# This is supplemental material for Book A of your set of Federal Regulations

Title 38, Parts 0, 1, 2, 12, 14-16, 18–20, 25-26, 38-45, 48–49, 74–75

#### General

#### **Veterans Benefits Administration**

Supplement No. 86

Covering period of *Federal Register* issues through November 3, 2008

Copyright © 2008 Jonathan Publishing

#### **Need Assistance?**

Questions concerning MISSING SUPPLEMENTS, need for ADDITIONAL BOOKS, and other DISTRIBUTION LIST issues for this loose-leaf service should be directed to:

Department of Veterans Affairs
Veterans Benefits Administration
Administration
Mail Code: 20M33
810 Vermont Avenue, N.W.
Washington DC 20420
Telephone: 202/273-7588

Fax: 202/275-5947 E-mail: coarms@vba.va.gov

Questions concerning the FILING INSTRUCTIONS for this loose-leaf service, or the reporting of SUBSTANTIVE ERRORS in the text, may be directed to:

Jonathan Publishing 855 Yorks Crossing Driftwood TX 78619 Telephone: 512/858-1225

Fax: 512/858-1230

E-mail: jonpub@austin.rr.com

Copyright © 2008 Jonathan Publishing

#### **GENERAL INSTRUCTIONS**

Custom Federal Regulations Service™

#### Supplemental Materials for Book A

Code of Federal Regulations
Title 38, Parts 0, 1, 2, 12, 14-16, 18-20, 25-26, 39-45, 48-49, 75

General

#### **Veterans Benefits Administration**

Supplement No. 86

5 November 2008

Covering the period of Federal Register issues through November 3, 2008

When **Book** A was originally prepared, it was current through final regulations published in the *Federal Register* of 21 April 1992. These supplemental materials are designed to keep your regulations up to date. You should file the attached pages immediately, and record the fact that you did so on the *Supplement Filing Record* which begins on page A-8 of Book A, *General*.

### To ensure accuracy and timeliness of your materials, it is important that you follow these simple procedures:

- 1. Always file your supplemental materials immediately upon receipt.
- 2. Before filing, always check the Supplement Filing Record (page A-8) to be sure that all prior supplements have been filed. If you are missing any supplements, contact the Veterans Benefits Administration at the address listed on page A-2.
- 3. After filing, enter the relevant information on the Supplement Filing Record sheet (page A-8)—the date filed, name/initials of filer, and date through which the *Federal Register* is covered.
- 4. If as a result of a failure to file, or an undelivered supplement, you have more than one supplement to file at a time, be certain to file them in chronological order, lower number first.
- 5. Always retain the filing instructions (simply insert them at the back of the book) as a backup record of filing and for reference in case of a filing error.
- 6. Be certain that you *permanently discard* any pages indicated for removal in the filing instructions in order to avoid confusion later.

To execute the filing instructions, simply remove and throw away the pages listed under Remove These Old Pages, and replace them in each case with the corresponding pages from this supplement listed under Add These New Pages. Occasionally new pages will be added without removal of any old material (reflecting new regulations), and occasionally old pages will be removed without addition of any new material (reflecting rescinded regulations)—in these cases the word None will appear in the appropriate column.

#### **FILING INSTRUCTIONS**

#### Book A, Supplement No. 86 November 5, 2008

Remove these <u>old pages</u>	Add these <u>new pages</u>	Section(s) <u>Affected</u>
Do not file this supplement until you confirm that all prior supplements have been filed		
1.303-2 to 1.460-5	1.303-2 to 1.460-5	§1.460
1.485a-1 to 1.485a-2	1.485a-1 to 1.485a-2	§1.485a
1.514a-1 to 1.514b-1	1.514a-1 to 1.514b-1	§1.514b

Be sure to complete the Supplement Filing Record (page A-8) when you have finished filing this material.

#### **HIGHLIGHTS**

#### Book A, Supplement No. 86 November 5, 2008

Supplement Highlights references: Where substantive changes are made in the text of regulations, the paragraphs of *Highlights* sections are cited at the end of the relevant section of text. Thus, if you are reading §3.263, you will see a note at the end of that section which reads: "Supplement *Highlights* references—6(2)." This means that paragraph 2 of the *Highlights* section in Supplement No. 6 contains information about the changes made in §3.263. By keeping and filing the *Highlights* sections, you will have a reference source explaining all substantive changes in the text of the regulations.

**Supplement frequency**: This Book A (*General*) was originally supplemented twice a year, in April and October. Beginning 1 August 1995, supplements will be issued *every month* during which a final rule addition or modification is made to the parts of Title 38 covered by this book. Supplements will be numbered consecutively as issued.

#### Modifications in this supplement include the following:

- 1. On 3 November 2008, the VA published a final rule, effective that same date, to adopt with changes an interim final rule implementing provisions of the Veterans Benefits, Health Care, and Information Technology Act of 2006 concerning disclosure of information to organ, tissue and eye procurement organizations. The rule provides authority for the VA to provide individually-identifiable VA medical records of veterans or dependents of veterans who are deceased or whose death is imminent to representatives of organ procurement organizations, eye banks, and tissue banks to determine whether the patients are suitable potential donors; modifies the interim final rule to clarify the definition of *near death* and to correct a grammatical error in the definition of *procurement organization*; and clarifies that eye bank and tissue bank registration with FDA must have an active status. Changes:
  - In §1.460, revised definitions for near death and procurement organization;
  - In §1.485a, revised paragraph (d); and
  - In §1.514b, revised paragraph (d).

Reserved

## Release of Information From Department of Veterans Affairs Records Relating to Drug Abuse, Alcoholism or Alcohol Abuse, Infection With the Human Immunodeficiency Virus (HIV), or Sickle Cell Anemia

**Note**: Sections 1.460 through 1.499 of this part concern the confidentiality of information relating to drug abuse, alcoholism or alcohol abuse, infection with the human immunodeficiency virus, or sickle cell anemia in VA records and are applicable in combination with other regulations pertaining to the release of information from VA records. Sections 1.500 through 1.527, Title 38, Code of Federal Regulations, implement the provisions of 38 U.S.C. §\$5701 and 5702. Sections 1.550 through 1.559 implement the provisions of 5 U.S.C. §552 (The Freedom of Information Act). Sections 1.575 through 1.584 implement the provisions of 5 U.S.C. §552a (The Privacy Act of 1974).

The provisions of §§1.460 through 1.499 of this part pertain to any program or activity, including education, treatment, rehabilitation or research, which relates to drug abuse, alcoholism or alcohol abuse, infection with the human immunodeficiency virus, or sickle cell anemia. The statutory authority for the drug abuse provisions and alcoholism or alcohol abuse provisions of §§1.460 through 1.499 is §111 of Pub. L. 94-581, the Veterans Omnibus Health Care Act of 1976 (38 U.S.C. §§7331 through 7334), the authority for the human immunodeficiency virus provisions is §121 of Pub. L. 100-322, the Veterans' Benefits and Services Act of 1988 (38 U.S.C. §7332); the authority for the sickle cell anemia provisions is §109 of Pub. L. 93-82, the Veterans Health Care Expansion Act of 1973 (38 U.S.C. §§1751-1754).

**Authority**: 38 U.S.C. §§1751–1754 and 7331–7334.

Source: §§1.460–1.499 published at 60 FR 63929, Dec. 13, 1995, unless otherwise indicated.

#### §1.460 Definitions.

For purposes of §§1.460 through 1.499 of this part, the following definitions apply:

Agreement. The term "agreement" means a document that a VA health care facility develops in collaboration with an Organ Procurement Organization, eye bank or tissue bank with written, detailed responsibilities and obligations of the parties with regard to identifying potential donors and facilitating the donation process.

Alcohol abuse. The term "alcohol abuse" means the use of an alcoholic beverage which impairs the physical, mental, emotional, or social well-being of the user.

Contractor. The term "contractor" means a person who provides services to VA such as data processing, dosage preparation, laboratory analyses or medical or other professional

services. Each contractor shall be required to enter into a written agreement subjecting such contractor to the provisions of §§1.460 through 1.499 of this part; 38 U.S.C. 5701 and 7332; and 5 U.S.C. 552a and 38 CFR 1.576(g).

Deceased. The term "deceased" means death established by either neurological criteria (brain death) or cardiopulmonary criteria (cardiac death). Brain death is the irreversible cessation of all brain function. Cardiac death is the irreversible cessation of circulatory and respiratory function. In both cases, "irreversible" means that function will not resume spontaneously and will not be restarted artificially.

Diagnosis. The term "diagnosis" means any reference to an individual's alcohol or drug abuse or to a condition which is identified as having been caused by that abuse or any reference to sickle cell anemia or infection with the human immunodeficiency virus which is made for the purpose of treatment or referral for treatment. A diagnosis prepared for the purpose of treatment or referral for treatment but which is not so used is covered by §§1.460 through 1.499 of this part. These regulations do not apply to a diagnosis of drug overdose or alcohol intoxication which clearly shows that the individual involved is not an alcohol or drug abuser (e.g., involuntary ingestion of alcohol or drugs or reaction to a prescribed dosage of one or more drugs).

Disclose or disclosure. The term "disclose" or "disclosure" means a communication of patient identifying information, the affirmative verification of another person's communication of patient identifying information, or the communication of any information from the record of a patient who has been identified.

*Drug abuse*. The term "drug abuse" means the use of a psychoactive substance for other than medicinal purposes which impairs the physical, mental, emotional, or social well-being of the user.

Eye bank and tissue bank. The term "eye bank and tissue bank" means an "establishment" as defined in 21 CFR 1271.3, pursuant to section 361 of the Public Health Service Act (42 U.S.C. 264) that has a valid, current registration with the Federal Food and Drug Administration (FDA) as required under 21 CFR part 1271.

*Individual*. The term "individual" means a veteran, as defined in 38 U.S.C. 101(2), or a dependent of a veteran, as defined in 38 U.S.C. 101(3) and (4)(A).

Infection with the human immunodeficiency virus (HIV). The term "infection with the human immunodeficiency virus (HIV)" means the presence of laboratory evidence for human immunodeficiency virus infection. For the purposes of §§1.460 through 1.499 of this part, the term includes the testing of an individual for the presence of the virus or antibodies to the virus and information related to such testing (including tests with negative results).

*Informant*. The term "informant" means an individual who is a patient or employee or who becomes a patient or employee at the request of a law enforcement agency or official and who at the request of a law enforcement agency or official observes one or more patients or

employees for the purpose of reporting the information obtained to the law enforcement agency or official.

*Near death.* The term "near death" means that in the clinical judgment of the patient's health care provider based on defined clinical triggers, the patient's death is imminent.

Organ Procurement Organization. The term "Organ Procurement Organization" (OPO) means an organization that performs or coordinates the procurement, preservation, and transportation of organs and maintains a system of locating prospective recipients for available organs.

Patient. The term "patient" means any individual or subject who has applied for or been given a diagnosis or treatment for drug abuse, alcoholism or alcohol abuse, infection with the human immunodeficiency virus, or sickle cell anemia and includes any individual who, after arrest on a criminal charge, is interviewed and/or tested in connection with drug abuse, alcoholism or alcohol abuse, infection with the human immunodeficiency virus, or sickle cell anemia in order to determine that individual's eligibility to participate in a treatment or rehabilitation program. The term patient includes an individual who has been diagnosed or treated for alcoholism, drug abuse, HIV infection, or sickle cell anemia for purposes of participation in a VA program or activity relating to those four conditions, including a program or activity consisting of treatment, rehabilitation, education, training, evaluation, or research. The term "patient" for the purpose of infection with the human immunodeficiency virus or sickle cell anemia, includes one tested for the disease.

Patient identifying information. The term "patient identifying information" means the name, address, social security number, fingerprints, photograph, or similar information by which the identity of a patient can be determined with reasonable accuracy and speed either directly or by reference to other publicly available information. The term does not include a number assigned to a patient by a treatment program, if that number does not consist of, or contain numbers (such as social security, or driver's license number) which could be used to identify a patient with reasonable accuracy and speed from sources external to the treatment program.

*Person*. The term "person" means an individual, partnership, corporation, Federal, State or local government agency, or any other legal entity.

Procurement organization. The term "procurement organization" means an organ procurement organization, eye bank, and/or tissue bank as defined in this section.

Records. The term "records" means any information received, obtained or maintained, whether recorded or not, by an employee or contractor of VA, for the purpose of seeking or performing VA program or activity functions relating to drug abuse, alcoholism, tests for or infection with the human immunodeficiency virus, or sickle cell anemia regarding an identifiable patient. A program or activity function relating to drug abuse, alcoholism, infection with the human immunodeficiency virus, or sickle cell anemia includes evaluation, treatment, education, training, rehabilitation, research, or referral for one of these conditions. Sections 1.460 through 1. 499 of this part apply to a primary or other diagnosis, or other information which identifies, or could reasonably be expected to identify, a patient as having a drug or alcohol abuse condition,

infection with the human immunodeficiency virus, or sickle cell anemia (e.g., alcoholic psychosis, drug dependence), but only if such diagnosis or information is received, obtained or maintained for the purpose of seeking or performing one of the above program or activity functions. Sections 1.460 through 1.499 of this part do not apply if such diagnosis or other information is not received, obtained or maintained for the purpose of seeking or performing a function or activity relating to drug abuse, alcoholism, infection with the human immunodeficiency virus, or sickle cell anemia for the patient in question. Whenever such diagnosis or other information, not originally received or obtained for the purpose of obtaining or providing one of the above program or activity functions, is subsequently used in connection with such program or activity functions, those original entries become a "record" and §§1.460 through 1.499 of this part thereafter apply to those entries. Segregability: these regulations do not apply to records or information contained therein, the disclosure of which (the circumstances surrounding the disclosure having been considered) could not reasonably be expected to disclose the fact that a patient has been connected with a VA program or activity function relating to drug abuse, alcoholism, infection with the human immunodeficiency virus, or sickle cell anemia.

1.460-4

- (1) The following are examples of instances whereby records or information related to alcoholism or drug abuse are covered by the provisions of §§1.460 through 1.499 of this part:
- (i) A patient with alcoholic delirium tremens is admitted for detoxification. The patient is offered treatment in a VA alcohol rehabilitation program which he declines.
- (ii) A patient who is diagnosed as a drug abuser applies for and is provided VA drug rehabilitation treatment.
- (iii) While undergoing treatment for an unrelated medical condition, a patient discusses with the physician his use and abuse of alcohol. The physician offers VA alcohol rehabilitation treatment which is declined by the patient.
- (2) The following are examples of instances whereby records or information related to alcoholism or drug abuse are not covered by the provisions of §§1.460 through 1.499 of this part:
- (i) A patient with alcoholic delirium tremens is admitted for detoxification, treated and released with no counseling or treatment for the underlying condition of alcoholism.
- (ii) While undergoing treatment for an unrelated medical condition, a patient informs the physician of a history of drug abuse fifteen years earlier with no ingestion of drugs since. The history and diagnosis of drug abuse is documented in the hospital summary and no treatment is sought by the patient or offered or provided by VA during the current period of treatment.
- (iii) While undergoing treatment for injuries sustained in an accident, a patient's medical record is documented to support the judgment of the physician to prescribe

certain alternate medications in order to avoid possible drug interactions in view of the patient's enrollment and treatment in a non-VA methadone maintenance program. The patient states that continued treatment and follow-up will be obtained from private physicians and VA treatment for the drug abuse is not sought by the patient nor provided or offered by the staff.

(iv) A patient is admitted to the emergency room suffering from a possible drug overdose. The patient is treated and released; a history and diagnosis of drug abuse may be documented in the hospital summary. The patient is not offered treatment for the underlying conditions of drug abuse, nor is treatment sought by the patient for that condition.

Third party payer. The term "third party payer" means a person who pays, or agrees to pay, for diagnosis or treatment furnished to a patient on the basis of a contractual relationship with the patient or a member of his or her family or on the basis of the patient's eligibility for Federal, State, or local governmental benefits.

Treatment. The term "treatment" means the management and care of a patient for drug abuse, alcoholism or alcohol abuse, infection with the human immunodeficiency virus, or sickle cell anemia, or a condition which is identified as having been caused by one or more of these conditions, in order to reduce or eliminate the adverse effects upon the patient. The term includes testing for the human immunodeficiency virus or sickle cell anemia.

Undercover agent. The term "undercover agent" means an officer of any Federal, State, or local law enforcement agency who becomes a patient or employee for the purpose of investigating a suspected violation of law or who pursues that purpose after becoming a patient or becoming employed for other purposes. (Authority: 38 U.S.C. 7334)

VHA health care facility. The term "VHA health care facility" means a VA medical center, VA emergency room, VA nursing home or other facility as defined in 38 U.S.C. 1701(3).

[60 FR 63929, Dec. 13, 1995, as amended at 72 FR 48241, Aug. 23, 2007; 73 FR 65260, Nov. 3, 2008]

Supplement *Highlights* references: 78(1), 86(1).

#### §1.485a Eye, organ and tissue donation.

- A VHA health care facility may disclose the individually-identified medical record information of an individual covered by §§1.460 through 1.499 of this part to an authorized representative of a procurement organization for the purpose of facilitating determination of whether the individual is a suitable potential organ, eye, or tissue donor if:
  - (a) The individual is currently an inpatient in a VHA health care facility;
- (b) The individual is, in the clinical judgment of the individual's primary health care provider, near death or deceased;
- (c) The VHA health care facility has a signed agreement with the procurement organization in accordance with the applicable requirements of the United States Department of Health and Human Services (HHS); and
- (d) The VHA health care facility has confirmed with HHS that it has certified or recertified the organ procurement organization as provided in the applicable HHS regulations. VA medical centers must verify annually in January of each calendar year with the Food and Drug Administration (FDA) that an eye bank or tissue bank has complied with the FDA registration requirements of 21 CFR part 1271 and that the registration status is active before permitting an eye bank or tissue bank to receive protected health information. (Authority: 38 U.S.C. 5701(k), 7332(b)(2)(E))

[72 FR 48242, Aug. 23, 2007, as amended at 73 FR 65260, Nov. 3, 2008]

Supplement *Highlights* references: 78(1), 86(1).

Reserved

#### §1.514a Disclosure to private psychologists.

When a beneficiary elects to obtain therapy or analysis as a private patient from a private psychologist, such information in the medical record as may be pertinent may be released. Generally, only information developed and documented by Department of Veterans Affairs psychologists will be considered pertinent, although other information from the medical record may be released if it is determined to be pertinent and will serve a useful purpose to the private psychologist in rendering his or her services. Information will be released under this section upon receipt of the written authorization of the beneficiary or his or her duly authorized representative. Information will be forwarded to private psychologists directly, not through the beneficiary or representative, without charge and with the stipulation that it is released with consent of or on behalf of the patient and must be treated as confidential as is customary in regular professional practice.

[34 FR 13368, Aug. 19, 1969]

#### §1.514b Disclosures to procurement organizations.

A VHA health care facility may disclose the name and home address of an "individual" as defined in §1.460 to an authorized representative of a "procurement organization" as also defined in §1.460 for the purpose of facilitating a determination by the procurement organization of whether the individual is a suitable potential organ, eye, or tissue donor if:

- (a) The individual is currently an inpatient in a VHA health care facility;
- (b) The individual is, in the clinical judgment of the individual's primary health care provider, near death or is deceased as defined in §1.460;
- (c) The VHA health care facility has a signed agreement with the procurement organization in accordance with the applicable requirements of the United States Department of Health and Human Services (HHS); and
- (d) The VHA health care facility has confirmed with HHS that it has certified or recertified the organ procurement organization as provided in the applicable HHS regulations. VA medical centers must verify annually in January of each calendar year with FDA that an eye bank or tissue bank has complied with the FDA registration requirements of 21 CFR Part 1271 and that the registration status is active before permitting an eye bank or tissue bank to receive protected health information. (Authority: 38 U.S.C. 5701(k), 7332(b)(2)(E))

[72 FR 48242, Aug. 23, 2007, as amended at 73 FR 65260, Nov. 3, 2008]

Supplement *Highlights* references: 78(1), 86(1).