enterprise-wide basis. The VHA HIPAA Program Management Office (PMO) has responsibility for national level BAAs. A current list of VHA National BAAs is available at http://vaww1.va.gov/cbo/hipaa/signedbaa1.asp. Before creating a facility or local level BAA, contact the VHA HIPAA PMO to determine if the contracted services are already covered via a national BAA.

NOTE: If an individual or entity arrangement is encountered that falls within the BA definition, but is not included in the following list, seek VHA HIPAA PMO or VHA Privacy Office advice regarding whether the arrangement needs to be treated as a BA relationship.

- a. Department of Justice.
- b. Department of Defense (DOD), excluding treatment activities with DOD.
- c. Joint Commission on Accreditation of Healthcare Organizations (JCAHO).
- d. National Commission on Quality Assurance (NCQA.)
- e. Department of Treasury.
- f. Department of Labor.
- g. Food and Drug Administration.
- h. National Institutes of Health.
- i. Nuclear Regulatory Commission.
- j. VHA Affiliations, including affiliated Institutional Review Boards.

- k. Other organizations or entities that accredit VHA health care or educational activities.
- 1. Billing collection agencies, when VHA contracts for their services.
- m. Contractors, or other entities, that need access to health information to perform the contract or service for VHA.

DE-IDENTIFICATION OF DATA

- 1. **Individually-identifiable Health Information.** Health information that does not identify an individual and to which there is no reasonable basis to believe that the information can be used to identify an individual is not individually-identifiable health information.
- 2. **De-identification.** VHA would consider health information not individually-identifiable health information only if the steps outlined in subparagraphs 2a or 2b are met:
- a. A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually-identifiable applying such principles and methods:
- (1) Determines that the risk that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information is very small; and
 - (2) Documents the methods and results of the analysis that justify such determination.
- b. VHA does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information. The following identifiers of the individual or of relatives, employers, or household members of the individual are removed:
 - (1) Names.
- (2) All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:
- (a) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and
- (b) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
- **NOTE:** The Veterans Health Administration (VHA) considers the de-identification standard of the HIPAA Privacy Rule for address acceptable or protecting Address under Title 38 United States Code (U.S.C.) 5701.
- (3) All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.

- (4) Telephone numbers.
- (5) Fax numbers.
- (6) Electronic mail addresses.
- (7) Social Security Numbers.
- (8) Medical record numbers.
- (9) Health plan beneficiary numbers.
- (10) Account numbers.
- (11) Certificate and/or license numbers.
- (12) Vehicle identifiers and serial numbers, including license plate numbers.
- (13) Device identifiers and serial numbers.
- (14) Web Universal Resource Locators (URLs).
- (15) Internet Protocol (IP) address numbers.
- (16) Biometric identifiers, including finger and voice prints.
- (17) Full-face photographic images and any comparable images.
- (18) Any other unique identifying number, characteristic, or code, except as permitted by paragraph 3.

NOTE: Scrambling of names and social security numbers is <u>not</u> considered de-identifying health information for the purposes of this Handbook.

3. Re-identification

- a. VHA may assign a code, or other means of record identification, in order to allow information de-identified under subparagraph 2b, or to be re-identified by VHA, provided that:
- (1) The code or other means of record identification is not derived from, or related to, information about the individual and that the code is not otherwise capable of being translated so as to identify the individual;
- (2) The code, or other means of re-identification, is not used or disclosed by VHA for any other purpose; and

- (3) VHA does not disclose the mechanism (e.g., algorithm or other tool) for reidentification.
- b. The code or other means of record identification is not considered one of the identifiers that must be excluded for de-identification. *NOTE:* When disclosing de-identified data to non-VA entities this code needs to be removed.

NON-VHA SYSTEMS OF RECORDS

Copies of Department of Veterans Affairs (VA) and government-wide system of records notices listed in the following table can be obtained from the Government Printing Office (GPO) Privacy Act Issuances web site at:

http://www.access.gpo.gov/su_docs/aces/PrivacyAct.shtml.

System Name	System Number	System Manager	Responsible Office	Types of Records
Applicants for	02VA135	05	Human Resources	Title 38
Employment under				Employment
Title 38				
Employee Medical	08VA05	05	Human Resources	Title 38
File System Records				Employment
Employee Unfair	09VA05	05	Human Resources	Employment
Labor Practice				
Charges, etc.				
VA Supervised	37VA27	27	Regional Office	Fiduciary
Fiduciary/Beneficiar				Records
y and General				
Investigative Records				
Compensation,	58VA21/	21/22	Regional Office	Compensation.
Pension, Education	22/28			Pension,
and Rehabilitation				Rehabilitation
Records				Records
Police and Security	103VA07B	07B	VA Police and	Law
Records-VA			Security Service	Enforcement
General Personnel	Office of	OPM	Human Resources	Title 5
Records	Personnel			Employment
	Management			
	(OPM), i.e.,			
	Government			
T. 1	(GOVT)-1	ODM	II D	TD: 4 . 7
Employee	OPM and/or	OPM	Human Resources	Title 5
Performance File	GOVT-2			Employment
System Records	ODM 1/	ODM	II D	Tid. 5
Recruiting,	OPM and/or	OPM	Human Resources	Title 5
Examining, and	GOVT-5			Employment
Placement Records	ODM 1/	ODM	II D	T:41 . f
Personnel	OPM and/or	OPM	Human Resources	Title 5
Research and Test	GOVT-6			Employment
Validation Records				

System Name	System	System	Responsible	Types of
	Number	Manager	Office	Records
File on Position	OPM and/or	OPM	Human Resources	Title 5
Classification	GOVT-9			Employment
Appeals, Job				
Grading Appeals,				
Retained Grade or				
Pay Appeals				
Employee Medical	OPM and/or	OPM	Human Resources	Title 5
File System Records	GOVT-10			Employment

HOW TO PROCESS A REQUEST FOR ACCESS TO INDIVIDUALLY-IDENTIFIABLE INFORMATION WHEN THE REQUEST INCLUDES ACCESS TO SENSITIVE INFORMATION

- 1. Sensitive information is information that, if disclosed to the individual, may have a serious adverse effect on the individual's mental or physical health. Such information may require explanation, or interpretation, by an intermediary, or assistance in the information's acceptance and assimilation in order to preclude an adverse impact on an individual's mental or physical health.
- 2. When individuals request access to or a copy of their records (which includes medical, social, and/or psychological information) maintained at a Department of Veterans Affairs (VA) health care facility, a sensitive record review must be conducted on all information determined to meet criteria established by the Veterans Health Administration (VHA) Privacy Office or the System Manager for the concerned VHA system of records. All mental health information meets the criteria for a sensitive records review.
- 3. The facility Privacy Officer, System Manager or designee (e.g., Release of Information unit) must make an initial review of the record based on the established criteria to determine whether the medical and/or psychological information could cause harm to the individual resulting in the need for a sensitive record review.
- a. If, upon initial review against the established criteria, the facility Privacy Officer, System Manager, or designee, concludes that the information would not cause harm, the request for access to or copies of records must be granted.
- b. If, upon initial review against the established criteria, the facility Privacy Officer, System Manager, or designee, concludes that the information could cause harm, the request and related record must be referred to a designated facility physician or psychologist, as appropriate, for a sensitive record review to determine if the record needs to be disclosed directly to the individual, or if a physician needs to discuss the subject information in the record with the individual before providing the records to the patient.
- 4. A request and related records referred to a designated facility physician or psychologist for review will result in one of the following actions:
- a. If the designated facility physician or psychologist reviews a record and believes that the medical and/or psychological information should not be given <u>directly</u> to the individual because it could have an adverse effect on that individual, the facility Privacy Officer, System Manager, or designee, must advise the individual in writing that:
- (1) The information requested may be disclosed to a private physician or professional person selected by the individual;

- (2) A meeting can be arranged for the individual to report to a designated location in the facility for discussion of the record with a designated VA physician, upon request; and
- (3) If neither of the preceding two options are acceptable to the individual that the request will be considered denied (see subpar. 4b of this Appendix on how to process a denial).
- b. If the designated facility physician or psychologist believes that the medical and/or psychological information should not be given <u>directly</u> or <u>indirectly</u> to an individual because it could have an adverse effect on that individual, and that any access to the information could be physically or mentally harmful to the individual, access may be denied. *NOTE:* Such a denial situation needs to be an unusual, very infrequent occurrence.
- (1) Where denial of a request for access is made, the physician or psychologist must fully document in the record the justification for making the denial, specifically stating the rationale for considering the information medically injurious.
- (2) The physician or psychologist's opinion that physical access needs to be denied must be reviewed by the health care facility Director.
- (3) If the Director, upon the advice of the Chief of Staff, determines that physical access will not be granted, the individual making the request must be promptly advised in writing of:
 - (a) The decision,
 - (b) The reasons for the denial of the request, and
- (c) That the denial may be appealed to the General Counsel (02), Department of Veterans Affairs, 810 Vermont Avenue, NW, Washington, DC 20420, as provided in Title 38 Code of Federal Regulations (CFR) 1.577(d).
- (4) The facility must furnish the individual with a copy of any requested portion of the record that is deemed non-sensitive.
- c. If the designated facility physician or psychologist believes that disclosure of the medical and/or psychological information directly to an individual would <u>not</u> have an adverse effect on that individual, the facility Privacy Officer, System Manager or designee must permit the individual to review the requested records and/or provide the individual with copies of the requested records.
- 5. When a VA Regional Office receives a request involving medical information in a claims folder and the responsible Regional Office personnel believe that the information is sensitive, the request and related record are to be referred to the appropriate VA health care facility for a decision concerning the appropriate method of disclosure. *NOTE:* The health care facility is responsible for completion of the medically-indicated disclosure action.

VETERANS HEALTH ADMINISTRATION DATA USE FORMS

Copies of the Veterans Health Administration (VHA) Data Use Forms are available on VHA Forms Intranet at http://vaww.va.gov/forms/medical/searchlist.asp. These are to be used for local reproduction. Since these are low use forms, they will not be stocked by the Hines Service and Distribution Center (formerly known as the Forms and Publications Depot).

1. Department of Veterans Affairs (VA) Form 10-0403, Responsible Requestor and Project Information Sheet.



2. VA Form 10-0403a, Data Use Agreement.



3. VA Form 10-0403b, Data Access List.



Department of Veterans Affairs	RESPONSIBLE RE	QUESTOR AND PRO	JECT INFORMATION SHEET
		IBLE REQUESTOR INFORMATIO	N
A. PRINCIPAL INVESTIGATOR (PI) OR REQUESTER NAME	RESPONSIBLE	B. CONTACT NAME (if same as ite	em A, mark PI go to N)
C. PHONE(S)	D. E-MAIL(S)	E. ORGANZIATION	
F. PROJECT IDENTIFICATION		G. PRIMARY OR SECONDARY I	FUNDING SOURCE
	PRO IFC	 TINFORMATION	
H. PROJECT TITLE	TROLES	I INI OKMATION	I. PROJECT COMPLETION DATE
J. DATASET REQUESTED			K. DATASET RETENTION DATE REQUESTED
			L. TYPE OF DATA REQUESTED
OTHER			PATIENT IDENTIFIABLE
N. ANALYTIC LINKS (e.g. by variable x to	o dataset y)		
IRB		_	ic Goals
Approval No Approval Not Required		STUDY PROTOC OTHER	
Q. COMMENT:			
P. REQUEST APPROVAL YES NO	R. APPROVAL SIGNATURE OF	CHIEF OFFICER OF VHA PROG	RAM OFFICE OR FACILITY OFFICIAL



DATA USE AGREEMENT

Initial all items. Initial each item to indicate agreement. Append ☐a signed and dated page to note ☐exceptions or non-applicable items.

a. I agree that the data provided (herein the data) will be used solely for the purpsoe of independent assessment and improvement of care for veterans.
b. I agree that unless otherwise amended in this document, the individuals with access to the data are listed in item 7 of this agreement.
c. I understand that the data will be available until the retention date specified in the DUA
d. I agree to create the appropriate administrative, technical, and physical safeguards necessary to protect the confidentiality of the data and to prevent unauthorized use or access to the data.
e. In the event that the data is used by a contractor, I agree to monitor compliance with Federal and VA privacy and security requirements
f. I agree to destroy the data after the approved retention date and to nofity the VHA Program Office, in writing, of the destruction
g. I agree that all ensuring reports, publications and presentations that are derived from use of these datasets will recognize the conribution of the VHA Program Office as a co-author, unless the Chief of the VHA Program Office declines this status.
h. I agree to submit all end products derived from these to the VHA Progam Office for review as stated in the DUA policy.
i. I agree not to identify any entities, either directly or by electronic linking the data to outside data sources, including specific networks, hospitals, specific hospital services or clinics except as stated in the DUA or with the express permission of the Chief Officer of VHA Program Office
j. For non-VA research, I agree to provide the VHA Program Office a copy of the relevant project IRB approval or IRB exception.
k. I agree to provide the VHA Program Office a written description of the study protocol or intended analysis.
l. I agree that data received will not be used for any research funded by non-VA sources (primary or secondary) unless specifically approved in writing by the VHA Program Office
m. I agree to submit an annual report to the VHA Program Office detailing all use of the data during the prior year and uses planned for the coming year. (The first report due one year from the date of inital data provision.)
I have read and agree to all the terms and conditions and policies described in this VHA Data Use Agreement. □
Principal Data Requestor Signature Date

Use of the Terms "VHA Program office and Chief Officer" shall be interpreted as "VHA Facility or \mathbb{I} "HA Network Official" appropriate based on the organizational level of the data holder.



DATA ACCESS LIST

Please print or type the names of individuals who will have access to the requested datasets. Indicate each individual's VA position title and practice site (or similar information).

Name	Title	Location
1.□		
2. □		
3. 🗆		
4. 🗆		
5. 🗆		
6. □		
7. 🗆		
8. 🗆		
9. 🗆		
10.□		
Please print or type the names of individual(s) individual's VA position title and practice site (responsible for all aspects of safe (or similar location).	eguarding the data. Indicate each
Name		Location
1. 🗆		

DATA USE AGREEMENT FOR LIMITED DATA SETS

1. '	This Data Use Agreement is entered into as of this	day of	, 200_, by ar	nd between
Vet	erans Health Administration (VHA) ("Covered Entity	y"), and		,
("D	ata Recipient").			

- 2. WHEREAS, the Covered Entity and the Data Recipient are committed to compliance with the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and its implementing regulations at Title 45 Code of Federal Regulations (CFR) Parts 160 and 164 (December 28, 2000, as amended on May 31, 2002; August 14, 2002; and February 20, 2003); and
- 3. WHEREAS, the purpose of this Agreement is to satisfy the obligations of Covered Entity under HIPAA and to ensure the integrity and confidentiality of certain information Disclosed by Covered Entity to Data Recipient, in the form of a limited data set, as defined in Standards for Privacy of Individually Identifiable Health Information ("the HIPAA Privacy Rule") at 45 CFR 164.514(e); and
- 4. WHEREAS, the Covered Entity and the Data Recipient acknowledge and affirm that a limited data set is still considered protected health information (PHI) and does not meet the standard for de-identified information, as both terms are defined in the HIPAA Privacy Rule; and
- 5. WHEREAS the Data Recipient acknowledges and affirms that the limited data set is requested for and will be used for ___(choose one: "research" or "public health purposes") only; and
- 6. WHEREAS the parties acknowledge and recognize that VHA may not disclose the limited data set to the Data Recipient until the parties execute this Data Use Agreement which complies with 45 CFR Section 164.514(e)(4)(ii).
- 7. The parties therefore agree as follows:

a. Identification of the Limited Data Set

- (1) The only individually-identifiable health information that the Covered Entity will disclose to the Recipient shall be the following information: *NOTE:* Insert information identifying and describing the limited data set. The information may not contain any of the following: name, address (other than town or city, state, or zip code), phone number, fax number, e-mail address, Social Security Number (SSN), medical record number, health plan number, account number, certificate and/or license numbers, vehicle identification, device identifiers, web universal resource locators (URL), internet protocol (IP) address numbers, biometric identifiers and full face photograph images.
- (2) The information described in the preceding qualifies as a limited data set under 45 CFR Section 164.514(e)(2).

Data Recipient

	APPENDIX F
(Date)	
	e: "research" or "public health activities") may
	The Data Recipient is permitted to use and disclose a Set only. <i>NOTE:</i> Choose one: "as outlined in the carrying out public health activities."
d. Conditions on Use and Disclosure	The Data Recipient agrees to the following:
(1) Data Recipient shall not use or furt set except as permitted under paragraph 3,	ther disclose information derived from the limited data or otherwise required by law;
(2) Data Recipient shall use appropriation outside the conditions set forth	te safeguards to prevent use or disclosure of the in this Data Use Agreement;
(3) Data Recipient shall report to Cove provided for by this Data Use Agreement t	ered Entity any use or disclosure of the information not to which it becomes aware;
· '	y of its agents, including a subcontractor, to whom it his Data Use Agreement, agrees to the same der this Data Use Agreement; and
(5) Data Recipient shall not attempt or limited data set and/or contact the individu	otherwise re-identify information derived from the tals to which the limited data set applies.
3. IN WITNESS WHEREOF, the parties lagreement under seal as of the day and year	have caused this Agreement to be duly executed as an ar first above written.
Data Recipient:	Covered Entity:

VHA